

ORIGINAL

**AXELACARE HEALTH
SOLUTIONS**

CN1606-022

June 13, 2016

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application Submittal to Establish a Home Health Agency
AxelaCare Health Solutions
Memphis, Shelby County

Dear Mrs. Hill:

This letter transmits an original and two copies of the subject application. The affidavit and filing fee are enclosed.

I am the contact person for this project. Brant Phillips is legal counsel. Please advise me of any additional information you may need. We look forward to working with the Agency on this project.

Respectfully,



John Wellborn
Consultant

**AXELACARE
HEALTH SOLUTIONS**

**CERTIFICATE OF NEED APPLICATION
TO ESTABLISH
A HOME HEALTH AGENCY
SERVING WEST TENNESSEE**

**LIMITED TO HOME INFUSION
OF IMMUNE GLOBULIN MEDICATIONS**

Submitted June 2016

PART A

1. Name of Facility, Agency, or Institution

AxelaCare Health Solutions		
<i>Name</i>		
5100 Poplar Avenue, Suite 2739		Johnson (Kansas)
<i>Street or Route</i>		<i>County</i>
Memphis	TN	38137
<i>City</i>	<i>State</i>	<i>Zip Code</i>

2. Contact Person Available for Responses to Questions

John Wellborn		Consultant	
<i>Name</i>		<i>Title</i>	
Development Support Group		jwdsg@comcast.net	
<i>Company Name</i>		<i>E-Mail Address</i>	
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
<i>Street or Route</i>	<i>City</i>	<i>State</i>	<i>Zip Code</i>
CON Consultant	615-665-2022	615-665-2042	
<i>Association With Owner</i>	<i>Phone Number</i>	<i>Fax Number</i>	

3. Owner of the Facility, Agency, or Institution

AxelaCare Health Solutions, LLC		913-747-3717	
<i>Name</i>		<i>Phone Number</i>	
c/o Office of General Counsel, AxelaCare, 15529 College Blvd			
<i>Street or Route</i>			<i>County</i>
Lenexa	Kansas	66219	
<i>City</i>	<i>State</i>	<i>Zip Code</i>	

4. Type of Ownership or Control (Check One)

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	x
D. Corporation (For-Profit)		I. Other (Specify):	
E. Corporation (Not-for-Profit)			

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS

5. Name of Management/Operating Entity (If Applicable) NA

<i>Name</i>		
<i>Street or Route</i>		<i>County</i>
<i>City</i>	<i>State</i>	<i>Zip Code</i>

6. Legal Interest in the Site of the Institution (Check One)

A. Ownership		D. Option to Lease	
B. Option to Purchase		E. Other (Specify):	
C. Lease of <u> 1 </u> Years, renewable			

7. Type of Institution (Check as appropriate—more than one may apply)

A. Hospital (Specify): General		I. Nursing Home	
B. Ambulatory Surgical Treatment Center (ASTC) Multi-Specialty		J. Outpatient Diagnostic Center	
C. ASTC, Single Specialty		K. Recuperation Center	
D. Home Health Agency	x	L. Rehabilitation Center	
E. Hospice		M. Residential Hospice	
F. Mental Health Hospital		N. Non-Residential Methadone	
G. Mental Health Residential Facility		O. Birthing Center	
H. Mental Retardation Institutional Habilitation Facility (ICF/MR)		P. Other Outpatient Facility (Specify):	
		Q. Other (Specify):	

8. Purpose of Review (Check as appropriate—more than one may apply)

		G. Change in Bed Complement Please underline the type of Change: Increase, Decrease, Designation, Distribution, Conversion, Relocation	
A. New Institution	x	H. Change of Location	
B. Replacement/Existing Facility		I. Other (Specify):	
C. Modification/Existing Facility			
D. Initiation of Health Care Service as defined in TCA Sec 68-11-1607(4) (Specify) <u> home health IgG </u>	x		
E. Discontinuance of OB Service			
F. Acquisition of Equipment			

9. Bed Complement Data

Not Applicable

(Please indicate current and proposed distribution and certification of facility beds.)

	Current Licensed Beds	CON approved beds (not in service)	Staffed Beds	Beds Proposed (Change)	TOTAL Beds at Completion
A. Medical					
B. Surgical					
C. Long Term Care Hosp.					
D. Obstetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolesc. Psych.					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid certified)					
M. Nursing Facility Lev. 1 (Medicaid only)					
N. Nursing Facility Lev. 2 (Medicare only)					
O Nursing Facility Lev. 2 (dually certified for Medicare & Medicaid)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child/Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

10. Medicare Provider Number: Not applicable
Certification Type:

11. Medicaid Provider Number: Not applicable
Certification Type:

12. & 13. See page 4

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

This is a proposed new home health agency limited to providing home infusion services and products to non-Medicare, non-TennCare, and typically non-homebound patients who need immune globulin medications.

The patients whom AxelaCare Health Solutions, LLC (“AxelaCare”) seeks authorization to serve do not meet Medicare Conditions of Participation (“COP”), except in rare instances. As one example, Medicare does not reimburse for home infusion for patients that are not “homebound”--and almost none of AxelaCare’s patients will be classified as homebound. Due to TennCare’s policy of limiting TennCare participation to providers with a Medicare provider number, AxelaCare is not allowed to contract with TennCare.

AxelaCare will continue to contract with existing home health agencies to serve Medicare- and TennCare-insured patients who are referred to AxelaCare, -- *i.e.*, patients for whom the referring physician prescribes an AxelaCare pharmaceutical product and requests AxelaCare to arrange to administer the patient’s infusion. The only exceptions will be Medicare enrollees who, in addition to their Medicare insurance option, also have alternate coverage under a privately purchased “Medicare replacement plan”. These patients will be few in number and will be accounted for as commercially insured patients, consistent with the source of reimbursement.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO’S/BHO’S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? No. IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO’S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT. DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO’S/BHO’S IN THE AREA.

The proposed agency is not eligible to seek contracts with TennCare managed care organizations (MCO’s) operating in its service area because the agency cannot participate in Medicare.

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

- The applicant seeks licensure as a home health agency limited to home infusions of AxelaCare immune globulin products (and nursing services necessary for those products), to serve a small number of privately insured West Tennessee patients who are immune-compromised, and whose physicians have prescribed use of AxelaCare specialty medications.
- Approval is requested for the entire West Tennessee service area, starting in CY 2017.
- The new agency will have its principal office in Memphis/Shelby County. Field nursing staff will be based in Memphis and also in one of more cities that are closer to the easternmost counties in the service area.
- The patients served by the project will not be eligible for Medicare or TennCare reimbursement for home care nursing, under existing reimbursement rules.

Ownership Structure

- Attachment A.4 contains more details, an organization chart, and information on the Tennessee facilities owned by this facility's parent organization.

Service Area

- The proposed service area consists of 21 West Tennessee counties -- all 20 counties that are west of the Tennessee River plus Hardin County. They are Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

Need

- Referring physicians who prescribe specialty pharmaceuticals provided by AxelaCare face serious delays in finding agencies who will administer specialty infusion care in a timely and optimal manner. The physicians and their patients need a provider who can (a) start infusions in the patient's home without delay; (b) provide highly skilled nurses specializing in specialty infusion; (c) provide superior communication to the physician

and pharmacist working with the patient; and (d) serve their West Tennessee patients who live in remote rural areas. All four criteria must be met for optimal care of this unique patient population. Yet, out of the 52 currently existing home health agencies in the service area, the applicant knows of only one (1) agency that meet all four criteria. Two (2) other agencies indicate that they have the capability to provide this type of care, but their service areas include only a few urbanized counties in the service area. Providing intravenous immune globulin infusions in the home is a specialty service that almost no existing agencies are staffed to provide.

- Delays in starting home care infusions immediately upon the physician's orders forces patients either to incur the burden of turning to a freestanding or outpatient infusion center, or even on occasion to remain in a hospital extra days. Extra time in a hospital drives up costs. Use of facilities outside the patient home requires frequent and burdensome commuting on multiple days. Such commuting imposes on these immune-compromised patients a risk of contracting opportunistic infections through exposure to other persons. Commuting is also less convenient and typically more expensive than obtaining infusion care in one's home.
- At an annual caseload of only 65 patients in Year Two, this project can greatly improve care for immune-compromised patients with very special needs without having any significant adverse impact on existing home health providers, who collectively served more than 39,000 patients in 2015. In fact, given that existing agencies will probably increase their caseloads by more than 3,000 patients by Year One of this project, it is likely that AxelaCare's entry will not have even a noticeable impact on existing agencies.

Existing Resources

- Publicly available data do not provide patient care data specific to patients receiving immune globulin infusions. The applicant knows of 52 home health agencies serving the area, but has not been able to identify more than one that meets all four of the criteria for optimal care that are stated above

Project Cost, Funding, and Financial Feasibility

- The estimated \$69,628 cost of the project is very minimal. Excluding lease payments, the capital cost is only \$58,000. This will be funded entirely by the applicant's parent company.
- The AxelaCare home health nursing service that is proposed in this application will operate at a financial loss. But AxelaCare's Kansas-based specialty pharmacy that supports the nursing service is already licensed and operating throughout Tennessee; and it will be profitable enough to absorb those losses. There will be a positive margin when those two components of care delivery are viewed in combination.

Staffing

- The project requires only 6 FTE's of skilled care nurses, all of whom are RN's.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 *et seq.*) INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

This project for a new home health agency will require establishment of a home office in Memphis/Shelby County.

The home office will be established in leased space -- a one-room, 149-SF office in the Executive Suite (Suite 2700) on the 27th floor of the Clark Tower, a commercial office building located at 5100 Poplar Avenue, Memphis, Shelby County, Tennessee 38137. The home office will be used only by the agency's administrative staff, which consists of one person. It requires no renovation or installation of patient care equipment. Minimal furnishings will be required. No clinical equipment or supplies will be stored in this space. As done by AxelaCare in other States, all patient pharmaceuticals, supplies and equipment needed for home infusion of immune globulin medications will be direct-shipped from Kansas to the patients' homes.

APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF \$5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF \$2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART.....

Not applicable.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

The home office will be an administrative space only. No clinical services will be provided in that space. The applicant is leasing finished space at market rates. The project requires no remodeling, renovation or new construction.

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

A. The Applicant

AxelaCare Health Solutions, LLC (“AxelaCare”) is the Certificate of Need applicant. The applicant LLC is wholly owned by UnitedHealth Group Incorporated through seven wholly owned intermediary corporations and LLC’s, which are shown in the organization chart in Attachment One of the application.

AxelaCare is America’s fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission, and holds the Joint Commission’s Gold Seal of Approval for the quality of its programs. AxelaCare’s National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction which it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

AxelaCare is both a licensed pharmaceutical provider and a home health services provider. As a provider of medications, AxelaCare pharmacies prepare and ship home infusion pharmaceuticals to patients in 48 States. As a services provider in 17 States (through 33 branch offices) AxelaCare operates a full-scope program that integrates (a) the AxelaCare Pharmacy with (b) AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of those medications in patients’ homes, as directed by their physicians. AxelaCare nurses and pharmacists in all 17 states are available 24/7 for patient assistance and for consultation with referring physicians -- before, during and after the patient’s infusion.

Five of those states -- Illinois, Indiana, Texas, Virginia and New Jersey -- require licensure to provide home care, as does Tennessee. This project seeks Tennessee licensure to establish an integrated AxelaCare home infusion program across all of West Tennessee for patients utilizing AxelaCare infusion medications for immune globulin. This CON application will be followed by two more CON applications requesting similar

authorization for Middle and East Tennessee with the objective of becoming one of the few statewide providers of home infusion of immune globulin medications.

B. The Project

1. Limited Scope of Services

“Specialty home infusion” is the process of providing very specialized medicines intravenously in a patient’s home, with the presence and support of a skilled registered nurse who works under the direction of the patient’s referring physician. It is a type of home health care that very few Tennessee home health agencies are staffed or willing to provide.

AxelaCare is requesting approval to become licensed as a home health agency based in Memphis and authorized to provide direct services and product for specialty home infusion of *its immune globulin medications only*. These services would be limited to adult and pediatric patients in 21 contiguous West Tennessee counties, using AxelaCare’s own skilled registered nursing staff. The service will provide infusion of Immune Globulin either directly into the vein or through a subcutaneous (under the skin) site.

The applicant is not requesting authorization for infusion of other medications. This limitation to only one narrow type of specialty infusion (immune globulin products) distinguishes this project from all other home health agencies in the project service area. In this application, the service is abbreviated as “IVIG” (intravenous immune globulin).

2. Physical Facilities Required for the Services

Licensure of the project will require AxelaCare to establish a home office in the proposed service area. The site selected for the home office is Suite 2700 on the 27th floor of the “Clark Tower” building at 5100 Poplar Avenue, Memphis, Shelby County, Tennessee 38137. The leased space will consist of one 149-SF office in an Executive Suite on that floor. The office will be used only by the agency’s administrative staff,

which consists of one person. It requires no renovation or installation of patient care equipment. Consistent with AxelaCare's operations in other states, minimal furnishings will be required, and no clinical equipment or supplies will be stored in this space. The pharmaceuticals, supplies, and equipment needed for home infusion of immune globulin medications will be direct-shipped to the patients' homes, where AxelaCare registered nurses will administer and manage the infusion process in consultation with the AxelaCare pharmacist and the patient's physician.

3. Counties to be Served

The proposed service area consists of 21 Tennessee counties. They are Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties. Please see the Attachments for a map of this area and its location within the State of Tennessee.

4. Staffing of the Services

The applicant projects employment of 6.0 FTE's of clinical and administrative staff in Year Two. That number includes 3.3 FTE's of CRNI's (Certified Infusion RN's) who will provide specialized infusion home care.

The RN's will be specially trained in starting and managing home infusions. They will be trained thoroughly in the AxelaCare infusion program and in the use of Axela's CareExchange software--which is an iPad platform for documenting patient dosages and responses. CareExchange permits real-time communication with the team pharmacist and the referring physician while the nurse is on-site. Nurses employed by AxelaCare for this service will be asked to have, or to obtain within one year of employment, the Certified Registered Nurse Infusion (CRNI) designation which denotes special competence in managing infusions.

The AxelaCare staff's specialization in home infusion care of the immune globulin recipient, and the CRNI designation that AxelaCare nurses will attain in

Tennessee are another distinction between this service and almost all other home health care organizations operating in West Tennessee.

5. Schedule for Implementing the Services

If granted final CON approval on or before October 2016, Axelacare projects occupancy of its office, State licensure and initiation of patient care by the end of CY2016. The first full year of operation is projected to be CY2017.

6. Costs and Funding of the Project

There are very few costs associated with the project, which requires only leasing and furnishing one small administrative/management home office in Shelby County. The total cost for CON purposes, which includes the value of the leased space, is estimated at \$69,628. Of that, \$58,000 is the actual capital cost of implementing the project. The balance of \$11,628 is the lease outlay during the first term of the lease, which is required to be included in calculating project costs for CON review purposes. All required capital costs will be provided by UnitedHealth Group, the applicant's parent company in the form of a cash transfer.

C. Patient Needs Addressed By the Project

Immune Globulin is a medicine that contains antibodies, which are tiny proteins that patrol the blood stream to alert the body to germs, which the body then can destroy through complex "immune system" responses.

Specialists in many areas of medicine use immune globulin infusions (IVIG) when other therapies have failed. Referring medical specialties most likely to utilize this AxelaCare program will include neurologists, immunologists, oncologists, and dermatologists. They prescribe immune globulin therapy to treat patients with challenging immune system disorders of many kinds, including the following (several of which are briefly described near the end of this response).

- Peripheral Neuropathy (PN)
- Small Fiber Neuropathy (SFN)
- Primary Immunodeficiency Disease (PIDD)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Guillain-Barre Syndrome (GBS)
- Multifocal Motor Neuropathy (MMN)
- Myasthenia Gravis (MG)
- Multiple Sclerosis (MS)
- Pemphigoid / Pemphigus
- Common Variable Immunodeficiency Disease (CVID)
- Chronic Granulomatous Disease (CGD)
- Hyper IgM Syndrome
- Selective IgA Deficiency (SIgAD)
- Severe Combined Immunodeficiency Disease (SCID)
- Wiskott-Aldrich Syndrome
- X-linked Agammaglobulinemia
- Auto-immune Encephalopathy (AE)
- Dermatomyositis
- Idiopathic Thrombocytopenia Purpura (ITP)
- Lambert-Eaton Myasthenic Syndrome (LEMS)
- Mononeuritis Multiplex
- Polymyositis
- Transplant-related Conditions
- Stiff-person Syndrome (SPS)

The patients who will be served by this project are often among the most challenged of home health patients. Their care requires very sophisticated management by their physicians and the skilled care nurses who carry out prescribed home infusions.

Very few home health agencies are willing and able to offer ready availability of the specialized skilled nursing staff that is needed when providing IVIG infusions at home. Optimal nursing care for IVIG infusion requires significant nursing experience and training. It requires the nurse to spend long hours with the patient over a prolonged treatment period, during which significant monitoring of patient responses takes place. In the AxelaCare service model, nurses also record patient data continuously for the referring physician to review during and after the course of the dosing -- and for post-care research, as explained below.

D. AxelaCare's Program for Delivery of Home Infusion Care for IVIG Patients

AxelaCare is dedicated solely to comprehensive excellence in specialty home infusion care. Its highly trained and experienced clinical staff are its own employees. Its internal Quality Improvement program is among the most robust in the industry. And, most notably, the technology it uses in the patient's home during the infusion treatment is continuously gathering clinical data that is made available not only to the patient's physician, but also to medical researchers (with properly obtained consent) -- thus advancing medical knowledge in a complex and evolving area of medicine. AxelaCare's sequence of services to its West Tennessee IVIG patients will be as follows:

1. Patient and Physician Contacts

AxelaCare has relationships with medical specialists in the service area and will work with them to ensure that patient referral processes are straightforward and efficient. When a referral is made, the AxelaCare staff will secure required information and paperwork from the physician's office and will send it to an AxelaCare Pharmacy. The Pharmacy will (a) assign a Pharmacist with 24/7 availability to the patient; (b) prepare the prescribed pharmaceuticals; and (c) direct-ship them in the correct dosages to the patient's home for infusion. An AxelaCare specialty home infusion nurse will be assigned to provide care to the West Tennessee patient.

2. Comprehensive Assistance to the Patient Prior to Infusion

After contacting the referred patient, AxelaCare's Care Team will simplify arrangements for the patient's insurance coverage, evaluating all benefit sources and potential coverage, obtaining letters of medical necessity, securing coverage for patients previously denied, educating the patient on available benefits and the patient's projected costs, coordinating with the physician's office for timely approvals and prior authorizations and coordinating direct billing to insurance and other payment sources.

3. The Initial Home Visit

An initial home visit is scheduled so that the skilled care infusion nurse can become personally acquainted with the patient and his/her home environment, discuss the infusion process, answer patient questions, establish a schedule of visits, and obtain required patient consent to share with the patient's physician and with AxelaCare's research center a set of clinical data and information to be obtained during infusion sessions.

4. Preparation for Infusion or "Dosing"

Before home infusion begins, many patients need oral or venous hydration and/or premedication to lower the risks associated with infusion, which can include headaches and blood pressure changes. In infusion medicine, a "dose" is not a "visit" or "hours" as in most home health care. A dose is a prescribed amount of medication to be administered in a single "dosing cycle". A dosing cycle can take from ***one to five consecutive days***, depending on the amount to be infused and on the infusion rate that the patient can tolerate without having negative reactions. Dosing cycles may be required at weekly intervals.

5. Care During the Infusion Sessions

A nursing visit in a dosing cycle can be from 2 to 10 hours daily in duration, depending on the prescription, the dose amount, dose rate and patient reactions to the infusion. Before, during, and after infusion, the AxelaCare nurse follows detailed protocols, that include periodically taking vital signs, taking spirometry readings, discussing the patient's bodily responses to the infusion, requesting patient performance of simple physical tests such as grip strength measurement and rising from a chair to walk across the room.

6. CareExchange Technology

One of the distinguishing advantages of AxelaCare "bedside" services is CareExchange -- a unique and proprietary technology tool developed by AxelaCare in

2012. Continuously during every dosing day, the nurse gathers and enters all clinical data and patient descriptions of pain, fatigue, etc. into an iPad fitted with CareExchange software. CareExchange organizes this information into clear and usable reports that are then transmitted over secure electronic channels to the patient's AxelaCare pharmacist and to the patient's physician.

With this "real-time" data, both the pharmacist and the referring physician specialist can more quickly evaluate patient reactions to the medication and can direct appropriate adjustments such as variations in the dosing rate or dosing amount, as indicated by digitally documented patient reactions. In addition, the infusion nurse can identify and discuss issues with the AxelaCare pharmacist during, as well as after, infusion (the pharmacist is available 24/7), and the pharmacist and nurse can telephonically alert the physician to patient response issues and can discuss modifications of the treatment.

CareExchange's capturing and analysis of patient response data during the dosing cycle, and its rapid communication to the treatment team, helps both the patient and the referring physician. From the *patient's* perspective, it ensures that patients are receiving optimal therapy for maximum effectiveness of the infusion medication. The technology tracks patient progress and changes in the patient's condition. It establishes baseline and trending information to compare those changes. From the *physician's* perspective, it provides real-time data between patient office visits, to help manage the patient's condition; it allows rapid adjustment of the prescribed therapy to find the most effective dose; and it gives a better understanding of how the therapy is working and how it might work for other patients with similar conditions.

7. Use of Patient Data for Research

The AxelaCare program does not end with completion of the dosing. With patient consent, the clinical data gathered by CareExchange is compiled centrally at AxelaCare and is used to advance medical knowledge in this complex and evolving area of care. It is used in clinical trials with independent researchers. It is used in research published in clinical journals and in seminars presented at professional gatherings.

AxelaCare is currently working on clinical trials and journal publications with medical staff at Northwestern University, the University of Minnesota, the University of Virginia, Columbia University Medical Center, the University of Kansas and the “Neurology at John’s Creek” practice group in Georgia. AxelaCare’s ongoing contributions to clinical research is one of the special benefits of permitting AxelaCare to expand into Tennessee. Its program will contribute to the orderly development of more effective healthcare services not only in Tennessee, but also throughout the field of infusion medicine.

8. Examples of Disorders That Often Require Immune Globulin (IVIG) Therapy

- Peripheral neuropathy--This is a disorder of the peripheral nervous system (the system connecting the brain and spine to limbs, muscles, skin, and internal organs). It affects approximately 60% of all diabetics. Symptoms often start in the fingers and toes, and can include muscle weakness and even paralysis if motor nerves are affected. Other symptoms may include burning pain in the hands and feet; sharp electric shock pains; problems in gripping; sensitivity to pain, touch and temperature; bowel and bladder dysfunction; sweating; and abnormal blood pressure.
- Small fiber neuropathy--Most prevalent among the elderly and many diabetics (50% prevalence), this peripheral nervous system disorder most often starts with numbness in the toes and a burning sensation in the feet. It is often worse at night, creating sleep difficulties. It may develop into pain and burning, or loss of feeling, or “pins and needles” feelings or numbness in hands and feet. It may cause cramping, fatigue, inability to sweat, dry eyes, dizziness, difficulty in breathing, difficulty with elimination and increased heart rate.
- Primary immunodeficiency (PID)--There are over 200 types of PID, and they are inherited disorders all involving a shortage of antibodies that result in more frequent sicknesses and decreased ability to get better from an infection. Maladies typically experienced include frequent pneumonia and bronchitis, ear and sinus infections, sore throats, coughs, colds and flu, fungal infections, rare viruses and slowness of wound healing. In children, PID can also result in slow growth and below-normal weight.

- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)--This disorder is very difficult to correctly diagnose. It afflicts men at twice the rate of women. It is a chronic disorder requiring long-term treatment. Symptoms can be mild or can progress to the point where they impair motor skills. Symptoms may include weakness or loss of feeling in extremities; difficulty of movement in climbing stairs or standing on tip-toe; weakness of hands; loss of balance; and sensations of numbness, tingling, prickling or burning.
- Guillain-Barre Syndrome (GBS)--This is rare illness of unknown origin. Patient symptoms typically begin as weakness or tingling in the feet and legs, spreading in an upward direction through arms, legs and torso. Extreme cases can result in paralysis. Potential symptoms include unsteadiness and clumsiness in walking; muscle contraction and blurred vision; back pain; difficulty in eye movement, facial movement, speaking, chewing or swallowing; and breathing difficulty when diaphragm and chest areas are affected.
- Multifocal Motor Neuropathy (MMN)--This rare muscle disorder causes increasing muscle weakness over time. It is often misdiagnosed as ALS or Lou Gehrig's Disease. Its symptoms include muscle cramps, wasting and shrinkage; involuntary twitching and spasms; numbness and tingling; difficulty getting up from a seated position and in climbing steps.
- Myasthenia Gravis (MG)-- This disorder is rare, most often affecting men over 60 years of age and women under 40. Persons with this condition may have difficulty in breathing, chewing, swallowing, climbing steps, lifting and gripping objects, speaking and rising from a seated position. They may often suffer from weak arm and chest muscles, drooping head or eyes, fatigue, double vision and balance issues.
- Multiple Sclerosis (MS)--Most commonly diagnosed between the ages of 20 and 40, MS symptoms vary from mild to severe. It is difficult to predict the onset or effects of patients; symptoms are often triggered by events such as fevers, hot baths, sun exposure or stress. Symptoms include blurred or double vision or vision loss; distorted perception of red/green colors; tremors; pain; "pins and needles" feelings in spots; and difficulty walking or getting up from a seated position. Other symptoms may include arm and leg weakness; coordination and balance problems; spasms; dizziness; loss of sensation;

hearing loss; issues of bowel and bladder control; and fatigue and depression. Patients may have periods of relief of symptoms; or the symptoms may get progressively worse with few or no remission periods.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

- 1. ADULT PSYCHIATRIC SERVICES**
- 2. ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS**
- 3. BIRTHING CENTER**
- 4. BURN UNITS**
- 5. CARDIAC CATHETERIZATION SERVICES**
- 6. CHILD AND ADOLESCENT PSYCHIATRIC SERVICES**
- 7. EXTRACORPOREAL LITHOTRIPSY**
- 8. HOME HEALTH SERVICES.....**

A. Demand for Home Infusion Services Is Increasing Nationally

Although the targeted under-65 populations are slowly increasing in West Tennessee, the uses and demand for intravenous immune globulin medications is likely to increase rapidly in that region. This is consistent with national trends.

Immune globulin infusion (IVIG) is used to treat a wide range of disorders. While the most common use of IVIG therapy is in treating primary immune deficiencies, its efficacy in numerous other disorders is well-documented. Off-label prescription of these successful medications far exceeds the volumes for FDA-approved usages and off-label research is burgeoning. It is estimated that for every USFDA- approved indication, there are more than ten non-FDA-approved indications. Current research is even exploring IVIG's potential for reducing development of Alzheimer's and increasing live births for women with secondary recurrent miscarriage issues. (Rhodes and McFalls; On- and Off-Label Uses and Clinical Trials of IG).

According to an August 2015 editorial in Frontiers in Immunology, "There has been a steady increase in demand for immune globulin medications over the past 20 years, in in research into the mechanisms through which it has been found to help with certain conditions... (This is) an exciting and fruitful area of clinical research, and well-suited to contribute to the ongoing evolution in medicine toward more individualized and patient-centric paradigms."

Although Medicare has not allowed most of its enrollees to receive home infusion nursing services, Congress recently asked the General Accounting Office (“GAO”) to look into the need to revisit that position. GAO Report GAO-10-426 identified that commercial insurers have long covered home infusion therapy comprehensively and have had good experience with its cost-benefit impact and quality of care. GAO recommended that HHS study this to inform Congress about potential program costs, savings and other issues that would be associated with comprehensive Medicare benefits for home infusion therapy. HHS now has such a study underway. Medicare has preliminarily reported that “there was approximately a 60% growth rate in Medicare beneficiaries...receiving immune globulin treatment over the past 5 years...”, and that infusions were given primarily in hospitals, outpatient departments, infusion suites and physician offices. There is already Congressional support for draft legislation authorizing Medicare to cover infusions in the more convenient and lower-cost home setting when physicians and patients prefer it.

B. Many Home Health Agencies are Reluctant to Provide Home Infusion Services

There are 52 home health agencies licensed to serve one or more of the counties in the proposed West Tennessee service area. But this highly specialized IVIG service is very challenging and unprofitable for almost all of them, so few agencies offer it. There are several reasons why home health agencies (“HHA’s”) providing routine home health services seldom offer IVIG.

(1) There are *risks of adverse patient reactions*, especially to the first infusion. These risks are not acceptable to most agencies. Less complex and more predictable patients are sought by most agencies.

(2) The infusions also require a *highly skilled infusion registered nurse*. Most agencies do not have such staff available at the time that it is needed and do not provide staff training required to create a high level of competency in home infusion care.

(3) IVIG infusions require the home health nurse to be present and to be highly observant and active in the recording of patient clinical information for periods of time *2-10 hours per session*. Few home health agencies want to offer a service that ties up the nurse for

more than two hours. Many nurses do not want to spend such long hours in this demanding type of home care.

(4) The best home infusion care for complex patients enables immediate nursing consultation with the referring physician office and/or with the assigned pharmacist, during the infusion session (not just afterwards). Best practice in this area now requires new technologies to empower the home infusion nurse to do this. To respond to this need, AxelaCare has developed its own iPad-based CareExchange technology, which allows its nurses to optimize the accuracy, ease and speed of gathering information and communicating it to the physician and team pharmacist -- both during and after infusion sessions, as appropriate. Home health agencies providing only general home health care do not typically invest in such technology and training for the benefit of such a small patient population as the IVIG patient.

C. The Shortage of Home Infusion Providers in West Tennessee

Because of the limitations described above, almost none of the service area's numerous home health agencies meet area needs for home infusion of patients requiring immune globulin.

The applicant conducted a telephone survey of almost all licensed area home health agencies to determine if they were currently staffed or had a subcontract in place to provide immune globulin home infusion without delay. (Five area agencies were not contacted because they do not serve the Memphis area and also serve fewer than three rural counties. One was not contacted because it serves only pregnant women and does not infuse immune globulin. Three of five area Amedysis agencies were contacted and they were assumed to be representative of the other two agencies.) The results are shown below in Table One below.

Out of forty-six listed agencies, forty provided information. Only *one* respondent was currently prepared *region-wide* to provide timely IVIG home care that would include the most costly, risky, and labor-intensive first dosing session. Only *two* other agencies were similarly prepared; but they are licensed to serve only six urban counties in this region. They cannot meet patient needs in fifteen more rural counties.

Table One: AxelaCare Telephone Survey of Home Health Agencies in Project Service Area

Health Statistics ID	Agency County	Agency	Are you staffed at this time, or do you have a staffing subcontract in place, to provide IV infusion of immune globulin (IVIG) upon request?		
			NO	YES, WITH OWN STAFF	YES, WITH SUBCONTRACTED STAFF
79456	Shelby	Accredo Health Group, Inc.	X		
79146	Shelby	Amedisys Home Care	X*		
33103	Hamilton	Amedisys Home Health	X*		
57075	Madison	Amedisys Home Health Care	X		
79246	Shelby	Amedisys Home Health Care	X		
79386	Shelby	Amedisys Tennessee, LLC (D/B/A Amedisys HH)	X		
79256	Shelby	Americare Home Health Agency, Inc	X		
09065	Carroll	Baptist Memorial Home Care & Hospice	X		
79276	Shelby	Baptist Trinity Home Care	X		
79446	Shelby	Baptist Trinity Home Care - Private Pay	X		
79546	Shelby	Best Nurses, Inc.	X		
38015	Haywood	Careall Homecare Services	X		
92025	Weakley	Careall Homecare Services (University HH, LLC)	X		
79556	Shelby	Coram/CVS Specialty Infusion Service		(IN 21 WEST TN COUNTIES)	
36025	Hardin	Deaconess Homecare	X		
19494	Davidson	Elk Valley Health Services Inc	X		
57095	Madison	Extencicare Home Health of West Tennessee	X		
66035	Obion	Extencicare Home Health of Western Tennessee	X		
79206	Shelby	Family Home Health Agency	X		
79496	Shelby	Functional Independence Home Care, Inc	X		
36035	Hardin	Hardin Medical Center Home Health (HMC HH)	NR		
unassigned on 6/10	Shelby	Hemophilia Preferred Care of Memphis	x		
40075	Henry	Henry County Medical Center Home Health	X		
19544	Davidson	Home Care Solutions, Inc	X		
79486	Shelby	Home Health Care of West Tennessee, Inc	X		
79376	Shelby	Homechoice Health Services			(IN 4 WEST TN COUNTIES)
79226	Shelby	Intrepid USA Healthcare Services	X		
57165	Madison	Intrepid USA Healthcare Services (F.C. of TN)	X		
79536	Shelby	Maxim Healthcare Services, Inc.			(IN 6 WEST TN COUNTIES)
57055	Madison	Medical Center Home Health	X		
79106	Shelby	Meritan, Inc.	X		
79316	Shelby	Methodist Alliance Home Care	X		
24026	Fayette	NHC Homecare	X		
27025	Gibson	NHC Homecare	X		
79506	Shelby	No Place Like Home, Inc	X		
79136	Shelby	Quality Home Health Service	X		
23035	Dyer	Regional Home Care - Dyersburg	NR		
57085	Madison	Regional Home Care - Jackson	NR		
39035	Henderson	Regional Home Care - Lexington	NR		
79526	Shelby	Still Waters Home Health Agency	X		
03025	Benton	Tennessee Quality Homecare - Northwest	X		
20045	Decatur	Tennessee Quality Homecare - Southwest	NR		
27085	Gibson	Volunteer Home Care, Inc	X		
20055	Decatur	Volunteer Homecare of West Tennessee	X		
24036	Fayette	Where The Heart Is	X		
79236	Shelby	Willowbrook Visiting Nurse Association	X		

- Notes:
1. Excludes 5 agencies that do not serve the Memphis MSA, or more than 2 rural counties in the project service area. Excludes Alere (serves only pregnant women).
 2. Asterisks denote 2 of Amedisys' 5 area agencies who were not surveyed but are assumed to not offer IVIG based on responses of 3 sister Amedisys agencies.
 - * 3. NR indicates that agency did not respond to multiple phone requests for information.

The subcontracting option mentioned above should be clarified. Today, if AxelaCare receives a referral from a physician, AxelaCare can deliver AxelaCare pharmaceuticals to the home, but it cannot provide the in-home nursing care -- unless it works through a licensed home health agency in a contracted relationship. However, AxelaCare's experience with subcontractors has not been optimal. In some cases, despite diligent effort, AxelaCare was unable to locate a partnering home health agency that was staffed and willing to provide infusion care promptly upon the physician's request. Response time is an essential consideration. Delay means that the immune-compromised patient must start making multiple burdensome trips to an outpatient or physician infusion center, until home care teams can be activated to serve that patient at home.

Such delays impose risks and avoidable travel and service costs on these immune-compromised patients, who should have been able to start infusions more quickly and economically in their homes without the infection risks of being exposed to other people when traveling to a remote location. And, when the dosages require multiple infusions several days a week, then these sick patients suffer real inconvenience and excessive travel times -- especially if they live many miles from infusion facilities.

Another difficulty being encountered by AxelaCare is that some of its contracted agency nurses have not performed up to company expectations in the use of the CareExchange technology, which requires training and dedication to master and is essential to optimizing quality of care and the compilation of clinically sophisticated databases for AxelaCare's research studies. This advance in "hand-held" or "bedside" technology is valuable to physicians, patients and researchers. It allows AxelaCare to ensure that all meaningful patient data is consistently gathered, is available for use during and after the infusion and is preserved for researching effective treatment strategies for other patients.

Because of these difficulties, the applicant feels that West Tennessee's referring physicians and their immune-compromised patients do not yet have sufficient choice of home health care providers for IVIG therapy. For *routine* health care, patients in every West Tennessee county have a choice of 10 to 20 competing providers. But for home infusion of immune globulin medications -- a risky and complex type of *highly*

specialized care--AxelaCare cannot identify more than one agency that can offer it (including first dosing) timely in more than 6 of the 21 West Tennessee counties. This shortage of choice is in stark contrast to routine home health care. It can be remedied by approving this application.

Letters in the Attachments to this application attest to the need for the AxelaCare nursing program to be allowed into this service area. Three letters, from Shankar Natarajan, M.D., Rahul Sonone, M.D., and Rivers Collison, R.N., are from Memphis Neurology, a five-office physician practice group dealing with disorders of the nervous system. A fourth letter is from Dr. Tulio Bertorini in the Wesley Neurology Clinic, a nine-physician specialty clinic in Memphis focusing on the diagnosis, treatment and research of neurological disorders. There are two letters from Washington, D.C. medical specialty practices who treat Tennessee patients (Tracy Freeman, M.D. and Susan Greenburg, FNP, of National Integrated Health Associates; and Charles Gant, M.D. of International Precision Medicine Associates). A Tennessee patient and Doctor of Pharmacy, Chad Hartman (who lives outside the West Tennessee service area), has written a statement describing the advantage to patients like himself in having a single source to provide both the Immune Globulin pharmaceutical and the nursing care needed to infuse it properly.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

Not applicable to a proposed home health agency.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF \$2.0 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

1. For fixed site major medical equipment (not replacing existing equipment):
 - a. Describe the new equipment, including:
 1. Total Cost (As defined by Agency Rule);
 2. Expected Useful Life;
 3. List of clinical applications to be provided; and
 4. Documentation of FDA approval.
 - b. Provide current and proposed schedule of operations.

2. For mobile major medical equipment:
 - a. List all sites that will be served;
 - b. Provide current and/or proposed schedule of operations;
 - c. Provide the lease or contract cost;
 - d. Provide the fair market value of the equipment; and
 - e. List the owner for the equipment.

3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.) In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Not applicable. The project does not include major medical equipment.

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

- 1. SIZE OF SITE (IN ACRES);**
- 2. LOCATION OF STRUCTURE ON THE SITE;**
- 3. LOCATION OF THE PROPOSED CONSTRUCTION; AND**
- 4. NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.**

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

See Attachment B.III.A.

B.III.B.1. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

In a home health project, the site of service is the patient home, which can be in any service area county. The table on the following page shows the drive time and distances between the proposed home office in Shelby County and a major community in each of the 21 counties in the proposed service area of the project.

But the distance between the counties and the Memphis home office is not particularly meaningful because AxelaCare field nurses will be located in communities across the service area -- not just in Memphis.

Field nurses' points of origin for making home visits cannot be known until they are employed. So, the applicant cannot predict the geographical distribution of its field-based nursing staff outside Shelby County. However, AxelaCare obviously will distribute its nurses in such a way as to make their drive times to patients acceptable, and to make service to outlying rural counties a reality. One probable option will be stationing one or more nurses in Madison County and/or adjacent counties.

County	Community	Distance	Drive Time
1. Benton	Camden	136 mi.	132 min.
2. Carroll	Huntingdon	110 mi.	113 min.
3. Chester	Henderson	79.4 mi.	100 min.
4. Crockett	Alamo	72.1 mi.	85 min.
5. Decatur	Decaturville	123 mi.	131 min.
6. Dyer	Dyersburg	76.9 mi.	98 min.
7. Fayette	Somerville	49.0 mi.	53 min.
8. Gibson	Milan	95.0 mi.	110 min.
9. Hardeman	Bolivar	67.7 mi.	74 min.
10. Hardin	Savannah	115.0 mi.	121 min.
11. Haywood	Brownsville	54.7 mi.	61 min.
12. Henderson	Lexington	102.0 mi.	103 min.
13. Henry	Paris	136 mi.	141 min.
14. Lake	Tiptonville	111 mi.	138 min.
15. Lauderdale	Ripley	63.0 mi.	84 min.
16. Madison	Jackson	79.3 mi.	82 min.
17. McNairy	Selmer	91.1 mi.	99 min.
18. Obion	Union City	116.0 mi.	141 min.
19. Shelby	Memphis	NA	NA
20. Tipton	Covington	40.4 mi.	59 min.
21. Weakley	Martin	126.0 mi.	137 min.

Source: Google Maps, 4-21-16.

Note: Home office is at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, 38137.

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

- 1. EXISTING SERVICE AREA (BY COUNTY);**
- 2. PROPOSED SERVICE AREA (BY COUNTY);**
- 3. A PARENT OR PRIMARY SERVICE PROVIDER;**
- 4. EXISTING BRANCHES AND/OR SUB-UNITS; AND**
- 5. PROPOSED BRANCHES AND/OR SUBUNITS.**

Not applicable. The application is not for a home care organization.

C(I) NEED

C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.

A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES THAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.

B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE...(Not applicable to this project)

Guidelines for Growth 2000: Project-Specific Guidelines

Home Health Services

- 1. The need for home health agencies/services shall be determined on a county by county basis.**
- 2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services that county. The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.**
- 3. Using recognized population sources, projections for four years into the future will be used.**
- 4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.**

This "need" projection is made by the Tennessee Department of Health (TDH). The most current version is a 2015-2020 projection of need by county. The TDH projections for this project's service area are attached on the following page. None of its 21 counties is projected to have an unmet generic need for additional home healthcare services.

However, that projection is neither accurate nor relevant to this specialty project. First, the projection methodology is stated as a "general guideline" and it uses a simple 1.5% planning factor for each county's population. A one-size-fits all methodology is not informative for such a specialized "niche" need as immune-compromised patients seeking IVIG therapy. Second, the Guidelines projection methodology -- which predated the rising importance of home care -- is seriously outdated on its face. There were 39,117 actual home health agency patients served in 2015 (an evidence-based indicator of need). That utilization was 61.7% higher than the 24,186 patients that the 1.5% formula would have predicted as "needed" in this service area. This fact, standing alone, confirms that the formula does not accurately predict need or utilization.

Joint Annual Report of Home Health Agencies - 2015 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2020 vs. 2015)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2015 Pop.	Use Rate	Projected 2020 Pop.	Projected Capacity	Projected Need (.015 x 2020 Pop.)	Need or (Surplus) for 2020
Tennessee	1,635	1,473	170,384	6,735,706	0.0252956409	7,108,031	179,802	106,620	(73,182)
Benton	12	11	684	16,655	0.0410687481	16,741	688	251	(436)
Carroll	13	13	1,465	28,430	0.0515300739	28,207	1,454	423	(1,030)
Chester	13	13	545	18,076	0.0301504758	18,978	572	285	(288)
Crockett	12	11	567	14,845	0.0381946783	15,080	576	226	(350)
Decatur	15	15	648	11,939	0.0542759025	12,077	655	181	(474)
Dyer	9	9	1,902	39,155	0.0485761716	39,872	1,937	598	(1,339)
Fayette	21	20	707	43,631	0.0162040751	48,510	786	728	(58)
Gibson	14	14	1,870	51,119	0.0365813103	52,438	1,918	787	(1,132)
Hardeman	15	14	920	27,285	0.0337181602	27,278	920	409	(511)
Hardin	16	15	1,101	26,479	0.0415801201	26,783	1,114	402	(712)
Haywood	15	13	649	18,477	0.0351247497	18,128	637	272	(365)
Henderson	12	12	1,209	29,101	0.0415449641	30,298	1,259	454	(804)
Henry	11	10	1,270	33,267	0.0381759702	34,055	1,300	511	(789)
Lake	7	6	357	8,230	0.0433778858	8,579	372	129	(243)
Lauderdale	14	12	907	28,529	0.0317922114	29,186	928	438	(490)
McNairy	14	14	1,138	27,019	0.0421185092	27,760	1,169	416	(753)
Madison	18	17	3,220	102,429	0.0314364096	106,352	3,343	1,595	(1,748)
Obion	10	10	1,314	31,722	0.0414223567	31,559	1,307	473	(834)
Shelby	26	26	16,269	953,899	0.0170552648	981,022	16,732	14,715	(2,016)
Tipton	21	19	1,172	66,234	0.0176948395	71,196	1,260	1,068	(192)
Weakley	15	15	1,203	35,894	0.0335153508	36,360	1,219	545	(673)
PSA TOTAL	303	289	39,117	1,612,415		1,660,459	40,146	24,906	(15,237)

*Most recent year of Joint Annual Report data for Home Health Agencies

Data is projected four years from the year the Home Health data was **finalized, not the actual year of Home Health data.

Population Data Source: The University of Tennessee Center for Business and Economic Research (UTCBER) Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.

Note: Population data will not match the UTCBER data exactly due to rounding.

The State Health Plan and the *Guidelines for Growth* appropriately focus on home health needs in general for an entire population; but this specialty project should not be disqualified from consideration on the basis of this plainly outdated and unreliable formula. This is especially true because other criteria in the *Guidelines* recognize the need to consider local physician and patient viewpoints about current needs; and those viewpoints strongly support this application.

5. Documentation from referral sources:

a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

The applicant is providing letters of referral support from referring physicians and others. Please see the Attachments.

b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant will serve referrals of only one type of patient: those who need immune globulin infusions, or the IVIG patient. These are immune-compromised patients.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant is providing letters of support from these patients. Please see the Attachments.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

As discussed at length in Section B.II.C. above (Need for the Project), AxelaCare proposes to provide a type of infusion service that is very different from services provided by almost all other agencies in the area. AxelaCare's program will:

- provide home infusion only for the immune-compromised patient, whose physician specialist prescribes infusions of AxelaCare's own immune globulin products and refers patients to AxelaCare to arrange immediate infusion services;
- utilize only highly skilled registered nurses who have documented competency in managing IVIG infusions and seek all available certifications for this specialty care process;
- mobilize and deploy the infusion team of nurse and pharmacist as rapidly as required to allow the patient to receive the first infusion at home -- thereby avoiding the increased costs, inconveniences and risks of commuting to distant infusion centers or outpatient acute care facilities;
- provide care for the 2-10 hour sessions that immune globulin recipients require on multiple visits for prolonged periods of time;
- provide state-of-the-art "bed-side" technology for complete, accurate and real-time documentation of the infusion process and patient reactions, and for communicating that to the treatment team pharmacist and the referring physician during and after the infusion when the need arises,.
- gather and preserve real-time patient clinical data that is useful to academic research in this rapidly evolving area of medicine.

The applicant is aware of only one licensed home health agency that can provide all of these advantages to immune-compromised patients in all 21 West Tennessee counties--rural ones as well as urbanized ones. Two other agencies have similar clinical capability but they are not authorized to provide it outside of six urban counties in the service area. This extreme lack of choice for patients is in stark contrast to the abundant choice that physicians and patients enjoy for *routine* home health care (10-20 agencies for every county). Consumers who are immune-compromised are disadvantaged by this lack of choice. They and their physicians deserve reasonable options for high-quality and responsive specialty IVIG therapy, just as they enjoy for routine home care.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

a. The average cost per visit by service category shall be listed.

b. The average cost per patient based upon the projected number of visits per patients shall be listed.

As explained in Section C.II.6.A below, AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a “gross charge” that is discounted by “contractual adjustments” to yield “net revenue”. The revenue figures shown in Section B of the Projected Data Charts are the billed or “expected” revenues, i.e., the projected receipts based on pre-negotiated reimbursement contracts before deductions for charity and bad debt.

The table below shows the average expected charge/revenue data per patient and per visit for AxelaCare’s nursing services (home office and field staff) in West Tennessee. That is what AxelaCare is applying to add to its ongoing pharmaceutical distributions in Tennessee.

Table Three: Axela Health Solutions, West Tennessee Nursing and Home Office (Excluding Pharmaceuticals)		
	Year One--CY2017	Year Two-CY2018
Expected Nursing Revenue	\$259,200	\$374,400
Visits	1,080 visits	1,560 visits
Expected Average Revenue/Visit	\$240	\$240
Patients (Cases)	45	65
Expected Average Revenue/Patient	\$5,760	\$5,750

Table Four on the second following page provides available charge and cost information filed by area home health agencies in their most recent 2015 Joint Annual Reports. The data is for skilled nursing only, which is the only home health service proposed in this application. The data do not allow a meaningful comparison to AxelaCare’s very different pricing structure.

AxelaCare pays its infusion nurses between \$37 and \$45 per hour; an average is approximately \$40 per hour. AxelaCare projects Year One (2017) average expected nursing revenues of \$240 per visit.

The only comparable specialty infusion-specific charge data identified by the applicant in publicly available sources was CN1406-018, approved in 2014 for Coram/CVS Specialty Infusion Services to do specialty home infusion care. In that document, Coram projected average charges for its “specialty infusion patient” at \$290-\$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is \$240 for the nursing component. This is consistent with the Coram projections. The Coram 2015 Joint Annual Report provides no data on average charges. It is Coram’s first such report since becoming operational in late 2015.

For existing home health agencies as a group, the table on the next page shows that those who reported JAR financial data had an average cost per visit of \$105.86, an average charge per visit of \$103.33, and an average charge per hour of \$29.58.

Table Four: Comparative 2015 Cost and Charge Data Reported by West Tennessee Agencies Skilled Nursing Only

Health Statistics ID	Agency County	License Number	Agencies (52)	Cost per Visit	Avg Chg per Visit	Avg Chg per Hour
03025	Benton	8	Tennessee Quality Homecare - Northwest	52.00		
09065	Carroll	19	Baptist Memorial Home Care & Hospice	204.00		
19494	Davidson	42	Elk Valley Health Services Inc		\$79.00	\$35.00
19544	Davidson	56	Home Care Solutions, Inc	90.00		
20045	Decatur	221	Tennessee Quality Homecare - Southwest	50.00		
20055	Decatur	63	Volunteer Homecare of West Tennessee	88.00	\$120.00	\$40.00
23035	Dyer	77	Regional Home Care - Dyersburg	61.00		
24026	Fayette	291	NHC Homecare	111.00		
24036	Fayette	612	Where The Heart Is	60.00		
27025	Gibson	85	NHC Homecare	91.00		
27085	Gibson	285	Volunteer Home Care, Inc	105.00	\$120.00	\$40.00
33103	Hamilton	113	Amedisys Home Health	41.00		
36025	Hardin	290	Deaconess Homecare	144.00		
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)	99.00		
38015	Haywood	288	Careall Homecare Services	82.00		\$25.00
39035	Henderson	139	Regional Home Care - Lexington	57.00		
40075	Henry	122	Henry County Medical Center Home Health	188.00		
41034	Hickman	125	St. Thomas Home Health	98.00		
57055	Madison	174	Medical Center Home Health	97.00		
57075	Madison	177	Amedisys Home Health Care	46.00		
57085	Madison	178	Regional Home Care - Jackson	80.00		
57095	Madison	120	Extendicare Home Health of West Tennessee	100.00		
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)	136.00		
60024	Maury	181	NHC Homecare	110.00		
60074	Maury	194	Careall Homecare Services	101.00		\$23.00
66035	Obion	188	Extendicare Home Health of Western Tennessee	102.00		
79106	Shelby	237	Meritan, Inc.	143.00		
79136	Shelby	224	Quality Home Health Service (Extended Health Care, Inc.)	110.00		
79146	Shelby	239	Amedisys Home Care	62.00		
79206	Shelby	229	Family Home Health Agency	196.00		
79226	Shelby	214	Intrepid USA Healthcare Services	136.00		
79236	Shelby	244	Willowbrook Visiting Nurse Association	99.00		
79246	Shelby	215	Amedisys Home Health Care	54.00		
79256	Shelby	216	Americare Home Health Agency, Inc	150.00		
79276	Shelby	241	Baptist Trinity Home Care	177.00		
79316	Shelby	233	Methodist Alliance Home Care	160.00		
79376	Shelby	240	Homechoice Health Services	108.00	\$66.00	\$15.00
79386	Shelby	238	Amedisys Tennessee, LLC (Amedisys HH)	54.00		
79446	Shelby	242	Baptist Trinity Home Care - Private Pay (1 Patient only)		\$155.00	\$45.00
79456	Shelby	347	Accredo Health Group, Inc			
79466	Shelby	459	Alere Women's and Children's Health LLC			
79486	Shelby	227	Home Health Care of West Tennessee, Inc	123.00		\$33.00
79496	Shelby	610	Functional Independence Home Care, Inc			
79506	Shelby	611	No Place Like Home, Inc			\$35.00
79526	Shelby	616	Still Waters Home Health Agency	65.00		
79536	Shelby	618	Maxim Healthcare Services, Inc.		\$80.00	\$38.00
79546	Shelby	621	Best Nurses, Inc.			
79556	Shelby	120	Coram CVS/Specialty Infusion Service			
92025	Weakley	276	Careall Homecare Services	83.00		\$26.00
96010	Alcorn Co, MS	296	Magnolia Regional Health Care Home Hospice	178.00		
96020	Fulton Co., KY	297	Regional Home Care Parkway	155.00		
	Shelby		Hemophilia Preferred Care of Memphis			
Average of Agencies Reporting Costs & Charges				105.86	103.33	29.58

Note: Hemophilia Preferred Care of West Tennessee Not Yet Licensed and Operating as of -----
 Source: Joint Annual Reports of Home Health Agencies

**The Framework for Tennessee's Comprehensive State Health Plan
Five Principles for Achieving Better Health**

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how this CON application supports the principle, if applicable.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.

Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

Authorization of AxelaCare to provide home infusion nursing will address the needs of immune-compromised IVIG recipients to obtain AxelaCare medications in the most economical setting, without incurring needless extra time in the hospital for first dosages. Approval will eliminate burdensome commuting to remote infusion facilities, or having added risks of infections through exposure to other persons when they go to those infusion facilities.

2. Access to Care

Every citizen should have reasonable access to health care.

Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

Provision of the proposed service to all of the region's 21 counties will improve access to this type of care for rural residents of the region, whose counties are not served by a choice of home IVIG infusion providers. Those using AxelaCare home nursing teams will be spared multiple long drives to remote infusion centers.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. **The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.**

This type of patient, in this region of Tennessee, deserves expansion of choice among specialty providers of IVIG home infusion care. Only one known provider of this

service now serves all West Tennessee counties, and two other agencies provide it only in urban area counties. This compares poorly to the 10-20 agencies serving those counties for more routine home health needs. This project encourages reasonable levels of provider competition, and allows into the market an innovative national home care provider whose infusion management technology is valuable to the entire caregiver team.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.

The applicant has a robust quality assurance program, in which regional and corporate clinical staff continuously review patient data to ensure that AxelaCare nurses maintain the highest standard of competence and provide the best possible patient outcomes for every infusion session. The CareExchange technology used by AxelaCare nurses facilitates achieving optimal care during the infusion itself, allowing pharmacist and physician team members to participate in treatment decisions real-time as infusion proceeds, reflecting changing patient needs for changes in dosage amounts, infusion rates, and other services. The AxelaCare program ensures the highest possible quality of treatment outcomes in this difficult and complex area of care.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.

The project provides additional assurances to physicians and patients that their home infusion provider will be of the highest level of competence. Staffing the project will create an experienced and highly qualified specialty nursing staff for expanded service to rural counties as well as the urbanized Memphis area.

C(1).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG-RANGE DEVELOPMENT PLANS, IF ANY.

AxelaCare's goal is to become a Statewide provider of specialty home infusion nursing care for a very small group of West Tennessee patients whose physicians have prescribed infusion of AxelaCare immune globulin pharmaceuticals. Similar limited-scope applications for Middle and East Tennessee may be filed in the future, to achieve Statewide immune globulin home care for this patient group.

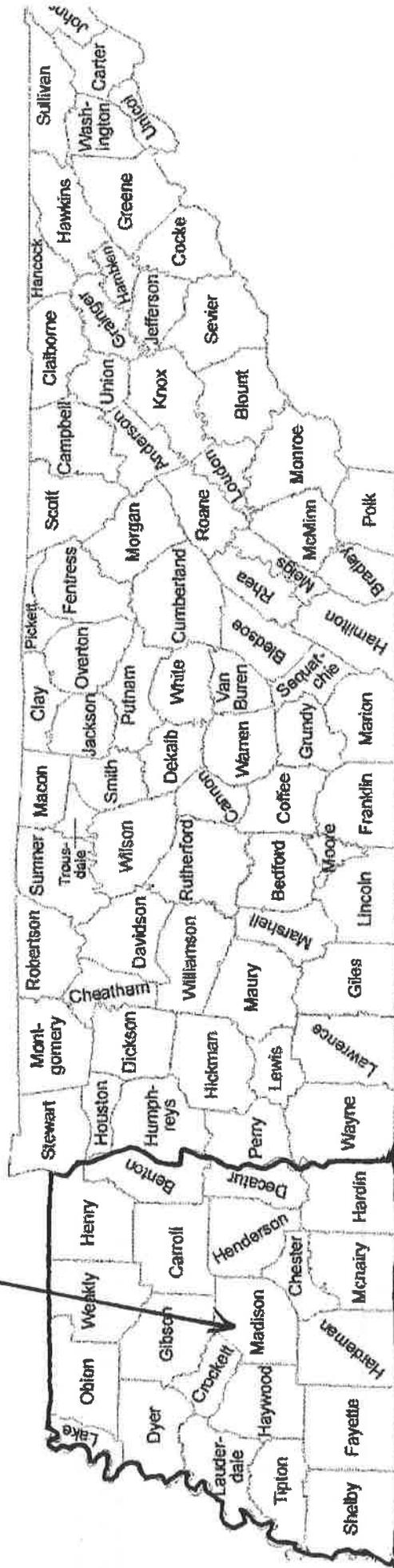
C(I).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2" X 11" SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

The proposed service area consists of 21 Tennessee counties. These are Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties. A map showing the area's location within Tennessee is provided following this page, and also in the Attachments to the application.

The applicant also has provided in the Attachments (Miscellaneous section) a projected patient origin for the project's patients, and the most current State report showing which agencies are now utilized by residents of these counties for all home care needs. Again, the applicant notes that the service proposed by this application is not currently available areawide, on a timely basis, from more than one of the many agencies authorized to provide home care in West Tennessee.

This is a reasonable area to cover. Nurses who will provide the proposed home care will reside throughout the region, so that they have acceptable drive times to the patients' homes. For example, there will be nurses residing in both Memphis and Jackson. Table Six-A in this application shows that five of the area's home health agencies are licensed to serve all twenty-one counties, and eight of them serve nineteen or more of the twenty-one counties. For home health services, whose nurses are typically residing in multiple locations in the service area, a large regional service area such as West Tennessee is not unusual or impractical.

AXELACARE WEST TENNESSEE
PROJECT SERVICE AREA



C(I).4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

The service area's median age is 39.9 years, which is close to the Tennessee average of 38.0 (2010 census). The service area's total population is increasing more slowly than the State's total population.

Whereas infusion services are needed in particular by the elderly population, this project will serve primarily patients below the age of 65, who are inordinately subject to neurological conditions regarded as immune system disorders.

The service area's population under the age of 65 is 85.4% of the total population, increasing to 85.6% over the next five years. These percentages are similar to the corresponding State percentages. The area population younger than 65 is increasing slowly -- at 0.2% annually, compared to the Statewide rate of 2.1%.

West Tennessee's rates of TennCare enrollment and of persons living in poverty are higher than Tennessee's rates. An estimated 27.4% of the service area residents are enrolled in TennCare, compared to 22.0% statewide. An estimated 22.0% of service area residents live in poverty, compared to 18.3% statewide.

Table Five on the following page provides detailed demographic statistics for each service area county.

**Table Five: AlexaCare Health Solutions--West Tennessee
Demographic Characteristics of Primary Service Area Population To Be Served By the Project
2016-2020**

Primary Service Area Counties	Median Age - 2010 Census	Total Population 2016	Total Population 2020	Total Population % Change 2016 - 2020	Total Population <Age 65 2016	% of Population	Total Population < Age 65 2020	% of Population	< 65 Age Population - Change 2016 - 2020	Median Household Income	TennCare Enrollees Mar 2016	Percent of 2015 Population Enrolled in TennCare	Persons Below Poverty Level 2015	Persons Below Poverty Level as % of Population US Census
Benton	45.4	16,672	16,741	0.4%	12,557	75.3%	12,173	73.0%	-3.1%	\$34,087	4,351	26.1%	3,568	21.4%
Carroll	42.0	28,380	28,207	-0.6%	22,388	78.9%	21,706	76.5%	-3.0%	\$36,168	8,059	28.4%	5,903	20.8%
Chester	36.2	18,260	18,978	3.9%	15,089	82.6%	15,388	84.3%	2.0%	\$41,028	4,034	22.1%	3,670	20.1%
Crockett	39.6	14,884	15,080	1.3%	12,076	81.1%	12,001	80.6%	-0.6%	\$37,298	4,150	27.9%	2,828	19.0%
Decatur	44.3	11,963	12,077	1.0%	9,033	75.5%	8,814	73.7%	-2.4%	\$37,219	3,044	25.4%	2,381	19.9%
Dyer	39.3	39,306	39,872	1.4%	32,453	82.6%	32,235	82.0%	-0.7%	\$41,426	11,269	28.7%	7,704	19.6%
Fayette	41.9	44,637	48,510	8.7%	35,906	80.4%	37,339	83.7%	4.0%	\$55,623	7,191	16.1%	6,562	14.7%
Gibson	39.9	51,394	52,438	2.0%	42,003	81.7%	42,183	82.1%	0.4%	\$37,460	13,736	26.7%	10,022	19.5%
Hardeman	39.2	27,283	27,278	0.0%	22,647	83.0%	22,107	81.0%	-2.4%	\$30,260	7,467	27.4%	6,903	25.3%
Hardin	43.5	26,557	26,783	0.9%	20,567	77.4%	20,102	75.7%	-2.3%	\$34,084	7,573	28.5%	5,763	21.7%
Haywood	39.2	18,410	18,128	-1.5%	15,333	83.3%	14,484	78.7%	-5.5%	\$33,922	6,119	33.2%	4,547	24.7%
Henderson	39.7	29,349	30,298	3.2%	24,112	82.2%	24,339	82.9%	0.9%	\$38,696	7,527	25.6%	5,606	19.1%
Henry	44.3	33,439	34,055	1.8%	25,511	76.3%	25,096	75.1%	-1.6%	\$38,694	8,450	25.3%	6,855	20.5%
Lake	38.3	8,299	8,579	3.4%	7,019	84.6%	7,180	86.5%	2.3%	\$29,214	2,311	27.8%	3,477	41.9%
Lauderdale	36.4	28,658	29,186	1.8%	24,574	85.7%	24,608	85.9%	0.1%	\$31,185	8,300	29.0%	7,107	24.8%
Madison	36.8	103,234	106,352	3.0%	86,953	84.2%	87,409	84.7%	0.5%	\$42,069	25,846	25.0%	21,576	20.9%
McNairy	41.6	27,179	27,760	2.1%	21,549	79.3%	21,432	78.9%	-0.5%	\$32,214	8,044	29.6%	6,387	23.5%
Obion	41.4	31,692	31,559	-0.4%	25,356	80.0%	24,662	77.8%	-2.7%	\$40,327	8,365	26.4%	6,592	20.8%
Shelby	34.6	959,361	981,022	2.3%	842,527	87.8%	845,788	88.2%	0.4%	\$46,213	276,265	28.8%	220,653	23.0%
Tipton	36.6	67,250	71,196	5.9%	58,118	86.4%	60,152	89.4%	3.5%	\$53,133	14,205	21.1%	10,357	15.4%
Weakley	37.0	36,066	36,360	0.8%	29,662	82.2%	29,241	81.1%	-1.4%	\$35,845	7,766	21.5%	7,754	21.5%
Tennessee PSA	39.9	1,622,273	1,660,459	2.4%	1,385,433	85.4%	1,388,439	85.6%	0.2%	\$38,389	444,072	27.4%	356,214	22.0%
State of Tennessee	38.0	6,812,005	7,108,031	4.3%	5,720,489	84.0%	5,841,736	85.8%	2.1%	\$44,621	1,525,548	22.4%	1,246,597	18.3%

Sources: TDOH Population Projections, 2015; U.S. Census QuickFacts; TennCare Bureau. PSA data is unweighted average, or total, of county data.

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

These factors have been discussed extensively in B.II.C. and other sections of the application. The applicant's experience is that commercially insured patients seeking home infusion of immune globulin pharmaceuticals often experience difficulties in obtaining home nursing to administer first and subsequent medication doses in a timely way.

As a consequence, those immune-compromised patients are forced to remain in the hospital for more (expensive) days than necessary to begin infusions pending creation of a competent home nursing team. Or, they must begin traveling back and forth to a freestanding or practice-based infusion center. This second option involves burdensome drive times and additional risks of exposure to opportunistic infections.

The project meets the special needs of a very small, but very compromised, patient population that is well-known to the applicant through its long experience in many other States.

West Tennessee's rural counties have an immediate need for an additional provider of immune globulin home infusion services.

Although Medicare rules deny reimbursement for home services of this type for Medicare enrollees, the applicant will serve all other types of adequately insured patients, regardless of their age, gender, race, ethnicity or income. And, based on its national experience, the applicant projects providing charity care of 2% of expected revenue receipts (before bad debt deductions).

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY....

Tables on the following pages identify all home health agencies currently authorized to serve this area, and provide utilization statistics for them.

Tables

- Tables Six-A, B: Service area counties that are authorized for each approved agency.
- Tables Seven-A, B: Patients served during 2015, in each agency's authorized counties within the project service area.
- Tables Eight-A, B, C: Area agencies' patient utilization 2013-2015, with agencies' dependence on patients from the project service area.
- Tables Nine-A, B, C: Agencies' TennCare gross revenues (charges) as a percent of their total gross revenues, and a ranking by level of TennCare participation.

Remarks

1. There are fifty-two agencies approved to serve this project's 21-county service area. Two are not currently licensed.
2. Only 1 in 10 of the agencies (i.e., 5 agencies) are authorized to serve all 21 of the project service area counties.
3. The agencies served 39,026 home care patients in the service area in 2015.
4. Their 2015 patient utilization was 6.1% higher than two years before, in 2013.
5. If this rate of increase continues, then in 2017--this project's Year Two of operation--the existing agencies will serve 3,092 more patients (50,652 X 1.061%).
6. The applicant's projected 65 patients in Year Two equate to less than two-tenths of one percent (0.17%) of all the agencies' total caseloads in 2015.
7. The agencies' 34.4% *average* TennCare utilization is misleading. Only 11 agencies had a TennCare mix of 34% or higher. Almost half the agencies (24) had zero participation and 9 more had lower than 10% participation.

Table Seven-A: Patients Served in 2015 by Agencies in The Project's Proposed Service Area--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agency	Benton	Carroll	Chester	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Lake	Lauderdale	Madison	McNairy	Obion	Shelby	Tipton	Weakley	Total
79456	Shelby	347	Accredo Health Group, Inc						1								1					21		23	
79466	Shelby	459	Alere Women's and Children's Health LLC						8		6						6	28				332	19	401	
79146	Shelby	239	Amedisys Home Care						1													947		948	
33103	Hamilton	113	Amedisys Home Health																					0	
57075	Madison	177	Amedisys Home Health Care	105	74	32	140	24	294	x	172	78	197	52	21	363	253	409	117	273			98	2,702	
79246	Shelby	215	Amedisys Home Health Care						51													686	0	737	
79386	Shelby	238	Amedisys Tennessee, LLC						4					1								140	409	554	
79256	Shelby	216	Americare Home Health Agency, Inc																			807	21	828	
09065	Carroll	19	Baptist Memorial Home Care & Hospice	15	207	1				11					8	1	11						2	257	
79276	Shelby	241	Baptist Trinity Home Care						155													2,871	143	3,169	
79446	Shelby	242	Baptist Trinity Home Care - Private Pay																			1		1	
79546	Shelby	621	Best Nurses, Inc.																			9		9	
38015	Haywood	288	Careall Homecare Services			50	62	2	5	3	51	71	8	109	49		155	125	19			74		763	
60074	Maury	194	Careall Homecare Services					7			107								14					128	
92025	Weakley	276	Careall Homecare Services	26	97			2	100		145					47	74			308				484	1,283
79556	Shelby	120	Coram CVS/Specialty Infusion Service						1													3		4	
36025	Hardin	290	Deaconess Homecare								55	280			33			24	257					726	
19494	Davidson	42	Elk Valley Health Services Inc	4	7		4	1	6		14	2	17	5	4	8	1	7	2	12		19	1	3	118
57095	Madison	120	Extendicare Home Health of West Tennessee	61	76	16	71	7	155	5	33	8	1	9	5	77	9	120	147	16		338	40	2	1,196
66035	Obion	188	Extendicare Home Health of Western Tennessee								9					46				219				46	320
79206	Shelby	229	Family Home Health Agency																			504		504	
79496	Shelby	610	Functional Independence Home Care, Inc						70										76			1,775	70	1,915	
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)																						327
unassign.	Shelby	625	Hemophilia Preferred Care of Memphis (NR)																						
40075	Henry	122	Henry County Medical Center Home Health	53	35											319									418
19544	Davidson	56	Home Care Solutions, Inc																						0
79486	Shelby	227	Home Health Care of West Tennessee, Inc						23								25					468	61	577	
79376	Shelby	240	Homechoice Health Services						60		155			175		101						977	57	1,525	
79226	Shelby	214	Intrepid USA Healthcare Services																			565		565	
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)	13	28	28	7		11	77	10	15	52	103		10	131	16				28	3	532	
96010	Alcorn Co. MS	296	Magnolia Regional Health Care Home Hospice								12						74		48					60	
79536	Shelby	618	Maxim Healthcare Services, Inc.						4		17											162	7	275	
57055	Madison	174	Medical Center Home Health	28	65	58	15	8		350	194	22	70	83		588	52				652		6	1,539	
79106	Shelby	237	Meridian, Inc.																						652
79316	Shelby	233	Methodist Alliance Home Care						45													2,952	181	3,178	
24026	Fayette	291	NHC Homecare						148		69			19		1	6					171	7	421	
27025	Gibson	85	NHC Homecare							279					20	27		164						29	666
60024	Maury	181	NHC Homecare																						0
79506	Shelby	611	No Place Like Home, Inc																			79	1	80	
79136	Shelby	224	Quality Home Health Svc (Extended Hlth Care)						3													284	4	291	
23035	Dyer	77	Regional Home Care - Dyersburg						865		49					137	225			25				1,331	
57085	Madison	178	Regional Home Care - Jackson	7	52	63	1		13	190	81	39	140			9	523	217	126			14	330	1,805	
39035	Henderson	139	Regional Home Care - Lexington	25	482	14		45			11				481	77	9						19	1,163	
96020	Fulton Co., KY	297	Regional Home Care Parkway																			42		6	48
41034	Hickman	125	St. Thomas Home Health																					1	1
79526	Shelby	616	Still Waters Home Health Agency																			58		58	
03025	Benton	8	Tennessee Quality Homecare - Northwest	145	101					65					155		1						93	629	
20045	Decatur	221	Tennessee Quality Homecare - Southwest								66			78			260	85						700	
27085	Gibson	285	Volunteer Home Care, Inc	215	274			463		425					196		717		231				71	2,685	
20055	Decatur	63	Volunteer Homecare of West Tennessee					416			157	75		324		2	213							1,289	
24036	Fayette	612	Where The Heart Is						13													1,015	16	1,044	
79236	Shelby	244	Willowbrook Visiting Nurse Association						88		17											433	19	561	
			TOTAL PATIENTS BY COUNTY	684	1,465	545	567	648	1,902	707	1,870	920	1,100	649	1,209	1,074	463	907	3,220	1,138	1,314	16,269	1,172	1,203	39,026

Total Number of Licensed Agencies--52

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)
 Note: Hemophilia Preferred Care was licensed in 7/15 and has not filed a 2015 Joint Annual Report.

Table Seven-B: Patients Served in 2015 by Agencies in the Project's Proposed Service Area--BY AGENCY ID NUMBER

Health Statistics ID	Agency County	License Number	Agency	Benton	Carroll	Chastert	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Lake	Lauderdale	Madison	McNairy	Obion	Shelby	Tipton	Weakley	Total	
03025	Benton	8	Tennessee Quality Homecare - Northwest	145	101		1			65					155			1		68			93	629		
09065	Carroll	19	Baptist Memorial Home Care & Hospice	15	207	1	1			11				8	1			11					2	257		
19494	Davidson	42	Elk Valley Health Services Inc	4	7	4	1	6		14	2	17	5	4	8	1	1	7	2	12	19	1	3	118		
19544	Davidson	56	Home Care Solutions, Inc																					0		
20045	Davidson	221	Tennessee Quality Homecare - Southwest		119		92					66		78				260	85					700		
20055	Decatur	63	Volunteer Homecare of West Tennessee	102			416			157	75			324				2	213					1,289		
23035	Dyer	77	Regional Home Care - Dyersburg			30		865		49					137	225				25				1,331		
24028	Fayette	291	NHC Homecare						148		69		19				1		6			171	7	421		
24036	Fayette	612	Where The Heart Is						13												1,015	16		1,044		
27025	Gibson	85	NHC Homecare	34	64	8	9	6		279				20	27			164	10				29	666		
27085	Gibson	285	Volunteer Home Care, Inc	215	274	93		463		425					196			717	231				71	2,685		
33103	Hamilton	113	Amedisys Home Health																					0		
36025	Hardin	290	Deaconess Homecare				20				55	280		33				24	257					726		
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)									250							76					327		
38015	Haywood	288	Careall Homecare Services															155	125	19			74	783		
39035	Henderson	139	Regional Home Care - Lexington	25	482	14	45				71	8	109	49				9					19	1,163		
40075	Henry	122	Henry County Medical Center Home Health	53	35							11		481	77								11	418		
41034	Hickman	125	St. Thomas Home Health	1											319									1		
57055	Madison	174	Medical Center Home Health	28	65	58	15	8		350	194	22	70	83				588	52				6	1,539		
57075	Madison	177	Amedisys Home Health Care	105	74	32	140	24	294	x	172	78	197	52	21	363		253	409	117	273		98	2,702		
57085	Madison	178	Regional Home Care - Jackson	7	52	63	1			13	190	81	39	140				9	523	217	126		330	1,805		
57095	Madison	120	Extendicare Home Health of West Tennessee	61	76	16	71	7	155	5	33	8	1	9	5	77	9	120	147	16			28	1,196		
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)	13	28	28	7			11	77	10	15	52	103			10	131	16			3	532		
60024	Mauzy	181	NHC Homecare																					0		
60074	Mauzy	194	Careall Homecare Services				7				107								14					128		
66035	Obion	188	Extendicare Home Health of Western Tennessee							9						46			219				46	320		
79106	Shelby	237	Meritran, Inc.																		652			652		
79136	Shelby	224	Quality Home Health Svc (Extended Hlth Care)						3												284	4		291		
79145	Shelby	239	Amedisys Home Care						1												947			948		
79206	Shelby	229	Family Home Health Agency																		504			504		
79226	Shelby	214	Intrepid USA Healthcare Services																		565			565		
79236	Shelby	244	Willowbrook Visiting Nurse Association									4									433	19		561		
79246	Shelby	215	Amedisys Home Health Care						88		17										807	21		828		
79256	Shelby	216	Americare Home Health Agency, Inc						51												2,871	143		3,169		
79276	Shelby	241	Baptist Trinity Home Care						155												977	57		1,525		
79316	Shelby	233	Methodist Alliance Home Care						45												140	409		554		
79376	Shelby	240	Homechoice Health Services						60		155		175				101							1,525		
79386	Shelby	238	Amedisys Tennessee, LLC						4			1												1		
79446	Shelby	242	Baptist Trinity Home Care - Private Pay																		1			1		
79456	Shelby	347	Accredo Health Group, Inc						1												21			23		
79466	Shelby	459	Alere Women's and Children's Health LLC						8		6		2					6	28		332	19		401		
79486	Shelby	227	Home Health Care of West Tennessee, Inc						23												468	61		577		
79496	Shelby	610	Functional Independence Home Care, Inc						70												1,775	70		1,915		
79506	Shelby	611	No Place Like Home, Inc																		79	1		80		
79526	Shelby	616	Still Waters Home Health Agency																		58			58		
79536	Shelby	618	Maxim Healthcare Services, Inc.						4		17		11					74			162	7		275		
79546	Shelby	621	Best Nurses, Inc.																		9			9		
79556	Shelby	120	Coram CVS/Specialty Infusion Service						1												3			4		
unassign.	Shelby	625	Hemophilia Preferred Care of Memphis																					1		
92025	Weakley	276	Careall Homecare Services	26	97	2		100		145				47	74					308			484	1,283		
96010	Alcorn Co., MS	296	Magnolia Regional Health Care Home Hospice									12							48					60		
96020	Fulton Co., KY	297	Regional Home Care Parkway																		42			48		
TOTAL PATIENTS BY COUNTY				684	1,465	545	567	648	1,902	707	1,870	920	1,100	649	1,209	1,074	463	907	3,220	1,138	1,314	16,269	1,172	1,203	39,026	
Total Number of Licensed Agencies--52																										

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)
 Note: Hemophilia Preferred Care was licensed in 7/16 and has not yet filed a 2015 Joint Annual Report.

**Table Eight-A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area
BY AGENCY NAME**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	20	21	23	23	100.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	373	335	438	401	91.6%
79146	Shelby	Amedisys Home Care	239	6/3/82	1,060	1,070	948	948	100.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	2,741	2,541	2,702	2,702	100.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	936	837	737	737	100.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	1,934	1,856	554	554	100.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	1,811	1,295	828	828	100.0%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	262	283	263	257	97.7%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	3,862	3,236	3,169	3,169	100.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	1	1	1	1	100.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	364	176	9	9	100.0%
38015	Haywood	Careall Homecare Services	288	6/7/84			786	783	99.6%
60074	Maury	Careall Homecare Services	194	2/9/84	609	881	614	128	20.8%
92025	Weakley	Careall Homecare Services	276	6/16/83	2,036	2,337	1,368	1,283	93.8%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84			4	4	100.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	1,330	2,122	1,120	726	64.8%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	277	293	457	118	25.8%
57095	Madison	Extencicare Home Health of West Tennessee	120	6/18/84	1,085	832	1,196	1,196	100.0%
66035	Obion	Extencicare Home Health of Western Tennessee	188	5/3/84	302	119	320	320	100.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	422	507	533	532	99.8%
79206	Shelby	Family Home Health Agency	229	3/10/77	379	428	504	504	100.0%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	953	1,494	1,915	1,915	100.0%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	341	205	348	327	94.0%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	363	408	428	418	97.7%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	1,930	1,689	1,813	0	0.0%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	1,010	754	577	577	100.0%
79376	Shelby	Homechoice Health Services	240	3/5/84	861	2,322	2,372	1,525	64.3%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	605	522	565	565	100.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	43	35	60	60	100.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	155	173	275	275	100.0%
57055	Madison	Medical Center Home Health	174	7/1/76	1,706	1,098	1,539	1,539	100.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	609	632	652	652	100.0%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	2,935	3,149	3,469	3,178	91.6%
24026	Fayette	NHC Homecare	291	6/6/83	226	301	421	421	100.0%
27025	Gibson	NHC Homecare	85	2/7/77	569	655	666	666	100.0%
60024	Maury	NHC Homecare	181	11/22/77	2,408	2,591	2,517	0	0.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	58	80	80	80	100.0%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	79	204	291	291	100.0%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	707	1,452	1,331	1,331	100.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	1,164	1,863	1,805	1,805	100.0%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	569	582	1,164	1,163	99.9%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	28	39	48	48	100.0%
41034	Hickman	St. Thomas Home Health	125	6/1/84	214	311	370	1	0.3%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	101	71	58	58	100.0%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,164	1,173	1,381	629	45.5%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,080	988	1,043	700	67.1%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,041	2,995	2,842	2,685	94.5%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,534	1,794	1,833	1,289	70.3%
24036	Fayette	Where the Heart Is	612	8/10/05	116	104	1,044	1,044	100.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	479	499	561	561	100.0%
AREAWIDE TOTALS AND AVERAGES					47,730	49,917	50,652	39,026	77.0%

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Notes: Hemophilia Preferred Care is omitted because it was not licensed until 7-15 and has not filed a 2015 Joint Annual Report.

Regional Home Care Parkway was licensed to serve Obion & Weakley Counties, but has now withdrawn from further service in TN.

Magnolia Regional Health Care Home Hospice totals include only TN patients. All others served are located out-of-state.

**Table Eight-B: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area
BY AGENCY ID**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,164	1,173	1,381	629	45.5%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	262	283	263	257	97.7%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	277	293	457	118	25.8%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	1,930	1,689	1,813	0	0.0%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,080	988	1,043	700	67.1%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,534	1,794	1,833	1,289	70.3%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	707	1,452	1,331	1,331	100.0%
24026	Fayette	NHC Homecare	291	6/6/83	226	301	421	421	100.0%
24036	Fayette	Where the Heart Is	612	8/10/05	116	104	1,044	1,044	100.0%
27025	Gibson	NHC Homecare	85	2/7/77	569	655	666	666	100.0%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,041	2,995	2,842	2,685	94.5%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	0	0.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	1,330	2,122	1,120	726	64.8%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	341	205	348	327	94.0%
38015	Haywood	Careall Homecare Services	288	6/7/84			786	783	99.6%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	569	582	1,164	1,163	99.9%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	363	408	428	418	97.7%
41034	Hickman	St. Thomas Home Health	125	6/1/84	214	311	370	1	0.3%
57055	Madison	Medical Center Home Health	174	7/1/76	1,706	1,098	1,539	1,539	100.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	2,741	2,541	2,702	2,702	100.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	1,164	1,863	1,805	1,805	100.0%
57095	Madison	Extencicare Home Health of West Tennessee	120	6/18/84	1,085	832	1,196	1,196	100.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	422	507	533	532	99.8%
60024	Maury	NHC Homecare	181	11/22/77	2,408	2,591	2,517	0	0.0%
60074	Maury	Careall Homecare Services	194	2/9/84	609	881	614	128	20.8%
66035	Obion	Extencicare Home Health of Western Tennessee	188	5/3/84	302	119	320	320	100.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	609	632	652	652	100.0%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	79	204	291	291	100.0%
79146	Shelby	Amedisys Home Care	239	6/3/82	1,060	1,070	948	948	100.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	379	428	504	504	100.0%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	605	522	565	565	100.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	479	499	561	561	100.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	936	837	737	737	100.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	1,811	1,295	828	828	100.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	3,862	3,236	3,169	3,169	100.0%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	2,935	3,149	3,469	3,178	91.6%
79376	Shelby	Homechoice Health Services	240	3/5/84	861	2,322	2,372	1,525	64.3%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	1,934	1,856	554	554	100.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	1	1	1	1	100.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	20	21	23	23	100.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	373	335	438	401	91.6%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	1,010	754	577	577	100.0%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	953	1,494	1,915	1,915	100.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	58	80	80	80	100.0%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	101	71	58	58	100.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	155	173	275	275	100.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	364	176	9	9	100.0%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84			4	4	100.0%
92025	Weakley	Careall Homecare Services	276	6/16/83	2,036	2,337	1,368	1,283	93.8%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	43	35	60	60	100.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	28	39	48	48	100.0%
AREAWIDE TOTALS AND AVERAGES					47,730	49,917	50,652	39,026	77.0%

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Notes: Hemophilia Preferred Care is omitted because it was not licensed until 7-15 and has not filed a 2015 Joint Annual Report.
Regional Home Care Parkway was licensed to serve Obion & Weakley Counties, but has now withdrawn from further service in TN.
Magnolia Regional Health Care Home Hospice totals include only TN patients. All others served are located out-of-state.

**Table Eight-C: Patients Served 2013-2015 by Home Health Agencies in the Project's Proposed Service Area
RANKED BY RELIANCE ON PROPOSED SERVICE AREA**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	707	1,452	1,331	1,331	100.0%
24026	Fayette	NHC Homecare	291	6/6/83	226	301	421	421	100.0%
24036	Fayette	Where the Heart Is	612	8/10/05	116	104	1,044	1,044	100.0%
27025	Gibson	NHC Homecare	85	2/7/77	569	655	666	666	100.0%
57055	Madison	Medical Center Home Health	174	7/1/76	1,706	1,098	1,539	1,539	100.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	2,741	2,541	2,702	2,702	100.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	1,164	1,863	1,805	1,805	100.0%
57095	Madison	Extencicare Home Health of West Tennessee	120	6/18/84	1,085	832	1,196	1,196	100.0%
66035	Obion	Extencicare Home Health of Western Tennessee	188	5/3/84	302	119	320	320	100.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	609	632	652	652	100.0%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	79	204	291	291	100.0%
79146	Shelby	Amedisys Home Care	239	6/3/82	1,060	1,070	948	948	100.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	379	428	504	504	100.0%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	605	522	565	565	100.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	479	499	561	561	100.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	936	837	737	737	100.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	1,811	1,295	828	828	100.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	3,862	3,236	3,169	3,169	100.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	1,934	1,856	554	554	100.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	1	1	1	1	100.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	20	21	23	23	100.0%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	1,010	754	577	577	100.0%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	953	1,494	1,915	1,915	100.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	58	80	80	80	100.0%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	101	71	58	58	100.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	155	173	275	275	100.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	364	176	9	9	100.0%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84			4	4	100.0%
96010	Alcom Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	43	35	60	60	100.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	28	39	48	48	100.0%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	569	582	1,164	1,163	99.9%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	422	507	533	532	99.8%
38015	Haywood	Careall Homecare Services	288	6/7/84			786	783	99.6%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	262	283	263	257	97.7%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	363	408	428	418	97.7%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,041	2,995	2,842	2,685	94.5%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	341	205	348	327	94.0%
92025	Weakley	Careall Homecare Services	276	6/16/83	2,036	2,337	1,368	1,283	93.8%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	2,935	3,149	3,469	3,178	91.6%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	373	335	438	401	91.6%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,534	1,794	1,833	1,289	70.3%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,080	988	1,043	700	67.1%
36025	Hardin	Deaconess Homecare	290	2/11/83	1,330	2,122	1,120	726	64.8%
79376	Shelby	Homechoice Health Services	240	3/5/84	861	2,322	2,372	1,525	64.3%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,164	1,173	1,381	629	45.5%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	277	293	457	118	25.8%
60074	Maury	Careall Homecare Services	194	2/9/84	609	881	614	128	20.8%
41034	Hickman	St. Thomas Home Health	125	6/1/84	214	311	370	1	0.3%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	1,930	1,689	1,813	0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	2,408	2,591	2,517	0	0.0%
AREAWIDE TOTALS AND AVERAGES					47,730	49,917	60,652	39,026	77.0%

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Notes: Hemophilia Preferred Care is omitted because it was not licensed until 7-15 and has not filed a 2015 Joint Annual Report.

Regional Home Care Parkway was licensed to serve Obion & Weakley Counties, but has now withdrawn from further service in TN.

Magnolia Regional Health Care Home Hospice totals include only TN patients. All others served are located out-of-state.

**Table Nine-A: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area
BY AGENCY NAME**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	\$0	\$0	0.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	\$532,931	\$187,059	35.1%
79146	Shelby	Amedisys Home Care	239	6/3/82	\$3,379,165	\$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	\$9,660,515	\$0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	\$11,268,119	\$0	0.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	\$2,560,156	\$0	0.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	\$5,994,682	\$0	0.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	\$4,597,317	\$82,434	1.8%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	\$851,909	\$0	0.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	\$8,819,896	\$0	0.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	\$105,992	\$0	0.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	\$587,773	\$34,944	5.9%
38015	Haywood	Careall Homecare Services	288	6/7/84	\$9,728,281	\$7,188,871	73.9%
60074	Maury	Careall Homecare Services	194	2/9/84	\$2,046,573	\$691,843	33.8%
92025	Weakley	Careall Homecare Services	276	6/16/83	\$9,728,043	\$4,694,898	48.3%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84	\$44,285	\$0	0.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	\$5,199,674	\$56,683	1.1%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	\$31,824,839	\$22,851,469	71.8%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	\$5,039,289	\$0	0.0%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	\$1,059,757	\$0	0.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	\$2,787,546	\$0	0.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	\$2,429,693	\$708,945	29.2%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	\$16,088,606	\$12,524,168	77.8%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	\$1,490,082	\$0	0.0%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	\$1,084,043	\$24,273	2.2%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	\$9,626,513	\$0	0.0%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	\$13,455,448	\$9,408,321	69.9%
79376	Shelby	Homechoice Health Services	240	3/5/84	\$9,939,690	\$3,110,466	31.3%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	\$2,631,668	\$0	0.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	\$1,911,049	\$0	0.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	\$12,648,142	\$11,875,369	93.9%
57055	Madison	Medical Center Home Health	174	7/1/76	\$4,852,062	\$0	0.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	\$2,517,728	\$361,846	14.4%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	\$7,676,244	\$92,400	1.2%
24026	Fayette	NHC Homecare	291	6/6/83	\$2,280,789	\$0	0.0%
27025	Gibson	NHC Homecare	85	2/7/77	\$3,599,719	\$0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	\$12,903,737	\$0	0.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	\$14,336,680	\$13,511,680	94.2%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	\$4,946,049	\$3,748,824	75.8%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	\$3,388,915	\$79,413	2.3%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	\$1,699,355	\$7,603	0.4%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	\$2,824,090	\$44,014	1.6%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	\$140,175	\$0	0.0%
41034	Hickman	St. Thomas Home Health	125	6/1/84	\$1,017,852	\$116,400	11.4%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	\$410,000	\$0	0.0%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	\$6,359,471	\$289,696	4.6%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	\$5,030,388	\$765,288	15.2%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	\$15,150,499	\$3,673,507	24.2%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	\$11,690,520	\$4,028,254	34.5%
24036	Fayette	Where the Heart Is	612	8/10/05	\$2,344,460	\$250,218	10.7%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	\$1,473,079	\$0	0.0%
AREAWIDE TOTALS AND AVERAGES					\$291,763,488	\$100,408,886	34.4%

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

**Table Nine-B: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area
BY AGENCY ID NUMBER**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	\$6,359,471	\$289,696	4.6%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	\$851,909	\$0	0.0%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	\$31,824,839	\$22,851,469	71.8%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	\$9,626,513	\$0	0.0%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	\$5,030,388	\$765,288	15.2%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	\$11,690,520	\$4,028,254	34.5%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	\$3,388,915	\$79,413	2.3%
24026	Fayette	NHC Homecare	291	6/6/83	\$2,280,789	\$0	0.0%
24036	Fayette	Where the Heart Is	612	8/10/05	\$2,344,460	\$250,218	10.7%
27025	Gibson	NHC Homecare	85	2/7/77	\$3,599,719	\$0	0.0%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	\$15,150,499	\$3,673,507	24.2%
33103	Hamilton	Amedisys Home Health	113	7/1/81	\$9,660,515	\$0	0.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	\$5,199,674	\$56,683	1.1%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	\$1,490,082	\$0	0.0%
38015	Haywood	Careall Homecare Services	288	6/7/84	\$9,728,281	\$7,188,871	73.9%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	\$2,824,090	\$44,014	1.6%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	\$1,084,043	\$24,273	2.2%
41034	Hickman	St. Thomas Home Health	125	6/1/84	\$1,017,852	\$116,400	11.4%
57055	Madison	Medical Center Home Health	174	7/1/76	\$4,852,062	\$0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	\$11,268,119	\$0	0.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	\$1,699,355	\$7,603	0.4%
57095	Madison	Extencicare Home Health of West Tennessee	120	6/18/84	\$5,039,289	\$0	0.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	\$2,787,546	\$0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	\$12,903,737	\$0	0.0%
60074	Maury	Careall Homecare Services	194	2/9/84	\$2,046,573	\$691,843	33.8%
66035	Obion	Extencicare Home Health of Western Tennessee	188	5/3/84	\$1,059,757	\$0	0.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	\$2,517,728	\$361,846	14.4%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	\$4,946,049	\$3,748,824	75.8%
79146	Shelby	Amedisys Home Care	239	6/3/82	\$3,379,165	\$0	0.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	\$2,429,693	\$708,945	29.2%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	\$2,631,668	\$0	0.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	\$1,473,079	\$0	0.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	\$2,560,156	\$0	0.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	\$4,597,317	\$82,434	1.8%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	\$8,819,896	\$0	0.0%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	\$7,676,244	\$92,400	1.2%
79376	Shelby	Homechoice Health Services	240	3/5/84	\$9,939,690	\$3,110,466	31.3%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	\$5,994,682	\$0	0.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	\$105,992	\$0	0.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	\$0	\$0	0.0%
79466	Shelby	Alerc Women's and Children's Health LLC	459	12/21/98	\$532,931	\$187,059	35.1%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	\$13,455,448	\$9,408,321	69.9%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	\$16,088,606	\$12,524,168	77.8%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	\$14,336,680	\$13,511,680	94.2%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	\$410,000	\$0	0.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	\$12,648,142	\$11,875,369	93.9%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	\$587,773	\$34,944	5.9%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84	\$44,285	\$0	0.0%
92025	Weakley	Careall Homecare Services	276	6/16/83	\$9,728,043	\$4,694,898	48.3%
96010	Alcom Co. MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	\$1,911,049	\$0	0.0%
96020	Fulton Co. KY	Regional Home Care Parkway	297	2/18/84	\$140,175	\$0	0.0%
AREAWIDE TOTALS AND AVERAGES					\$291,763,488	\$100,408,886	34.4%

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

**Table Nine-C: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Service Area
RANKED BY TENNCARE PERCENT OF TOTAL AGENCY GROSS CHARGES**

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
79506	Shelby	No Place Like Home, Inc	611	7/1/05	\$14,336,680	\$13,511,680	94.2%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	\$12,648,142	\$11,875,369	93.9%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	\$16,088,606	\$12,524,168	77.8%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	\$4,946,049	\$3,748,824	75.8%
38015	Haywood	Careall Homecare Services	288	6/7/84	\$9,728,281	\$7,188,871	73.9%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	\$31,824,839	\$22,851,469	71.8%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	\$13,455,448	\$9,408,321	69.9%
92025	Weakley	Careall Homecare Services	276	6/16/83	\$9,728,043	\$4,694,898	48.3%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	\$532,931	\$187,059	35.1%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	\$11,690,520	\$4,028,254	34.5%
60074	Mauzy	Careall Homecare Services	194	2/9/84	\$2,046,573	\$691,843	33.8%
79376	Shelby	Homechoice Health Services	240	3/5/84	\$9,939,690	\$3,110,466	31.3%
79206	Shelby	Family Home Health Agency	229	3/10/77	\$2,429,693	\$708,945	29.2%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	\$15,150,499	\$3,673,507	24.2%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	\$5,030,388	\$765,288	15.2%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	\$2,517,728	\$361,846	14.4%
41034	Hickman	St. Thomas Home Health	125	6/1/84	\$1,017,852	\$116,400	11.4%
24036	Fayette	Where the Heart Is	612	8/10/05	\$2,344,460	\$250,218	10.7%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	\$587,773	\$34,944	5.9%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	\$6,359,471	\$289,696	4.6%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	\$3,388,915	\$79,413	2.3%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	\$1,084,043	\$24,273	2.2%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	\$4,597,317	\$82,434	1.8%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	\$2,824,090	\$44,014	1.6%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	\$7,676,244	\$92,400	1.2%
36025	Hardin	Deaconess Homecare	290	2/11/83	\$5,199,674	\$56,683	1.1%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	\$1,699,355	\$7,603	0.4%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	\$851,909	\$0	0.0%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	\$9,626,513	\$0	0.0%
24026	Fayette	NHC Homecare	291	6/6/83	\$2,280,789	\$0	0.0%
27025	Gibson	NHC Homecare	85	2/7/77	\$3,599,719	\$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	\$9,660,515	\$0	0.0%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	\$1,490,082	\$0	0.0%
57055	Madison	Medical Center Home Health	174	7/1/76	\$4,852,062	\$0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	\$11,268,119	\$0	0.0%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	\$5,039,289	\$0	0.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	\$2,787,546	\$0	0.0%
60024	Mauzy	NHC Homecare	181	11/22/77	\$12,903,737	\$0	0.0%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	\$1,059,757	\$0	0.0%
79146	Shelby	Amedisys Home Care	239	6/3/82	\$3,379,165	\$0	0.0%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	\$2,631,668	\$0	0.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	\$1,473,079	\$0	0.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	\$2,560,156	\$0	0.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	\$8,819,896	\$0	0.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	\$5,994,682	\$0	0.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	\$105,992	\$0	0.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	\$0	\$0	0.0%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	\$410,000	\$0	0.0%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84	\$44,285	\$0	0.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	\$1,911,049	\$0	0.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	\$140,175	\$0	0.0%
AREAWIDE TOTALS AND AVERAGES					\$291,763,488	\$100,408,886	34.4%

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

C(1).6. PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE TWO (2) YEARS FOLLOWING COMPLETION OF THE PROJECT. ADDITIONALLY, PROVIDE THE DETAILS REGARDING THE METHODOLOGY USED TO PROJECT UTILIZATION. THE METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

Table Ten below shows AxelaCare management’s projected utilization in Years One and Two. Patients were projected by reviewing Tennessee referrals. That was increased to reflect the growth expected when physicians learn that AlexaCare has been authorized to rapidly provide well-equipped and highly competent nursing and pharmacy teams, as well as medications, to serve immune-compromised patients at any location in West Tennessee.

Table Ten: Projected Utilization of AxelaCare Healthcare Solutions CY2017 - CY2018		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560

The number of visits required to serve immune globulin infusion patients vary widely, depending on the physician’s direction as to dosage amount, rate of infusion, spacing of infusions (daily, alternating days, weekly, etc.) and duration of treatment. For CON purposes, AxelaCare used an average of 24 visits per patient per year.

C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.

- **ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST \$3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.**

- **THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.**

- **THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.**

- **FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.**

Licensure of the project will require AxelaCare to establish a home office in the agency's service area. The leased space will consist of one 149-SF office in an Executive Suite on that floor. It requires no new construction, modification or renovation. The only actual capital cost of the project other than the CON filing fee of \$3000 will be a minimal expense for office furnishings and equipment for one nurse manager (line A8) and legal and consulting fees (line A2). The latter estimate includes a contingency for legal expenses in the event the project is opposed.

Line B.1 is the fair market value of the facility being leased, calculated in the two alternative ways required by CON staff rules. The lease outlay was the larger of these two alternative calculations and was used in the Project Cost Chart.

Alternative Calculations

1. Lease Outlay Method

1 year first lease term X \$969 per month = **\$11,628 outlay in first term**

2. Pro Rata Fair Market Value Method

Value of land and building (current appraisal):	\$22,010,300 (See Attachments)
SF of building:	1,172,656 SF (See Attachments)
Area of leased space for this project:	149 SF (see lease document)
Calculation of FMV of space:	$149 \text{ SF} / 1,172,656 \text{ SF} \times \$22,010,300 =$
	\$2,797 FMV of leased space

PROJECT COSTS CHART--AXELACARE WEST TENNESSEE

V.1--4/12/16

A. Construction and equipment acquired by purchase:

1. Architectural and Engineering Fees	\$	<u>0</u>
2. Legal, Administrative, Consultant Fees (Excl CON Filing Fee)		<u>50,000</u>
3. Acquisition of Site		<u>0</u>
4. Preparation of Site		<u>0</u>
5. Construction Cost		<u>0</u>
6. Contingency Fund		<u>0</u>
7. Fixed Equipment (Not included in Construction Contract)		<u>0</u>
8. Moveable Equipment (List all equipment over \$50,000)		<u>5,000</u>
9. Other (Specify) _____		<u>0</u>

B. Acquisition by gift, donation, or lease:

1. Facility (inclusive of building and land)	Lease Outlay	<u>11,628</u>
2. Building only		<u>0</u>
3. Land only		<u>0</u>
4. Equipment (Specify) _____		<u>0</u>
5. Other (Specify) _____		<u>0</u>

C. Financing Costs and Fees:

1. Interim Financing	<u>0</u>
2. Underwriting Costs	<u>0</u>
3. Reserve for One Year's Debt Service	<u>0</u>
4. Other (Specify) _____	<u>0</u>

D. Estimated Project Cost
(A+B+C)

66,628

E. CON Filing Fee

3,000

F. Total Estimated Project Cost (D+E)

TOTAL \$ 69,628

Actual Capital Cost	58,000
Section B FMV	11,628

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY--2).

 A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;

 B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;

 C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;

 D. Grants--Notification of Intent form for grant application or notice of grant award;

 x **E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or**

 F. Other--Identify and document funding from all sources.

The project will be funded/financed by the applicant's parent company. Documentation of financing is provided in Attachment C, Economic Feasibility--2.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

Not applicable because the project does not require any kind of construction.

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

See the following pages for these charts, with notes where applicable. The applicant is not operational; so no Historic Data Chart is required.

Three Projected Data Charts have been submitted to provide clarification of how the project is financially feasible. One chart is for the proposed home nursing operation itself. The second chart is only for the AxelaCare operation in Lenexa, Kansas, that will support the nursing service by supplying pharmaceutical products to be infused. The third is the consolidated chart that reflects the full business income and expenses involved in offering an integrated program.

The AxelaCare home health nursing service that is proposed in this application will operate at a financial loss. But, the Kansas-based specialty pharmacy supporting the service is already licensed and operating throughout Tennessee, and it will be profitable enough to absorb those losses. There will be a positive margin when the two components of the operation are viewed in combination.

This is analogous to a project to expand a hospital emergency room: the expansion or the emergency room may operate at a loss when viewed in isolation. However, its losses will be absorbed into the overall hospital operation, which will show a positive operating margin with the new project open.

**PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE
NURSING AND HOME OFFICE ONLY--PHARMACEUTICALS EXCLUDED**

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		<u>CY 2017</u>	<u>CY 2018</u>
	PATIENTS	45	65
A.	Utilization Data VISITS	<u>1,080</u>	<u>1,560</u>
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u> </u>	\$ <u> </u>
2.	Outpatient Services-home health nursing visits	<u>259,200</u>	<u>374,400</u>
3.	Emergency Services	<u> </u>	<u> </u>
4.	Other Operating Revenue (Specify) <u>See notes page</u>	<u> </u>	<u> </u>
	Gross Operating Revenue	\$ <u>259,200</u>	\$ <u>374,400</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u> </u>	\$ <u> </u>
2.	Provision for Charity Care	<u>5,184</u>	<u>7,488</u>
3.	Provisions for Bad Debt	<u>2,592</u>	<u>3,744</u>
	Total Deductions	\$ <u>7,776</u>	\$ <u>11,232</u>
	NET OPERATING REVENUE	\$ <u>251,424</u>	\$ <u>363,168</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>369,840</u>	\$ <u>483,605</u>
2.	Physicians Salaries and Wages	<u> </u>	<u> </u>
3.	Supplies	<u>12,571</u>	<u>18,158</u>
4.	Taxes	<u> </u>	<u> </u>
5.	Depreciation	<u> </u>	<u> </u>
6.	Rent	<u>11,628</u>	<u>12,209</u>
7.	Interest, other than Capital	<u> </u>	<u> </u>
8.	Management Fees	<u> </u>	<u> </u>
	a. Fees to Affiliates	<u> </u>	<u> </u>
	b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9.	Other Expenses (Specify) <u>See notes page</u>	<u>2,160</u>	<u>2,640</u>
	<small>Dues, Utilities, Insurance, and Prop Taxes.</small>	<u> </u>	<u> </u>
	Total Operating Expenses	\$ <u>396,199</u>	\$ <u>516,612</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u> </u>	\$ <u> </u>
	NET OPERATING INCOME (LOSS)	\$ <u>(144,775)</u>	\$ <u>(153,444)</u>
F.	Capital Expenditures		
1.	Retirement of Principal	\$ <u> </u>	\$ <u> </u>
2.	Interest	<u> </u>	<u> </u>
	Total Capital Expenditures	\$ <u>0</u>	\$ <u>0</u>
	NET OPERATING INCOME (LOSS)		
	LESS CAPITAL EXPENDITURES	\$ <u>(144,775)</u>	\$ <u>(153,444)</u>

**PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE
PHARMACEUTICALS ONLY (FROM REGIONAL PHARMACY IN LENEXA, KANSAS)**

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2017	CY 2018
		45	65
	PATIENTS	<u>1,080</u>	<u>1,560</u>
	VISITS		
A.	Utilization Data		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u>4,320,000</u>	\$ <u>6,240,000</u>
2.	Outpatient Services		
3.	Emergency Services		
4.	Other Operating Revenue (Specify) <u>See notes page</u>		
	Gross Operating Revenue	\$ <u>4,320,000</u>	\$ <u>6,240,000</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u>86,400</u>	\$ <u>124,800</u>
2.	Provision for Charity Care	<u>43,200</u>	<u>62,400</u>
3.	Provisions for Bad Debt		
	Total Deductions	\$ <u>129,600</u>	\$ <u>187,200</u>
	NET OPERATING REVENUE	\$ <u>4,190,400</u>	\$ <u>6,052,800</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>333,500</u>	\$ <u>390,885</u>
2.	Physicians Salaries and Wages	<u>0</u>	<u>0</u>
3.	Supplies	<u>2,514,240</u>	<u>3,631,680</u>
4.	Taxes	<u>400,000</u>	<u>600,000</u>
5.	Depreciation	<u>3,333</u>	<u>7,500</u>
6.	Rent	<u>36,000</u>	<u>36,000</u>
7.	Interest, other than Capital		
8.	Management Fees		
	a. Fees to Affiliates		
	b. Fees to Non-Affiliates		
9.	Other Expenses (Specify) <u>See notes page</u>	<u>33,600</u>	<u>48,000</u>
	<small>Dues, Utilities, Insurance, and Prop Taxes.</small>		
	Total Operating Expenses	\$ <u>3,320,673</u>	\$ <u>4,714,065</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u>869,727</u>	\$ <u>1,338,735</u>
	NET OPERATING INCOME (LOSS)	\$ <u>869,727</u>	\$ <u>1,338,735</u>
F.	Capital Expenditures	10%	10%
1.	Equipment	\$ <u>200,000</u>	\$ <u>250,000</u>
2.	Interest		
	Total Capital Expenditures	\$ <u>200,000</u>	\$ <u>250,000</u>
	NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$ <u>669,727</u>	\$ <u>1,088,735</u>

**PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE
CONSOLIDATED OPERATIONS: NURSING, HOME OFFICE, & PHARMACEUTICALS**

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2017	CY 2018
	PATIENTS	<u>45</u>	<u>65</u>
A.	Utilization Data	<u>1,080</u>	<u>1,560</u>
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u> </u>	\$ <u> </u>
2.	Outpatient Services-home health nursing visits	<u>4,579,200</u>	<u>6,614,400</u>
3.	Emergency Services	<u>0</u>	<u>0</u>
4.	Other Operating Revenue (Specify) <u>See notes page</u>	<u>0</u>	<u>0</u>
	Gross Operating Revenue	\$ <u>4,579,200</u>	\$ <u>6,614,400</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u>0</u>	\$ <u>0</u>
2.	Provision for Charity Care	<u>91,584</u>	<u>132,288</u>
3.	Provisions for Bad Debt	<u>45,792</u>	<u>66,144</u>
	Total Deductions	\$ <u>137,376</u>	\$ <u>198,432</u>
	NET OPERATING REVENUE	\$ <u>4,441,824</u>	\$ <u>6,415,968</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>703,340</u>	\$ <u>874,490</u>
2.	Physicians Salaries and Wages	<u>0</u>	<u>0</u>
3.	Supplies	<u>2,526,811</u>	<u>3,649,838</u>
4.	Taxes	<u>400,000</u>	<u>600,000</u>
5.	Depreciation	<u>3,333</u>	<u>7,500</u>
6.	Rent	<u>47,628</u>	<u>48,209</u>
7.	Interest, other than Capital	<u>0</u>	<u>0</u>
8.	Management Fees		
a.	Fees to Affiliates	<u>0</u>	<u>0</u>
b.	Fees to Non-Affiliates	<u>0</u>	<u>0</u>
9.	Other Expenses (Specify) <u>See notes page</u>	<u>35,760</u>	<u>50,640</u>
	<small>Dues, Utilities, Insurance, and Prop Taxes.</small>		
	Total Operating Expenses	\$ <u>3,716,873</u>	\$ <u>5,230,677</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u>0</u>	\$ <u>0</u>
	NET OPERATING INCOME (LOSS)	\$ <u>724,951</u>	\$ <u>1,185,291</u>
F.	Capital Expenditures		
1.	Equipment	\$ <u>200,000</u>	\$ <u>250,000</u>
2.	Interest	<u>0</u>	<u>0</u>
	Total Capital Expenditures	\$ <u>200,000</u>	\$ <u>250,000</u>
	NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$ <u>524,951</u>	\$ <u>935,291</u>

D9--OTHER EXPENSES

NURSING P&L

	2017	2018
Postage	300	300
office phone	900	900
i-pad use fee	960	1440
	2160	2640

PHARMACEUTICALS/SERVICES P&L

	2017	2018
Postage	300	300
office phone	900	900
Pharma/Shipping	32400	46800
	33600	48000

COMBINED

	2017	2018
Postage	600	600
office phone	1800	1800
iPad Use Fee	960	1440
Pharma/Shipping	32400	46800
	35760	50640

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Eleven-A: Average Charges, Deductions, Net Charges, Net Operating Income West Tennessee Nursing Operations Only		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$5,760	\$5,760
Average Expected Revenue Per Visit	\$240	\$240
Average Deduction from Operating Revenue per Patient	\$173	\$173
Average Deduction from Operating Revenue per Visit	\$7	\$7
Average Net Charge (Net Operating Revenue) Per Patient	\$5,587	\$5,587
Average Net Charge (Net Operating Revenue) Per Visit	\$233	\$233
Average Net Operating Income after Expenses, Per Patient	-\$3,217	-\$3,217
Average Net Operating Income after Expenses, Per Visit	-\$134	-\$134

Table Eleven-B: Average Charges, Deductions, Net Charges, Net Operating Income Combined W. TN Nursing and Out of State Pharmaceutical Operations		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$101,760	\$101,760
Average Expected Revenue Per Visit	\$4,240	\$4,240
Average Deduction from Operating Revenue per Patient	\$3,053	\$3,053
Average Deduction from Operating Revenue per Visit	\$127	\$127
Average Net Charge (Net Operating Revenue) Per Patient	\$98,707	\$98,707
Average Net Charge (Net Operating Revenue) Per Visit	\$4,113	\$4,113
Average Net Operating Income after Expenses, Per Patient	\$16,110	\$18,235
Average Net Operating Income after Expenses, Per Visit	\$671	\$760

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

There are no current charges because the home nursing service is proposed, not operational. There are no current charges to be impacted or adjusted as a result of this project.

AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a “gross charge” that is discounted by “contractual adjustments” to yield “net revenue”. The revenue figures shown in Section B of the Projected Data Charts are the billed or “expected” revenues, i.e., the projected receipts based on pre-negotiated reimbursement contracts, before deductions for charity and bad debt.

The table below (repeated from a prior section of the application) shows the average expected charge/revenue data per patient and per visit for AxelaCare’s nursing services (home office and field staff) in West Tennessee. That is what AxelaCare is applying to add to its ongoing pharmaceutical distributions in Tennessee.

Table Three (Repeated): AxelaCare Healthcare Solutions, West Tennessee Nursing and Home Office (Excluding Pharmaceuticals)		
	Year One--CY2017	Year Two-CY2018
Expected Nursing Revenue	\$259,200	\$374,400
Visits	1,080 visits	1,560 visits
Expected Average Revenue/Visit	\$240	\$240
Patients (Cases)	45	65
Expected Average Revenue/Patient	\$5,760	\$5,750

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Although the applicant will not participate in Medicare for nursing services, Medicare pays for a 60-day episode of care at rates that vary by region and State. The approximate reimbursement of more than four visits is estimated by AxelaCare at \$2400.

The only specialty infusion-specific charge data identified by the applicant in recently approved CON projects are in CN1406-018, approved for Coram/CVS Specialty Infusion Services two years ago, in June 2014. Coram projected average charges for its West Tennessee “specialty infusion patient” at \$290-\$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is \$240 for the nursing component. This is consistent with the Coram projections.

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

Cost-effectiveness is demonstrated by the positive operating margin of the Projected Data Chart for the consolidated Nursing and Pharmaceutical components of the home health project. The Pharmaceutical operations attributable to the project will absorb losses projected by the Nursing operations of the project.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED.

The consolidated Nursing and Pharmaceutical Projected Data Chart demonstrates a positive cash flow beginning in Year One of the project.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

The anticipated payor mix for home care nursing services is 98% commercial (including Blue Cross and Medicare replacement plans), and 2% charity.

Year One expected revenue will be \$259,200. Commercial payor mix at 98% will be \$254,016. Charity care at 2% will be \$5,184.

C(II).10. PROVIDE COPIES OF THE BALANCE SHEET AND INCOME STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE INSTITUTION, AND THE MOST RECENT AUDITED FINANCIAL STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. FOR NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

These are provided for AxelaCare's parent company, in Attachment C, Economic Feasibility--10.

C(II)11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

A. A DISCUSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.

B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

Continuation of the status quo was rejected for reasons discussed at length throughout the application. Current patient care problems that need to be resolved include:

- Difficulties in finding agencies that are immediately staffed and ready to start patient infusions at home and are willing to provide care for sessions longer than 2 hours;
- Less than desirable results in training other agency's staff in the consistent and effective use of AxelaCare's handheld CareExchange technology, which is an optimal tool for ensuring complete, accurate, usable and real-time availability of patient clinical data to the team pharmacist and referring physician.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AND/OR WORKING RELATIONSHIPS, E.G., TRANSFER AGREEMENTS, CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

AxelaCare has, and expects to develop, referral and working relationships with a large number of hospitals, specialty medical practices and home health agencies in the Memphis area and the Jackson area.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

The applicant believes that the benefits of this project far outweigh the minuscule utilization impact that 65 AxelaCare home nursing patients would have on the overall array of 52 agencies serving West Tennessee. First, the AxelaCare patient volume is less than two-tenths of one percent of the 39,026 patients served by the agencies in this area last year. Second, at its current two-year rate of increase the agencies' caseloads in this area will increase by 3,092 patients by Year Two of the AxelaCare project. That should offset any conceivable adverse impact on existing agencies as a group.

On the positive side, the project has clear patient benefits for the health system. The project will encourage movement of IVIG infusion patients out of costlier and less convenient settings, where they now have to go in order to get a timely start of dosing for their disorders. It will manage their conditions with specialty-trained infusion nurses, using state-of-the-art information technology that enhances real-time communication between the care team and the patient's physician. The unique CareExchange technology also helps compile ever-larger databases that are usable for ongoing research to improve the effectiveness of these complex and evolving medications and their administration.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

RN's, and in particular infusion RN's, are the project's only clinical staff. Table Twelve below shows the Department of Labor and Workforce Development's 2015 occupational wage salary survey information for registered nurses.

Table Twelve: TDOL Surveyed Average Salaries for the Region				
Position	Entry Level	Mean	Median	Experienced
RN	\$45,906	\$59,308	\$58,872	\$66,019

Source: TDLWD Occupational Wages Surveys, 2015.

Please see the following page for Table Thirteen, which projects the project's required FTE's and salary ranges. The project will require the employment and deployment of only 6 FTE's in the nursing component of care (The pharmaceutical component based in Lexena, Kansas will not require additional staff to supply medications to the proposed nursing agency).

**Table Thirteen-A: Axelacare Healthcare Solutions-- West Tennessee
Projected Staffing**

Position Type (RN, etc.)	Yr 1-2017 FTE's	Yr 2-2018 FTE's	Each Position		Total CY2017 Salaries		Total CY2018 Salaries	
			Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Office Positions, Management and Clerical								
RN Home Care Director Memphis / Half Time in Office	0.50	0.50	\$85,000	\$103,000	\$42,500	\$51,500	\$43,775	\$53,045
Account Executive	1.00	1.00	\$65,000	\$85,000	\$65,000	\$85,000	\$66,950	\$87,550
Administrative Assistant (corporate-remote)	0.50	1.00	\$35,360	\$41,600	\$17,680	\$20,800	\$36,421	\$42,848
Subtotal, Home Office FTE's	2.00	2.50	\$185,360	\$229,600	\$125,180	\$157,300	\$147,146	\$183,443
Field Positions (Direct Patient Care)								
RN Home Care Director, Memphis / Half-Time Home in Field	0.50	0.50	\$85,000	\$103,000	\$42,500	\$51,500	\$42,500	\$51,500
Infusion RN's in the Field	2.00	3.00	\$76,960	\$87,360	\$153,920	\$174,720	\$230,880	\$262,080
Subtotal, Nurse FTE's Providing Home Infusion	2.50	3.50	\$161,960	\$190,360	\$196,420	\$226,220	\$273,380	\$313,580
Total FTE's	4.50	6.00	\$347,320	\$419,960	\$321,600	\$383,520	\$420,526	\$497,023
Salaries Plus Benefits (@15%)					\$369,840	\$441,048	\$483,605	\$571,576

Source: Axelacare management.

Note: RN Home Care Director spends half time as infusion nurse in the field. Table reflects that division of FTE's and salaries.

**Table Thirteen-B: Axelacare Healthcare Solutions-- West Tennessee
Projected Staffing - drug delivery**

Position Type (RN, etc.)	Yr 1-2017 FTE's	Yr 2-2018 FTE's	Each Position		Total CY2017 Salaries		Total CY2018 Salaries	
			Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Office Positions, Management and Clerical								
Pharmacist	1.00	1.00	\$145,000	\$180,000	\$145,000	\$180,000	\$149,350	\$185,400
Techs	1.00	1.00	\$40,000	\$50,000	\$40,000	\$50,000	\$41,200	\$51,500
Delivery	1.00	1.00	\$25,000	\$35,000	\$25,000	\$35,000	\$25,750	\$36,050
BackOffice	2.00	3.00	\$40,000	\$60,000	\$80,000	\$120,000	\$123,600	\$185,400
					\$0	\$0	\$0	\$0
Subtotal, Home Office FTE's	5.00	6.00	\$250,000	\$325,000	\$290,000	\$385,000	\$339,900	\$458,350
Salaries Plus Benefits (@15%)					\$333,500	\$442,750	\$390,885	\$527,103

Source: Axelacare management.

Note: RN Home Care Director spends half time as infusion nurse in the field. Table reflects that division of FTE's and salaries.

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

AxelaCare Health Solutions, LLC is familiar with State requirements for staffing a licensed home health agency. The small number of skilled RN's (4 FTE's) that are needed to operate the project are readily available through AxelaCare's corporate recruiting resources.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW POLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant so verifies.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

The applicant has no plans at this time to participate in training programs.

C(III).7(a). PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF MENTAL RETARDATION SERVICES, AND/OR ANY APPLICABLE MEDICARE REQUIREMENTS.

The applicant so verifies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE APPLICANT HAS RECEIVED OR WILL RECEIVE LICENSURE, CERTIFICATION, AND/OR ACCREDITATION

LICENSURE: The applicant will seek a limited home health agency license from the Board for Licensure of Healthcare Facilities, Tennessee Department of Health (TDH). The applicant's Specialty Pharmacy already holds a Tennessee non-resident pharmacy license and its associated Sterile Compounding License (granted by TDH).

CERTIFICATION: The applicant will not seek Medicare or TennCare certification.

ACCREDITATION: AxelaCare is Joint Commission accredited nationally and holds the Joint Commission's Gold Seal of Approval. AxelaCare's Specialty Pharmacy Program is also accredited by URAC (originally named the "Utilization Review Accreditation Program").

C(III).7(c). IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE CURRENT STANDING WITH ANY LICENSING, CERTIFYING, OR ACCREDITING AGENCY OR AGENCY.

AxelaCare's Lexena, Kansas Specialty Pharmacy and Sterile Compounding Licenses are in good standing.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

Please see the Attachments for copies of the applicant's licenses and most recent surveys and approved plans of correction.

C(III)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None have been identified.

C(III)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None have been identified.

C(III)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

To be provided under separate cover during the Supplemental Responses cycle.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE "GOOD CAUSE" FOR SUCH AN EXTENSION.

Not applicable. The applicant anticipates completing the project within the period of validity.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c):

September 28, 2016

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed		
2. Construction documents approved by TDH		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete		
10. * Issuance of license	93	12-30-16
11. *Initiation of service	111	1-1-17
12. Final architectural certification of payment		
13. Final Project Report Form (HF0055)		

*** For projects that do NOT involve construction or renovation: please complete items 10-11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

INDEX OF ATTACHMENTS

A.4	Ownership--Legal Entity and Organization Chart (if applicable)
A.6	Site Control
B.III.	Plot Plan
B.IV.	Floor Plan
C, Need--1	Documentation of Project-Specific Review Criteria <ol style="list-style-type: none">1. Performance Improvement Plan2. Patient Satisfaction Survey3. Emergency Response Protocols4. Financial Assistance Program
C, Need--1.A.3.	Qualifications of Professional Staff
C, Need--3	Service Area Maps
C, Economic Feasibility--2	Documentation of Availability of Funding
C, Economic Feasibility--10	Financial Statements of Funding Source
Miscellaneous Information	
	<ol style="list-style-type: none">1. Patient Origin Projection for the Project2. TDH Report of HHA's Currently Serving Area Residents3. URAC--Specialty Pharmacy4. TennCare Enrollment in Service Area5. Appraisal of Project Site
Support Letters	

A.4--Ownership
Legal Entity and Organization Chart

AxelaCare Health Solutions, LLC

Lenexa, KS

has been Accredited by

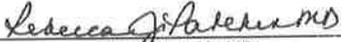


The Joint Commission

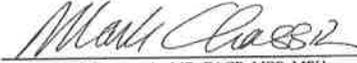
Which has surveyed this organization and found it to meet the requirements for the
Home Care Accreditation Program

April 18, 2015

Accreditation is customarily valid for up to 36 months.


Rebecca J. Patchin, MD
Chair, Board of Commissioners

ID #473713
Print/Reprint Date: 08/03/2015


Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.





**Tennessee
Secretary
of State**
Tre Hargett

Business Services Online > Find and Update a Business Record

Business Information Search

As of April 06, 2016 we have processed all corporate filings received in our office through March 31, 2016 and all annual reports received in our office through March 31, 2016.

Click on the underlined control number of the entity in the search results list to proceed to the detail page. From the detail page you can verify the entity displayed is correct (review addresses and business details) and select from the available entity actions - file an annual report, obtain a certificate of existence, file an amendment, etc.

Search: 1-2 of 2

Search Name: Starts With Contains

Control #:

Active Entities Only:

Control #	Entity Type	Name	Name Type	Name Status	Entity Filing Date	Entity Status
<u>000842223</u>	LLC	AxelaCare Health Solutions, LLC DELAWARE	Entity	Active	04/04/2016	Active
<u>000837285</u>	LLC	AXELACARE INTERMEDIATE HOLDINGS, LLC DELAWARE	Entity	Active	03/02/2016	Active

1-2 of 2

Information about individual business entities can be queried, viewed and printed using this search tool for free.

If you want to get an electronic file of all business entities in the database, the full database can be downloaded for a fee by [Clicking Here](#).

[Click Here](#) for information on the Business Services Online Search logic.

Division of Business Services
312 Rosa L. Parks Avenue, Snodgrass Tower, 6th
Floor
Nashville, TN 37243
615-741-2286
Email | Directions | Hours and Holidays | Methods of Payment

Business Filings and Information (615) 741-2286 | TNSOS.CORPINFO@tn.gov
 Certified Copies and Certificate of Existence (615) 741-6488 | TNSOS.CERT@tn.gov
 Motor Vehicle Temporary Liens (615) 741-0529 | TNSOS.MVTL@tn.gov
 Uniform Commercial Code (UCC) (615) 741-3276 | TNSOS.UCC@tn.gov
 Workers' Compensation Exemption Registrations (615) 741-0526 | TNSOS.WCER@tn.gov
 Apostilles & Authentications (615) 741-0536 | TNSOS.ATS@tn.gov
 Summons (615) 741-1799 | TNSOS.ATS@tn.gov
 Trademarks (615) 741-0531 | TNSOS.ATS@tn.gov

OUR MISSION

Our mission is to exceed the expectations of our customers, the taxpayers, by operating at the highest levels of accuracy, cost-effectiveness, and accountability in a customer-centered environment.

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Tennessee General Assembly
Bureau of Ethics and Campaign Finance
Tennessee Code Unannotated
NASS
State Comptroller
State Treasurer

APPLICATION FOR CERTIFICATE OF AUTHORITY
LIMITED LIABILITY COMPANY (ss-4233)



Business Services Division
Tre Hargett, Secretary of State
State of Tennessee
312 Rosa L. Parks AVE, 6th Fl.
Nashville, TN 37243-1102
(615) 741-2286

Filing Fee: \$50.00 per member
(minimum fee = \$300, maximum fee = \$3,000)

For Office Use Only

FILED

To The Secretary of the State of Tennessee:

Pursuant to the provisions of T.C.A. §48-249-904 of the Tennessee Revised Limited Liability Company Act, the undersigned hereby applies for a certificate of authority to transact business in the State of Tennessee, and for that purpose sets forth:

1. The name of the Limited Liability Company is: AxelaCare Health Solutions, LLC
If different, the name under which the certificate of authority is to be obtained is: _____

NOTE: The Secretary of State of the State of Tennessee may not issue a certificate of authority to a foreign Limited Liability Company if its name does not comply with the requirements of T.C.A. §48-249-106 of the Tennessee Revised Limited Liability Company Act. If obtaining a certificate of authority under an assumed Limited Liability Company name, an application must be filed pursuant to T.C.A. §48-249-106(d).

2. The state or country under whose law it is formed is: Delaware
and the date of its formation is: 05 / 05 / 2008 and the date it commenced doing business in Tennessee is: _____ / _____ / _____
Month Day Year

NOTE: Additional filing fees and proof of tax clearance confirming good standing may apply if the Limited Liability Company commenced doing business in Tennessee prior to the approval of this application. See T.C.A. §48-249-913(d) and T.C.A. §48-249-905(c)

3. This company has the additional designation of: _____

4. The name and complete address of its registered agent and office located in the state of Tennessee is:
Name: Corporation Service Company
Address: 2908 Poston Avenue
City: Nashville State: TN Zip Code: 37203 County: Davidson

5. Fiscal Year Close Month: December

6. If the document is not to be effective upon filing by the Secretary of State, the delayed effective date and time is: (Not to exceed 90 days)
Effective Date: _____ / _____ / _____ Time: _____
Month Day Year

7. The LLC will be: Member Managed Manager Managed Director Managed Board Managed Other

8. Number of Members at the date of filing: 1

9. Period of Duration: Perpetual Other _____ / _____ / _____
Month Day Year

10. The complete address of its principal executive office is:
Address: 15529 College Boulevard
City: Lenexa State: KS Zip Code: 66219

APPLICATION FOR CERTIFICATE OF AUTHORITY
LIMITED LIABILITY COMPANY (ss-4233)

Page 2 of 2



Business Services Division
Tre Hargett, Secretary of State
State of Tennessee
312 Rosa L. Parks AVE, 6th Fl.
Nashville, TN 37243-1102
(615) 741-2286

Filing Fee: \$50.00 per member
(minimum fee = \$300, maximum fee = \$3,000)

For Office Use Only

The name of the Limited Liability Company is: AxelaCare Health Solutions, LLC

11. The complete mailing address of the entity (if different from the principal office) is:

Address: _____
City: _____ State: _____ Zip Code: _____

12. Non-Profit LLC (required only if the Additional Designation of "Non-Profit LLC" is entered in section 3.)

I certify that this entity is a Non-Profit LLC whose sole member is a nonprofit corporation, foreign or domestic, incorporated under or subject to the provisions of the Tennessee Nonprofit Corporation Act and who is exempt from franchise and excise tax as not-for-profit as defined in T.C.A. §67-4-2004. The business is disregarded as an entity for federal income tax purposes.

13. Professional LLC (required only if the Additional Designation of "Professional LLC" is entered in section 3.)

I certify that this PLLC has one or more qualified persons as members and no disqualified persons as members or holders.
 I certify that this entity meets the requirement of T.C.A. §48-249-1123(b)(3)
Licensed Profession: _____

14. Series LLC (required only if the Additional Designation of "Series LLC" is entered in section 3.)

I certify that this entity meets the requirements of T.C.A. §48-249-309(i)
If the provisions of T.C.A. §48-249-309(i) (relating to foreign series LLCs) apply, then the information required by that section should be attached as part of this document.

15. Obligated Member Entity (list of obligated members and signatures must be attached)

This entity will be registered as an Obligated Member Entity (OME) Effective Date: _____ / _____ / _____
Month Day Year

I understand that by statute: THE EXECUTION AND FILING OF THIS DOCUMENT WILL CAUSE THE MEMBER(S) TO BE PERSONALLY LIABLE FOR THE DEBTS, OBLIGATIONS AND LIABILITIES FOR THE LIMITED LIABILITY COMPANY TO THE SAME EXTENT AS A GENERAL PARTNER OF A GENERAL PARTNERSHIP. CONSULT AN ATTORNEY.

16. Other Provisions: _____

3/31/2016
Signature Date

[Signature]
Signature

Member
Signer's Capacity (if other than individual capacity)

Edward Kramm
Name (printed or typed)



STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

AxelaCare Health Solutions, LLC
15529 COLLEGE BLVD
LENEXA, KS 66219-1351

April 4, 2016

Filing Acknowledgment

Please review the filing information below and notify our office immediately of any discrepancies.

SOS Control # :	000842223	Formation Locale:	DELAWARE
Filing Type:	Limited Liability Company - Foreign	Date Formed:	05/05/2008
Filing Date:	04/04/2016 10:16 AM	Fiscal Year Close:	12
Status:	Active	Annual Report Due:	04/01/2017
Duration Term:	Perpetual	Image # :	B0230-0234
Managed By:	Member Managed		

Document Receipt

Receipt # : 002615601

Filing Fee: \$300.00

Payment-Check/MO - CFS-1, NASHVILLE, TN

\$300.00

Registered Agent Address:
CORPORATION SERVICE COMPANY
2908 POSTON AVE
NASHVILLE, TN 37203-1312

Principal Address:
15529 COLLEGE BLVD
LENEXA, KS 66219-1351

Congratulations on the successful filing of your **Application for Certificate of Authority** for **AxelaCare Health Solutions, LLC** in the State of Tennessee which is effective on the date shown above. Please visit the Tennessee Department of Revenue website (apps.tn.gov/bizreg) to determine your online tax registration requirements. If you need to obtain a Certificate of Existence for this entity, you can request, pay for, and receive it from our website.

You must file an Annual Report with this office on or before the Annual Report Due Date noted above and maintain a Registered Office and Registered Agent. Failure to do so will subject the business to Administrative Dissolution/Revocation.

Tre Hargett
Secretary of State

Processed By: Jeff Cook

Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AXELACARE HEALTH SOLUTIONS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF APRIL, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "AXELACARE HEALTH SOLUTIONS, LLC" WAS FORMED ON THE FIFTH DAY OF MAY, A.D. 2008.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



4543052 8300

SR# 20162024445

You may verify this certificate online at corp.delaware.gov/authver.shtml

A handwritten signature in black ink, appearing to read "JBULLOCK". Below the signature is a horizontal line, and underneath the line, the text "Jeffrey W. Bullock, Secretary of State" is printed in a small font.

Authentication: 202079807

Date: 04-01-16

2016 APR 01 10:58 AM

Licensed Facilities

Last Updated: 4/15/2016 1:40:11 AM

For more information, please contact:

Health Care Facilities: (615)741-7221 or 1-888-310-4650

Current Listings:

Type = Manufacturer/Wholesaler/Distributor County = All Name = AxelaCare

[Click here to return to the search page](#)

Total Facilities:1

1.
AXELACARE HEALTH
SOLUTIONS LLC
15529 COLLEGE BLVD.
Lenexa , KS 66215
Attn: TIM WILSON
(877) 342-9352
Rank:

Administrator:
Owner Information:

Facility License
Number: 00003281
Status: Licensed
Date of Last Survey:
Accreditation Expires:
Date of Original
Licensure: 07/20/2010
Date of Expiration: 03/31/2017

RECEIVED APR 13 2015

41352
 STATE OF TENNESSEE
 DEPARTMENT OF
 HEALTH

ID NUMBER: 0000004637
 EXPIRATION DATE: 03/31/2017

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
 PHARMACY
 AXELACARE HEALTH SOLUTIONS, LLC

Paemarie OHO
 DIRECTOR, HEALTH RELATED BOARDS

AXELACARE HEALTH SOLUTIONS, LLC
 15529 COLLEGE BLVD.
 LENEXA KS 66219-1351



9544722
 41352

State of Tennessee

TENNESSEE BOARD OF PHARMACY
 PHARMACY
 AXELACARE HEALTH SOLUTIONS, LLC
 15529 COLLEGE BLVD.
 LENEXA KS 66219

*This is to certify that all requirements of the State of Tennessee
 have been met.*

ID NUMBER: 0000004637
 EXPIRATION DATE: 03/31/2017

CONTROLLED SUBSTANCE REGISTRATION

Paemarie OHO
 DIRECTOR, HEALTH RELATED BOARDS



RECEIVED APR 07 2015

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive
Nashville, TN 37243
tennessee.gov/health

TENNESSEE BOARD OF PHARMACY
(615) 741-2718 or Fax (615) 741-2722

March 31, 2015

AxelaCare Health Solutions, LLC
15529 College Blvd.
Lenexa, KS 66219

RE: STERILE COMPOUNDING MODIFIER

To Whom It May Concern:

This letter certifies that AxelaCare Health Solutions, LLC is qualified to engage in the practices of sterile compounding under Tennessee rules and regulations. This qualification is specific to the following facility:

LICENSE TYPE: Pharmacy
ADDRESS: 15529 College Blvd.
Lenexa, KS 66219
LICENSE NUMBER: 4637

COMMENTS: Please keep a copy of this letter on file at your facility. Once the board has completed implementation of the sterile compounding modifier, an updated license will be mailed to the address on record.

Sincerely,
Ailene Lynn
Administrative Assistant II
Tennessee Board of Pharmacy



UnitedHealth Group Incorporated
EIN: 41-1321939
100 % Owner of United HealthCare
Services, Inc.
9900 Bren Road, East, Minnetonka, MN
55343-9664

United HealthCare Services, Inc.
EIN: 41-1289245
100% Owner of Optum, Inc.
9900 Bren Road East, Minnetonka, MN
55343-9664

Optum, Inc.
EIN: 30-0580620
100 % Owner of OptumRX, Holdings,
LLC.
9900 Bren Road East, Minnetonka, MN
55343-9664

OptumRX Holdings, LLC
N/A
100 % Owner of OptumRX, Inc.
9900 Bren Road East, Minnetonka, MN
55343-9664

**OptumRX, Inc
(California)**
EIN: 30-0441200
100% Owner of AxelaCare Intermediate
Holdings, Inc.
9900 Bren Road East, Minnetonka, MN
55343-9664

**AxelaCare Intermediate
Holdings, LLC
(Delaware)**
EIN: 30-0842394
100% owner of AxelaCare, LLC
15529 College Blvd, Lenexa, KS 66219

**AxelaCare, LLC
(Delaware)**
EIN: 61-1708598
100% owner of AxelaCare Holdings,
Inc
15529 College Blvd., Lenexa, KS
66219

**AxelaCare Holdings, Inc.
(Delaware)**
EIN: 27-3918706
100% Owner of (Unknown), LLC
15529 College Blvd., Lenexa, KS 66219

**AxelaCare Health Solutions,
LLC
(Delaware)**
15529 College Blvd, Lenexa, KS 66219
EIN: Unknown

A.6--Site Control

B.III.--Plot Plan



CHEYENNE JOHNSON
Assessor of Property
 Shelby County, TN

[Property Search](#) [Property Details](#) [Maps](#)

Property

Property Address

5100 POPLAR AVE

Parcel ID

056033 00237

Owner Name

CLARK TOWER LLC

2015 Appraised Value

\$22,010,300

Property/Assessment Details

[Click Here](#)

Deed Information

[Click Here](#)

County Tax

[Click Here](#)

City Tax

[Click Here](#)

PROJECT ON
 27th FLOOR

CLARK TOWER

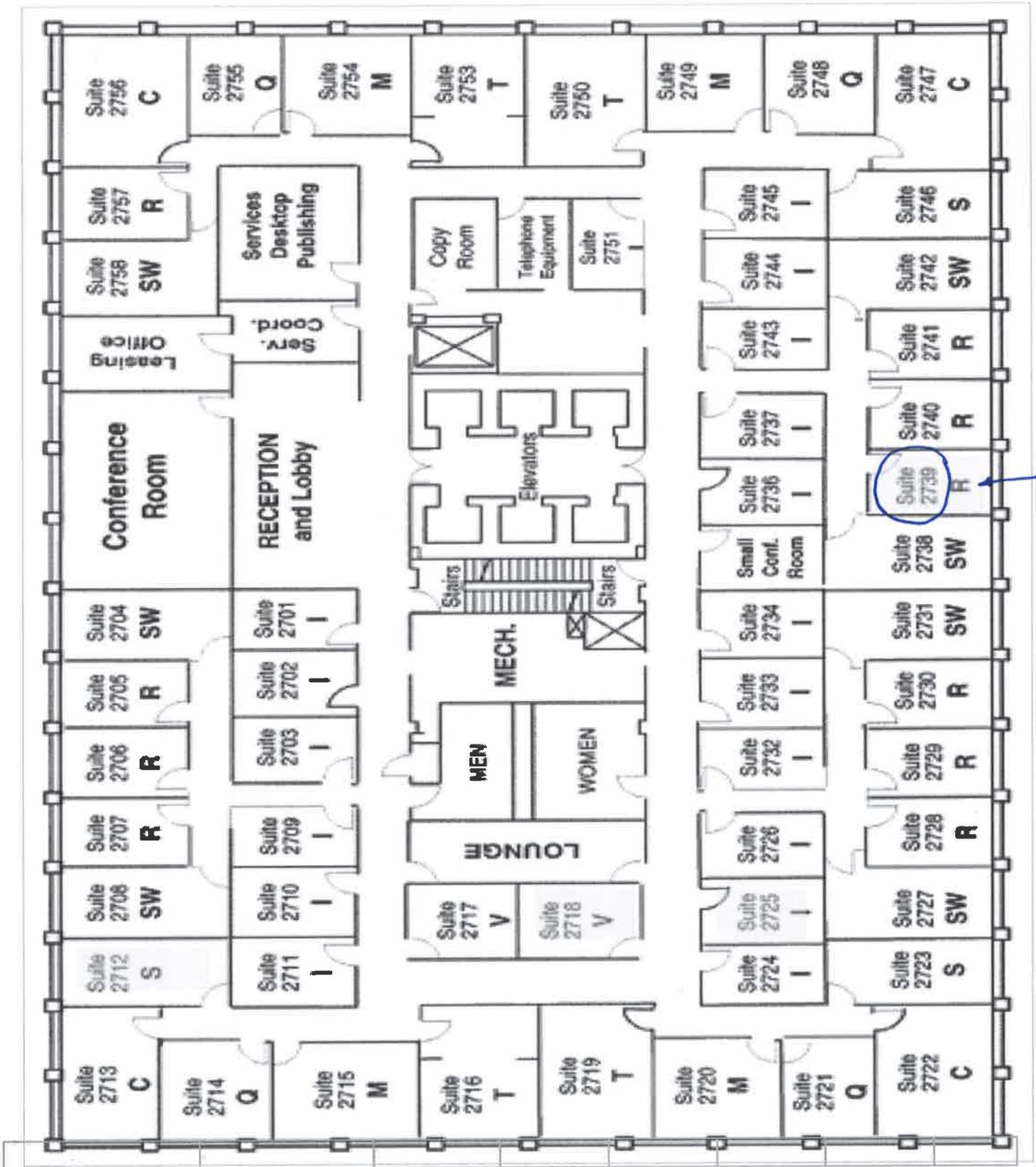
Layers

[Search Property Sales](#)

SITE 7.79 acres



B.IV.--Floor Plan



888.633.4237
regus.com

Regus

Andrew White 901.275.6390

Clark Tower – Office Availability 12/2013

C, Need--1.A
Documentation of Project-Specific Criteria

Policies and Procedures

SUBJECT:	Performance Improvement Plan	REFERENCE #:	6501
DEPARTMENT	Operations	EFFECTIVE DATE:	09/15/2014 10/2/2015
APPROVED BY:	Ted Kramm, CEO 	REVIEWED DATE:	05/20/2015, 08/20/2015 10/02/2015
		APPROVED DATE:	03/15/2014 08/28/2015 10/02/2015
REVISIONS:		REVISION DATE:	08/09/2015, 08/28/2015 10/02/2015 10/05/2015

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE AND PROGRAM SCOPE

The Performance Improvement Plan provides the framework for maximizing positive patient outcomes by continuously designing, measuring, assessing and improving performance. This will be accomplished via a dynamic process that monitors all functional activities of the organization, including patient focused functions and organizational functions.

Improving and sustaining improved performance is the goal of each office performance improvement program and activities. Nothing will be gained by data collection and analysis without an organization-wide strategy for improvement of performance. This may be accomplished in a single action or by a series of smaller actions to redesign a process to be more effective.

Most offices will identify more opportunities to improve than they have time to measure. It is important that priorities be set when the plan is first developed and then re-set as goals are achieved throughout the year. If measurement and assessment reveals no opportunities or need to improve, then priorities must be re-set and new processes selected to measure. Reassessment of the programs will be completed no less than annually.

This policy will also articulate the functions, roles and responsibilities of the corporate Performance Improvement/Quality Management Committee

This program description applies to both acute infusion and specialty pharmacy programs.

Policies and Procedures

RESPONSIBILITY

The Governing Body of AxelaCare Holdings is led by the CEO. He is ultimately responsible for the quality of patient/client care and will authorize adequate resources and support to establish and maintain a Performance Improvement Plan. The Governing Body of AxelaCare consists of the Senior Management. Authority over the company Performance Improvement is granted to the corporate performance improvement committee/Quality Management Leadership group from the CEO and Senior Leadership. This group/committee consists of members of senior leadership and relevant department heads. See Quality Org Chart. The program addresses all home care and specialty pharmacy programs and services, whether provided directly or through a written contract. The COO or designee has responsibility for assuring that there is an ongoing plan, and systematic process for the monitoring and evaluation of the quality and appropriateness of patient/client care and the clinical performance of the home care staff. In addition, he/she is responsible for the overall organization and coordination of the Quality Assurance activities. He/she must assure implementation of the Performance Improvement Program as it relates on high-risk, high-volume, and/or problem-prone activities.

The program shall be evaluated annually in the first quarter of each calendar year.

METRICS

Ongoing tracking of events are rolled into monthly data and evaluated quarterly. Benchmarks will reflect month over month changes as well as comparison to national rates based on therapy days and catheter days. Program metrics and progress towards goals are reported from the corporate PI committee to senior management. The CEO serves as chair of senior management and board of director representative. Evaluation of metrics are completed at a minimum of annually

Clinical

DEFINITIONS

Organizational Performance Trending (OPT)

Quality Improvement Project (QIP)

Senior Leadership-Senior Executives of AxelaCare Holdings reporting into CEO

POLICY

1. Each branch shall have a planned, systematic approach to process design and performance measurement and improvement utilizing data and statistical tools to determine progress towards goals
2. Based on the company mission and goals, the leaders will help set improvement priorities. The governing body and leaders are ultimately responsible for the actions and activities of the branches.

Policies and Procedures

3. The performance improvement program and policy and QIP's are reviewed as needed by corporate quality leadership at a minimum of annually and updated as necessary
4. The performance improvement activities shall be planned in a collaborative and interdisciplinary manner. Each branch will have a multi-disciplinary committee.
5. Each branch shall designate a person or persons to be responsible for coordinating all Performance Improvement (PI) activities.
6. This person or persons responsible for PI activities (PI Coordinator) can be a clinician or a non-clinician that has the ability to keep a multi-disciplinary group on task. This position is not solely responsible for implementation of the Performance Improvement program.
7. The PI coordinator is not necessarily a specific position, but a role incorporated into an individual job description . In specialty pharmacy branches the Pharmacy Manager also serves as the PI coordinator.
8. Each branch reports quarterly performance improvement activities to the corporate performance improvement committee for data review and trending of all locations
9. The VP of Nursing is designated as the responsible member of senior leadership responsible for the overall operation of the performance improvement program and serves as chair of the performance improvement committee. The VP of Pharmacy is designated as the alternate.
10. All staff, managers and owners share in the responsibility of performance improvement and will be involved in different aspects as priorities are identified. Orientation and training in their respective roles within the PI program **will occur upon hire and be documented in personnel files.**
11. Performance Improvement Plans are based in the principles of plan, do, check, act- PDCA. Plans are developed using data and statistical measures using and the use of national benchmarks based on patient and catheter days. Graphs and comparison data to national benchmarks are used to track improvement
12. All elements of the specialty program evaluation process will be reported at the quarterly Performance Improvement/Quality Management meetings

PROCEDURE

1. Duties of the PI Coordinator include:
 - 1.1 Assisting with overall development and implementation of the PI plan;
 - 1.2 Assisting with modifications to the PI Plan;
 - 1.3 Assisting in the identification of goals and related patient outcomes;
 - 1.4 Coordinating, participating and reporting of activities and results.;

Policies and Procedures

1.5 Assisting in monthly, quarterly and annual analysis of the problems, solutions and the PI Plan.

2. PI activities and program evaluation must include ongoing monitoring (data collection) of at least one important aspect of care (high risk, high volume or problem prone) related to each clinical service provided. Ongoing monitoring will also address at least one important administrative/operational aspect of function or service. Accreditation standards require data collection to measure the performance of medication management and blood/blood product use, when provided. Branch and corporate committees meet no less than quarterly

Examples for various programs include:

2.1 Pharmacy Services:

- Medication monitoring (effectiveness; medication errors; ADRs)
- Medication availability (e.g. stockouts, backorders, etc.)
- Dispensing accuracy and process (i.e. dispensing errors, prescription fill times)
- Adverse Drug Reactions including frequency of side effects
- Pain assessment
- Care planning (past due)
- Pediatric dosage calculations
- Monitoring of narrow therapeutic index drugs
- Monitoring of sterile preparation technique and environment i.e. end product testing and environmental testing
- Monitoring of product integrity i.e. temperature control during transport of products to patients
- Monitoring of sterile preparation technique and environment i.e. end product testing and environmental testing
- Compliance
- Delivery failures

2.2 Specialty Drug Management Program (potential source of data)

- Medication monitoring (effectiveness; medication errors)
- Medication availability (e.g. stockouts, backorders, etc.)
- Dispensing accuracy and process (i.e. dispensing errors, prescription fill times)
- Adverse Drug Reactions including frequency of side effects (assessment)
- Monitoring of narrow therapeutic index drugs
- Monitoring of product integrity i.e. temperature control during transport of products to patients; storage conditions (temperature logs, Inventory adjustment reports)
- Compliance-drug product selection and patient adherence (e.g. refill assessment)
- Delivery failures (e.g. FedEx exception report)
- Access to and availability of care (e.g. denial rate, appeal turnaround)
- Patient satisfaction/complaints
- Ig dosing optimization utilizing CareExchange data

Policies and Procedures

- Financial benefits of a specified program utilizing performance measures
 - Previous financial outcomes
 - Previous financial outcomes for purchasers
 - Projected financial outcomes for current or prospective purchasers

2.3 Nursing Services

- Patient education
 - Skilled procedures (PICC insertions)
 - Trouble-shooting pump problems
 - Pediatric assessment
 - Administration of new drugs/therapies
 - Documentation compliance
3. Data shall be routinely collected monthly utilizing CPR+, Care Link and Care Exchange as appropriate. Data shall be reported monthly and quarterly to the General Manager who will review and forward reports to Clinical Services. Clinical Services will report trended data the corporate to the Senior Leadership Team on a quarterly basis. Data reports and meeting minutes will be maintained by the corporate PI committee and can be located in the Company Z drive in the PI folder.
 4. OPT reports will be used as data collection tools and information from the OPT will be a component of the PI plan and trended data.
 5. Patient, referral source and payor satisfaction results and complaints will be included in PI data collection.
 6. Chart Audits
 - 6.1 Clinical chart reviews will be conducted using a standard tool and opportunities for improvement will be identified from the monthly audits and reported to the General Manager.
 - 6.2 Either 10% of active census or a minimum of 10 charts are to be reviewed monthly. Audits are due by the 10th of the month from the previous month
 - 6.3 Quarterly chart review reports are to be sent to corporate clinical services by the 10th day of the month after the completion of the quarter
 7. The performance management committee shall meet a minimum of at least quarterly and has authority for the AxelaCare performance improvement program. The committee develops and/or modifies branch quality improvement plans. All members review data and discuss trends, identifying opportunities for improvement, and approve new QIP's. The committee provides and guidance in the development and ongoing monitoring of all indicators and QIP's. Duties of the corporate performance improvement committee include, but are not limited to:

7.1 COO

Policies and Procedures

7.11 Meeting participation with focus on ensuring PI is cohesive with AxelaCare mission, vision and values

7.2 VP Nursing.

7.21 Meeting participation, serves as chair of corporate PI and AD-Hoc groups, provides reports to senior leadership

7.3 VP Pharmacy

7.31 Meeting participation, serves as alternate chair of corporate PI and AD-Hoc groups, evaluates need for policy revisions based on data review

7.4 Chief Compliance Officer/General Counsel

7.41 Meeting attendance, provides guidance on privacy issues

7.5 Branch Pharmacy Manager

7.51 Meeting attendance, presents branch quality data and core measures specific to pharmacy

7.6 Regional VP Operations

7.61 Meeting attendance, presents branch quality data related to operations

7.7 Director of Intake

7.71 Meeting attendance, presents data on service access

7.8 Director IT

7.81 Meeting attendance, presents system generated data and call center reports

8. The program evaluation of outcomes, clinical, and patient are tracked through SHP and reports that are reviewed by the local office and then reviewed by the corporate PI committee.

9. Program indicators or metrics that fall below threshold require an action plan to improve or correct the identified problem or meet acceptable levels of performance measures. Implementation of improvement plans shall be submitted no later than 1 month later quarterly report and quarterly meeting. The improvement plan will be included in the quality meeting minutes and a review of progress at the following quarterly meeting.

10. In the event of a payor requesting outcomes data, reports will be submitted with requested data and will be made available within 30 days of request.

Policies and Procedures

FORMS and DOCUMENTS

6501.F1 OPT Quality Report

6501.F2 Chart Audit Tool (2014)

6501. F3 Pharmacy Quality Control PI Quarterly Check

6501. F4 Branch Specific Performance Improvement Plan

Quality Org Chart

			Date of Event: _____		
Patient Information _____ N/A		SERVICE		THERAPY	
Patient Number _____		Pharmacy _____		Anti-Infective _____	
Start of Care ____/____/____		Nursing Branch _____		Ig _____	
Male _____ Female _____ Age _____		Nursing Agency _____		Chemotherapy _____	
Admitting Diagnosis _____		DME _____		Enteral _____	
		Other _____		Hydration _____	
ACCESS DEVICE EVENTS		Therapy interrupted (>2hrs)? Yes No		Therapy discontinued? Yes No	
ACCESS DEVICE					
Central Catheter (tunneled) _____		Intrathecal _____		Midclavicular _____	
Central Catheter (non-tunneled) _____		Peripheral _____		Port: Chest _____	
Epidural _____		PIC/Midline _____		Port: Peripheral _____	
Implanted Pump _____		PICC _____		SUBCUTANEOUS _____	
Access Device Brand _____					
LOSS OF PATENCY					
Caused by: Infiltration/Extravasation, *site _____		*approximate amount _____ mg _____ ml			
Catheter breakage/damage _____		Catheter pulled/fell out/dislodged _____		Thrombosis _____	
Inability to re-access _____		*Malposition _____			
Other _____		Unknown _____			
Intervention Replaced Removed Repaired _____		Declotted _____		(*method) None _____	
PHLEBITIS					
INS Grade 0 1 2 3 4 Unknown _____		Intervention Replaced Discontinued None _____			
PRIMARY BLOODSTREAM INFECTION					
Diagnosed By _____ culture, Results _____		not cultured _____		None _____	
Intervention Replaced Discontinued _____		Anti-Infective _____		(*medication) _____	
CATHETER SITE/TUNNEL INFECTION					
Intervention Replaced Removed _____		Treated w/Anti-Infective _____		None _____	
Diagnosed By _____ culture, Results _____		not cultured _____			
Therapy Occurrence					
Therapy interrupted (>2hrs)? Yes No		Medication discontinued? Yes No			
Medication _____ DOSE _____		FREQUENCY _____			
Medication _____ DOSE _____		FREQUENCY _____			
ADVERSE DRUG REACTION					
Intervention Changed to a different drug _____		Changed route _____		Changed dosage _____	
Changed frequency _____		Drug/fluids ordered to treat ADR _____		None _____	
Severity Minor _____ Major _____		Death _____		Unknown _____	
Duration Temporary _____		Permanent _____		Unknown _____	
Type of Reaction Diarrhea _____		Nausea/Vomiting _____		SOB _____	
Skin rash/hives _____		Unconsciousness _____		*Anaphylaxis _____	
Other _____		Unknown _____			
Other suspected drugs: _____		None _____			
MEDICATION INCIDENT (*attach details)					
Incorrect: medication _____ frequency _____		preparation _____ duration _____		dosage _____ route _____	
wrong patient _____		Caused by Pump Programming _____		Yes _____ No _____	
by: *RPh _____		*RN - Branch/HHA/SNF _____		*Patient/caregiver _____	
*Other _____		*Caused by patient non-compliance _____			
PATIENT EVENTS					
Therapy interrupted (>2hrs)? Yes No		Therapy discontinued? Yes No			
UNPLANNED ADMISSION/OBSERVATION					
To Hospital _____		E/R-Urgent Care _____		Other _____	
Due to Therapy-related occurrence:					
Phlebitis* _____		Primary Blood Stream Infection* _____			
Catheter/Tunnel Site Infection* _____		Loss of Catheter Patency* _____			
Adverse Drug Reaction* _____		Medication Incident* _____			
Noncompliance* _____		Equipment Failure _____			
Clinical Decline, not related to an event _____					
Symptoms _____					
*Infection, not catheter related _____					
Other: _____					
EQUIPMENT/PRODUCT FAILURE					
Was product or equipment damaged? Yes _____ No _____					
Did product perform as expected? Yes _____ No _____					
Manufacturer/Brand _____					
Supplier _____					
Catalog/Model Number _____					
Expiration Date ____/____/____ N/A _____					
Item Description _____					
*Form 3500A or 3500 completed and sent to:					
*Manufacturer Yes _____ No _____					
*FDA Yes _____ No _____					
*Date ____/____/____ By whom? _____					
PATIENT NONCOMPLIANCE					
Describe _____					
INSUFFICIENT MEDS/SUPPLIES					
Describe (or attach additional document) _____					
PATIENT EVENTS (continued)					
Therapy interrupted (>2hrs)? Yes No		Therapy discontinued? Yes No			
*INFECTION, NOT CATHETER RELATED					
(acquired post admission, not requiring hospitalization)					
URI _____ UTI _____ Wound _____					
Other _____					
Describe _____					
*PATIENT SAFETY					
*Fall _____					
*Chemo Spill _____					
*Needlestick: Clean _____ Contaminated _____					
*Other, explain _____					
OTHER					
Describe (attach details) _____					

* IMMEDIATE ACTIONS					
Physician Notified: Yes _____ No _____		N/A _____		Others notified _____	
Date ____/____/____		Time _____ am/pm		Date ____/____/____	
Physician Response _____		Responses _____		_____	
*Is this a Reviewable Event? Yes No If yes, refer to policy.					
*EVALUATION & FOLLOW-UP STRATEGY TO PREVENT RE-OCCURRENCE					
(Use additional document if needed)					

Signature of Person Completing Report _____					
Signature of General Manager _____					
Date ____/____/____					
Date ____/____/____					

Policies and Procedures

SUBJECT:	Patient Satisfaction Surveys	REFERENCE #:	6570
DEPARTMENT	Operations	EFFECTIVE DATE:	07/01/2014
APPROVED BY:	Ted Kramm, CEO 	REVIEWED DATE:	05/20/2015
		APPROVED DATE:	05/22/2015
REVISIONS:	AHS: 92(Inf4.2); SHI: POP021	REVISION DATE:	05/22/2015

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE

To provide a means to assess patient satisfaction with the service provided.

POLICY

Each patient on service will receive a Patient Satisfaction Survey

PROCEDURE

1. At appropriate intervals and no greater than monthly a Satisfaction Survey Report will be generated from CPR+.
2. Inactive (Discharged) patients or significant other will be handed or mailed a Satisfaction Survey Form.
3. Long-term active patients will be mailed a survey annually.
4. A self-addressed stamped envelope shall be provided to facilitate return.
5. The mailed and returned surveys will be tracked on the CPR+ satisfaction survey report and reported at the branch Performance Improvement meetings
6. The survey results will be entered into the SHP patient satisfaction database.
7. On a quarterly basis, the branch will review their patient satisfaction survey outcomes. The review will be submitted to the Corporate PI/QM committee as a standing agenda item at their quarterly meeting.

EXHIBITS/ATTACHMENTS

- 6570.A1 Satisfaction Survey Infusion Cover Letter
- 6570.A2 Patient Satisfaction Infusion Survey



Please take a few minutes to complete the survey by filling in the circle that best indicates your opinion about service you received. If a question does not apply to your situation, fill in the bubble that reads "Not Applicable". Simply return the survey to us using the enclosed envelope.

5. The staff helped you if you complained about problems with the service.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

6. The staff explained your rights and responsibilities.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

7. The staff explained how to voice a complaint.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

8. The medication(s) or supplies were delivered on time.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

9. The equipment was clean when delivered.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

1. The staff explained what to expect during your home care.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

2. The staff allowed you to participate in decisions that affect the care.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

3. The staff explained financial responsibility, insurance coverage, and cost (if any).
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

4. The staff explained your right to have personal health information kept private.
- Disagree
 - Mostly Disagree
 - Neither Agree nor Disagree
 - Mostly Agree
 - Strongly Agree
 - Not Applicable

001-07

 Strategic Healthcare Programs, LLC
 510 Castillo Street, 2nd Floor
 Santa Barbara, California 93101



032



123462

Policies and Procedures

SUBJECT:	Resuscitation CPR	REFERENCE #:	7030
DEPARTMENT	Clinical Operations	EFFECTIVE DATE:	03/01/2015
APPROVED BY:	Donald J Filibeck, <i>Donald J. Filibeck</i> VP Pharmacy Operations	REVIEWED DATE:	11/14/2014
		APPROVED DATE:	01/19/2015
REVISIONS:		REVISION DATE:	01/29/2016

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE

To establish company policy for the resuscitation of patients in the home.

DEFINITIONS/REFERENCES/REQUIREMENTS

CPR: Cardiopulmonary Resuscitation

ALS: Advanced Life Support

BLS: Basic Life Support

C-A-B: Compressions-Airway-Breathing

DNR: Do Not Resuscitate

AMA: American Heart Association

AED: Automated External defibrillator- a portable device used to treat sudden cardiac arrest. It sends an electric shock to the heart to restore normal heart rhythm.

POLICY

1. All Direct patient-care clinical staff shall be ALS or BLS CPR certified through an accepted training course. Online CPR certification is not accepted.
2. Any patient found without pulse or respiration, and does not have a DNR Order, will be resuscitated.
3. Clinician will utilize the most current American Heart Association procedures when performing CPR. Current method is: C-A-B
4. Non-clinical staff will not be required to obtain CPR certified or provide CPR in the event of Cardio Pulmonary Arrest.

Policies and Procedures

5. Patients/clients will be provided information about the organization's policies for resuscitation, medical emergencies and accessing "911" emergency services.
6. If an AED is available, use based on BLS guidelines.

PROCEDURE

1. Clinician establishes that the patient is without pulse and respirations.
2. Call 911 or ask someone else to do so. If no caretaker is present, the clinician is to call 911 first, then start CPR.
 - a. Inform 911 operator that CPR has been started
 - b. Provide patients address
3. Continue compressions and breaths -- 30 compressions, two breaths -- until help arrives.
4. The Clinician will give the paramedics the patient's medical history as required.
5. The Clinician will notify the physician, agency and family members after the support staff has arrived and when appropriate.

FORMS

EXHIBITS/ATTACHMENTS

7030A1 CPR Summary of Steps and Recommendations

Policies and Procedures

SUBJECT:	Handling Allergy /Anaphylaxis	REFERENCE #:	7035
DEPARTMENT	Clinical Operations	EFFECTIVE DATE:	03/01/2015
APPROVED BY:	Donald J Filibeck, <i>Donald J. Filibeck</i> VP Pharmacy Operations	REVIEWED DATE:	02/08/2015
		APPROVED DATE:	02/14/2015
REVISIONS:		REVISION DATE:	12/30/2015

SCOPE

This policy and procedure applies to pharmacies or other entities under the ownership or control of AxelaCare Holdings, Inc. (the Company).

PURPOSE

To detail an intervention plan in the event that a patient presents with an allergic/anaphylactic reaction.

DEFINITIONS/REFERENCES/REQUIREMENTS

Anaphylaxis Orders sheet

POLICY

If a patient experiences an allergic/anaphylactic reaction, patient management will be per procedure and/or physician order.

PROCEDURE

1. A physician's order for treating anaphylactic reactions should be obtained on all patients as needed.
2. The anaphylaxis kit may contain the following:
 - a. An adult and pediatric epinephrine injector (Epipen™).
 - b. An ampule of epinephrine as well as an appropriate syringe, needle and filter to draw up and administer - OPTIONAL
 - c. Diphenhydramine 50 mg capsule or syrup (25 mg/ml) - OPTIONAL.
 - d. Diphenhydramine Injection, 50mg/ml 1ml VL - OPTIONAL
3. The pharmacist and/or nurse must document in the patient's chart a medical, drug and allergy history and should be aware of cross sensitivity to related drugs.
4. If the patient develops a urticarial rash, the infusion should be discontinued until such time that the physician can be contacted and has indicated whether or not the infusion should be continued.

Policies and Procedures

5. If the patient develops any symptoms of anaphylaxis, the following should occur:
 - a. Mild Reaction (rash, itching, nausea, vomiting):
 - 1) Stop the infusion of the medication immediately.
 - 2) Call the physician for intervention instructions.
 - b. Severe Reaction (wheezing, difficulty in breathing, swelling of eyes, eyelids, or lips)
 - 1) Stop the infusion immediately (immediate action is required before notifying the physician).
 - 2) Establish and/or maintain an airway.
 - 3) Call the local paramedics (have another person call if possible).
 - 4) Follow the directions for use of the epinephrine injector.
 - 5) Call the physician.
6. The nurse will stay with the patient and be prepared to administer cardiopulmonary resuscitation (CPR). All nurses and pharmacists, who have direct patient contact, shall be certified in basic life support and have an understanding of the basic emergency intervention.
7. The nurse will stay with the patient and monitor vital signs every 30 minutes for a minimum of hour hours once the patient is symptom free if the physician does not order transportation to the hospital or the patient will be admitted to the hospital.
8. AxelaCare staff shall not transport the patient for additional medical intervention. Only family, caregivers or emergency personnel may transport the patient.

FORMS



Axelacare Health Solutions Corporate Policies and Procedures

Policy Number
AR 4.1

Financial Assistance Program

Page 1

Policy

AxelaCare Health Solutions, LLC ("AxelaCare") shall comply with all federal, state and local laws and regulations applicable to billing and collecting patients' co-insurance and deductible amounts. This policy may be revised at the discretion of the President and the Patient Financial Assistance Program Director. It is the policy of AxelaCare to make reasonable effort to collect a patient's co-insurance and deductible amounts on a regular basis by generating monthly statements to the patient and making follow up collections phone calls as required. Decisions to waive financial liability are made only on a case-by-case basis with final determination by the Review Committee.

Definitions

Requirements

Procedure

Responsibilities of AxelaCare

It is AxelaCare policy to bill for all applicable out-of-pocket amounts related to both medication and nursing services and to make reasonable efforts to collect such amounts in accordance with AxelaCare Collections Policies and Procedures (see AR Policies and Procedures Manual). However, if AxelaCare determines, in accordance with this policy, that a patient is financially unable to pay any out-of-pocket amounts, based upon satisfactory documentation to support the

financial hardship, AxelaCare may cease any billing or collection efforts with respect to the patient's out-of-pocket obligations for a period not to exceed one year, as the patient's financial profile may have significantly changed after one year's time. Eligibility for this Patient Financial Assistance Program must be established yearly.

The Patient Financial Assistance Program Administrator will monitor the annual expiration of each participating patient's eligibility and notify the Review Committee of upcoming expirations (with at least two month's notice). The Patient Financial Assistance Program Administrator will send each participating patient whose eligibility is due to expire a new financial worksheet update for completion at least thirty (30) days before the date on which his or her eligibility expires. If there is no response from a patient after ten (10) days, an AxelaCare representative who regularly works with the patient may make a follow-up phone call to the patient to verify receipt and understanding of the new Patient Financial Assistance Program application.

Responsibility for implementation of this Patient Financial Assistance Application Policy and Procedure lies ultimately with the Review Committee chaired by the President and will include the Department head of the Accounts Receivable Department and Clinical Department or assignee. A member of the Compliance Committee may also be included. The Patient Financial Assistance Program Administrator will regularly monitor and update the status of each

Axelacare Health Solutions Corporate Policies and Procedures

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Financial Assistance Program

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patient enrolled in the program and report his/her findings to the Review Committee at a regularly scheduled monthly meeting. The President may assign responsibility for individual determinations of waivers of co-insurance and/or deductible amounts to other members of the Review Committee who may make such determinations in accordance with this Policy and Procedure. The Review Committee may consult with the Legal Department on an as-needed basis regarding the application of this Policy and Procedure to ensure compliance with all applicable governing law.

- A copy of the final determination, with signature of the delegated representative of the Review Committee, will be maintained by the Reimbursement staff for a minimum period of one year.
- The Patient Financial Assistance Program Administrator will maintain each patient's individual Patient Financial Assistance program file (a file separate from his/her primary patient file) and keep these files under lock and key at all times to ensure compliance with HIPAA guidelines and patient confidentiality regulations.

Further to the above, it is understood that no employee shall engage in the following practices under any circumstances:

- Refuse care or treatment to any patient based on their written or verbal inability to pay for services for which they may incur financial expense.
- Imply or advertise that insurance payment will constitute "payment in full" or that the automatic waiver of co-insurance, deductibles and or out-of-pocket expenses will apply, or partially apply, without the express written authorization from the Review Committee following application.

- Waive co-insurance, deductibles or other out-of-pocket expenses without the express written authorization from the Review Committee following application.
- Target a specific patient-base, such as those with lower co-pays, those covered by a particular payor, or those referred by a particular physician or group, for the purpose of influencing reimbursement or to gain referrals.
- Solicit or distribute financial hardship forms without the verbal or written request of a patient.
- Inform a patient about the Patient Financial Assistance Program without a patient first addressing the issue of financial hardship. It is understood that billing and collection personnel may initiate contact with patients who have outstanding accounts to discuss payment of such accounts. Personnel may inform such patients of the Patient Financial Assistance Program and discuss the Patient Financial Assistance Program with such patients only after the patients express a concern about making payment on the account due to financial hardship.
- Complete a financial hardship form on behalf of any patient.
- Routinely use financial hardship forms.
- Charge patients who have obtained a waiver in accordance with this policy higher amounts than those charged to other patients for similar services for the purpose of offsetting the waiver.
- Fail to make reasonable efforts to collect a patient's balance (except where a waiver has been obtained).

Determination of Financial Need

Axelacare Health Solutions Corporate Policies and Procedures

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Financial Assistance Program

Page 3

Any patient who qualifies for state assistance for medical services (Medicaid) will be automatically approved for a full waiver of drug and nursing coverage, from Axelacare (less any contractual or required drug co-payment amounts), without providing for the full compliment of required paperwork. This qualification will remain in place as long as the patient is eligible for the state assistance.

If a patient is applying for SSI, proof of the application submission must be provided for before any waivers of co-insurance and/or deductible amounts can be performed.

The decision to waive any co-insurance and/or deductible amounts owed by a patient is made on a case-by-case basis. In order to ensure that decisions to waive co-insurance and/or deductible amounts are documented and based on standardized, objective criteria, and to verify that such waivers are granted in compliance with AxelaCare's charitable intent, each patient who desires financial assistance on any co-insurance and/or deductible amounts receives a letter (sample attached hereto as **Exhibit A**) describing AXELACARE's policy. The responsible party is invited to complete a Confidential Financial Worksheet (attached hereto as **Exhibit B**) and to submit the same to the Review Committee or to the Program Administrator. The Review Committee is not able to make financial eligibility determinations without a complete and executed Confidential Financial Worksheet being submitted by the patient.

The decision to waive co-insurance and/or deductible amounts is based on the financial information provided by the patient in the Confidential Financial Worksheet. No decision regarding financial inability may be made unless and until the patient has submitted a complete and executed Confidential

Financial Worksheet. In reviewing Confidential Financial Worksheets, the criteria set forth in **Exhibit C**, attached hereto, is considered. AxelaCare reserves the right to modify the criteria considered in reviewing Confidential Financial Worksheets without notice. Once a request for a waiver of co-insurance and/or deductible amounts is reviewed, the Reimbursement staff or other representative of the Finance Department, along with the patient's sales representative via conference call or in person, notifies the recipient and informs him or her as to the waiver. A Sample Waiver Request Determination Letter is attached hereto as **Exhibit D**.

Such permitted waivers of co-insurance and deductible amounts only may be granted, in whole or in part, on receipt of satisfactory documentation of the patient's financial hardship and upon approval of the Review Committee.

If a waiver is approved in whole or in part, the Accounts Receivable representative that is part of the Review Committee is responsible for documenting the patient's record in CPR+ in the insurance tab and for notifying the Patient Accounts Director so that the appropriate adjustments can be made to the account.

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Financial Assistance Program

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Records

Records will be maintained in accordance with policy
INF 4.2 Document Retention.

Forms



AxelaCare Health Solutions, LLC Policy and Procedure Manual		Policy Title: Financial Assistance Program
Standard:	Policy Number: AR 4.1	Pages: 15
Effective Date: May 5, 2008	Reviewed Date: August 8, 2008	Revised Date: January 19, 2010
Created By: KK	Approved By: KK	

Purpose:

The purpose of the Patient Financial Assistance Program and Application is to respond to patients' concerns regarding their documented inability to pay their patient responsibility expenses which include, but are not limited to the following: Patient Deductibles, Patient Co-Payments, Patient Co-Insurance, and Non-Covered Items. These expenses may be related to medications, nursing, supplies, or associated per diems.

Policy:

AxelaCare Health Solutions, LLC ("AxelaCare") shall comply with all federal, state and local laws and regulations applicable to billing and collecting patients' co-insurance and deductible amounts. This policy may be revised at the discretion of the President and the Patient Financial Assistance Program Director. It is the policy of AxelaCare to make reasonable effort to collect a patient's co-insurance and deductible amounts on a regular basis by generating monthly statements to the patient and making follow up collections phone calls as required. Decisions to waive financial liability are made only on a case-by-case basis with final determination by the Review Committee.

Procedure:

Responsibilities of AxelaCare

1. It is AxelaCare policy to bill for all applicable out-of-pocket amounts related to both medication and nursing services and

to make reasonable efforts to collect such amounts in accordance with AxelaCare Collections Policies and Procedures (see AR Policies and Procedures Manual). However, if AxelaCare determines, in accordance with this policy, that a patient is financially unable to pay any out-of-pocket amounts, based upon satisfactory documentation to support the financial hardship, AxelaCare may cease any billing or collection efforts with respect to the patient's out-of-pocket obligations for a period not to exceed one year, as the patient's financial profile may have significantly changed after one year's time. Eligibility for this Patient Financial Assistance Program must be established yearly.

2. The Patient Financial Assistance Program Administrator will monitor the annual expiration of each participating patient's eligibility and notify the Review Committee of upcoming expirations (with at least two month's notice). The Patient Financial Assistance Program Administrator will send each participating patient whose eligibility is due to expire a new financial worksheet update for completion at least thirty (30) days before the date on which his or her eligibility expires. If there is no response from a patient after ten (10) days, an AxelaCare representative who regularly works with the patient may make a follow-up phone call to the patient to verify receipt and understanding of the new Patient Financial Assistance Program application.
3. Responsibility for implementation of this Patient Financial Assistance Application Policy and Procedure lies ultimately with the Review Committee chaired by the President and will include the Department head of the Accounts Receivable Department and Clinical Department or assignee. A member of the Compliance Committee may also be included. The Patient Financial Assistance Program Administrator will regularly monitor and update the status of each patient enrolled in the program and report his/her findings to the Review Committee at a regularly

scheduled monthly meeting. The President may assign responsibility for individual determinations of waivers of co-insurance and/or deductible amounts to other members of the Review Committee who may make such determinations in accordance with this Policy and Procedure. The Review Committee may consult with the Legal Department on an as-needed basis regarding the application of this Policy and Procedure to ensure compliance with all applicable governing law.

4. A copy of the final determination, with signature of the delegated representative of the Review Committee, will be maintained by the Reimbursement staff for a minimum period of one year.
5. The Patient Financial Assistance Program Administrator will maintain each patient's individual Patient Financial Assistance program file (a file separate from his/her primary patient file) and keep these files under lock and key at all times to ensure compliance with HIPAA guidelines and patient confidentiality regulations.

Further to the above, it is understood that no employee shall engage in the following practices under any circumstances:

- Refuse care or treatment to any patient based on their written or verbal inability to pay for services for which they may incur financial expense.
- Imply or advertise that insurance payment will constitute "payment in full" or that the automatic waiver of co-insurance, deductibles and or out-of-pocket expenses will apply, or partially apply, without the express written authorization from the Review Committee following application.
- Waive co-insurance, deductibles or other out-of-pocket expenses without the express written authorization from the Review

Committee following application.

- Target a specific patient-base, such as those with lower co-pays, those covered by a particular payor, or those referred by a particular physician or group, for the purpose of influencing reimbursement or to gain referrals.
- Solicit or distribute financial hardship forms without the verbal or written request of a patient.
- Inform a patient about the Patient Financial Assistance Program without a patient first addressing the issue of financial hardship. It is understood that billing and collection personnel may initiate contact with patients who have outstanding accounts to discuss payment of such accounts. Personnel may inform such patients of the Patient Financial Assistance Program and discuss the Patient Financial Assistance Program with such patients only after the patients express a concern about making payment on the account due to financial hardship.
- Complete a financial hardship form on behalf of any patient.
- Routinely use financial hardship forms.
- Charge patients who have obtained a waiver in accordance with this policy higher amounts than those charged to other patients for similar services for the purpose of offsetting the waiver.
- Fail to make reasonable efforts to collect a patient's balance (except where a waiver has been obtained).

Determination of Financial Need

1. Any patient who qualifies for state assistance for medical services (Medicaid) will be automatically approved for a full waiver of drug and nursing coverage, from Axelacare (less any contractual or required drug co-payment amounts), without providing for the full compliment of required paperwork. This qualification will remain

in place as long as the patient is eligible for the state assistance.

2. If a patient is applying for SSI, proof of the application submission must be provided for before any waivers of co-insurance and/or deductible amounts can be performed.
3. The decision to waive any co-insurance and/or deductible amounts owed by a patient is made on a case-by-case basis. In order to ensure that decisions to waive co-insurance and/or deductible amounts are documented and based on standardized, objective criteria, and to verify that such waivers are granted in compliance with AxelaCare's charitable intent, each patient who desires financial assistance on any co-insurance and/or deductible amounts receives a letter (sample attached hereto as **Exhibit A**) describing AXELACARE's policy. The responsible party is invited to complete a Confidential Financial Worksheet (attached hereto as **Exhibit B**) and to submit the same to the Review Committee or to the Program Administrator. The Review Committee is not able to make financial eligibility determinations without a complete and executed Confidential Financial Worksheet being submitted by the patient.
4. The decision to waive co-insurance and/or deductible amounts is based on the financial information provided by the patient in the Confidential Financial Worksheet. No decision regarding financial inability may be made unless and until the patient has submitted a complete and executed Confidential Financial Worksheet. In reviewing Confidential Financial Worksheets, the criteria set forth in **Exhibit C**, attached hereto, is considered. AxelaCare reserves the right to modify the criteria considered in reviewing Confidential Financial Worksheets without notice. Once a request for a waiver of co-insurance and/or deductible amounts is reviewed, the Reimbursement staff or other representative of the Finance Department, along with the patient's sales representative via conference call or in person, notifies the recipient and informs him or her as to the waiver. A Sample Waiver Request Determination Letter is attached hereto as **Exhibit D**.

5. Such permitted waivers of co-insurance and deductible amounts only may be granted, in whole or in part, on receipt of satisfactory documentation of the patient's financial hardship and upon approval of the Review Committee.
6. If a waiver is approved in whole or in part, the Accounts Receivable representative that is part of the Review Committee is responsible for documenting the patient's record in CPR+ in the insurance tab and for notifying the Patient Accounts Director so that the appropriate adjustments can be made to the account.

Date

Patient Name

Address 1

Address 2

Dear:

Thank you for contacting AxelaCare Health Solutions, LLC regarding assistance with your deductible and/or co-insurance payment. We realize the financial difficulties that may arise when a patient has deductible and continuing co-insurance obligations for long-term health management. At the same time, we respect the Federal Office of Inspector General guidelines regarding the waiver of deductible and co-payment obligations. These guidelines require us to bill you for deductible and co-payment amounts that are determined to be due based on your health insurance benefits program. It is not our intent to place a severe financial burden on you and your family or to intrude upon the privacy concerns of your family. Your request for a waiver of deductible and co-insurance payments will be reviewed by the appropriate individuals in our organization.

Enclosed is a Financial Review Form. The completed Form will enable us to independently evaluate whether assistance may be extended to you in relation to your co-payment and/or deductible, and if so, the level that can be provided. Please complete the Form in its entirety using your **NET** (after deductions for payroll taxes) income totals. Return the Form to our office at your earliest convenience. As requested on the form, we do require that supporting documentation be included with your request so that we can accurately evaluate it. Supporting documentation includes proof of wages earned for all wage earners in your household (W-2s, pay stubs, SSI statements, child support documentation and / or tax returns) and proof of expenses (copies of monthly utility bills, mortgage payment stubs and other bills and expenses that you list on the form). Applications submitted without supporting documentation will be returned to you with a request for the additional information and will only be evaluated once the package is complete.

Your request will be treated confidentially and expeditiously. We will contact as soon as the review is completed.

Please contact me if you have any questions and/or concerns.

Sincerely,

Janet R. Gardner, RN, BSN
Program Administrator
(877) 342-9352

Please return completed form and supporting documentation to:

**AxelaCare Health Solutions, LLC
9730 Pflumm Rd
Lenexa, KS 66215**

Demographic Information

Patient Name: _____ Date of Birth: _____

Spouse/Parent Name: _____ SS#: _____

Address: _____ Home Phone: _____

Phone: _____ Cell _____

Name of Employer

Family Size

Patient: _____ Total # of persons in Household: _____

Spouse/Parent: _____ Number of Residents in School: _____

Spouse/Parent: _____ Other Dependents: _____

Net Income	Monthly	Expenses	Monthly
Total Household Income	_____	Rent/House Payment	
Child Support	_____	Bank, educational and other loans	
Social Security	_____	Car/Truck Payments	
SSI/Disability	_____	Utilities (electric, phone, gas, water)	
Other:	_____	Car Insurance	
Other:	_____	Health/Dental Insurance	
Other:	_____	Life Insurance	
		Property Insurance	
		Property Tax	
		Medical Fees (Dr, Pharmacy, Hosp)	
		Food/Clothing	

Educational Expenses

Other (child care, bus, etc.)

Explain:

Total Monthly Income

Total Monthly Expenses \$:

Remarks (use an additional sheet if necessary):

By signing below you certify that the above information is true and accurate and that this application is made to enable AxelaCare to judge your eligibility for reduced out-of-pocket expenses. If any of the information that you have given proves to be untrue, AxelaCare may re-evaluate your financial status and take action necessary to collect on your account.

Applicant Signature: _____

Date:

****** SUPPORTING DOCUMENTS MUST BE ATTACHED FOR THE APPLICATION
TO BE REVIEWED ******

Exhibit C

Review of Confidential Financial Worksheet

In reviewing the Confidential Financial Worksheet, personnel should take into account: (i) the reasonableness of expenses in each category, such as the amount of housing obligations (mortgage, rent/house payment) in relation to the area in which the beneficiary lives (*i.e.*, urban v. rural); (ii) the number of people in the beneficiary's household versus expenses and type of expenses; and (iii) the beneficiary's total cash flow compared to total assets.

Criteria for Financial Assistance Determination

Following the lead of other documented Patient Assistance/Hardship Policies that are available as public information AxelaCare will consider that any family's income that is equal to or less than 200% of the National Poverty Level will be approved for a full (*i.e.*, 100%) waiver of all co-payments and/or deductibles. Poverty levels are determined by the U.S. Department of Health and Human Services ("HHS"). The 2009 HHS Poverty Guidelines are as follows:

The Department of Health and Human Services' poverty guidelines for 2009

Department of Health and Human Services 2009 Poverty Guidelines			
Persons in Family or Household	48 Contiguous States and D.C.	Alaska	Hawaii
1	\$10,830	\$13,530	\$12,460
2	14,570	18,210	16,760
3	18,310	22,890	21,060
4	22,050	27,570	25,360
5	25,790	32,250	29,660
6	29,530	36,930	33,960
7	33,270	41,610	38,260
8	37,010	46,290	42,560
>8 persons	Add \$3,740 for each additional person	Add \$4,680 for each additional person	Add \$4,300 for each additional person
Source: U.S. Department of Health and Human Services, 2009 Poverty Guidelines, released February 28, 2009.			

SOURCE: *Federal Register*, Vol. 74, No. 14, January 23, 2009, pp. 4199-4201

Families that do not qualify for a waiver under the above criteria may be eligible for a full or partial waiver of co-pays and deductibles based on the family's discretionary income, as set forth below. Discretionary income is defined as the difference between the family's total net monthly income and total monthly expenses.

Family of 1 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$224	Full Waiver
\$225 - \$280	\$29.00
\$281 - \$335	\$43.00
\$336 - \$391	\$56.00
\$392 - \$446	\$70.00
\$447 - \$503	\$84.00
\$504 - \$560	\$112.00
Family of 2 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$301	Full Waiver
\$302 - \$377	\$38.00
\$378 - \$451	\$58.00
\$452 - \$526	\$75.00
\$527 - \$601	\$94.00
\$602 - \$678	\$114.00
\$679 - \$753	\$151.00
Family of 3 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$378	Full Waiver
\$379 - \$473	\$48.00
\$474 - \$567	\$72.00
\$568 - \$662	\$95.00
\$662 - \$755	\$119.00
\$756 - \$852	\$143.00
\$853 - \$947	\$189.00
Family of 4 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$456	Full Waiver
\$457 - \$570	\$58.00
\$571 - \$683	\$87.00
\$684 - \$797	\$ 114.00
\$798 - \$909	\$143.00

\$910 - \$1026	\$172.00
\$1027 - \$1141	\$228.00
Family of 5 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$533	Full Waiver
\$534 - \$667	\$68.00
\$668 - \$799	\$102.00
\$800 - \$932	\$133.00
\$933 - \$1064	\$167.00
\$1065 - \$1200	\$201.00
\$1201 - \$1334	\$267.00
Family of 6 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$611	Full Waiver
\$612 - \$764	\$78.00
\$765 - \$914	\$117.00
\$915 - \$1068	\$153.00
\$1069 - \$1218	\$191.00
\$1219 - \$1375	\$231.00
\$1376 - \$1528	\$306.00
Family of 7 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$688	Full Waiver
\$689 - \$861	\$88.00
\$862 - \$1030	\$131.00
\$1031 - \$1203	\$172.00
\$1204 - \$1373	\$216.00
\$1374 - \$1549	\$260.00
\$1550 - \$1722	\$344.00
Family of 8 Discretionary Income Chart	
Discretionary Income (Monthly)	Monthly Payment
\$0 - \$765	Full Waiver
\$766 - \$958	\$ 98.00
\$959 - \$1146	\$146.00

\$1147 - \$1339	\$192.00
\$1340 - \$1527	\$240.00
\$1528 - \$1723	\$289.00
\$1724 - \$1915	\$383.00

**C, Need--1.A.3.e.
Professional Qualifications
of Staff**

Dennis Perkins

6275 Piney River Road
Bartlett, TN 38135

901-864-6815
dennybobbie@bellsouth.net

EDUCATION: 1991 RN graduate of Baptist Hospital School of Nursing

EXPERIENCE:

June 2014- present: Benevere Specialty Pharmacy

POSITION: Infusion Nurse Coordinator

RESPONSIBILITIES: Responsible for teaching and administration of all medications requiring nursing support. Competent in administration of IVIG, Humira, Cimzia, Stelara, Growth Hormone, Hemophilia agents, and most other medications. Skilled at venipuncture, PICC and Central Line care in the pediatric and adult population. Also responsible for all aspects of obtaining and maintaining state licensure for 2 pharmacy branches, including procuring insurance contracts, such as multiple state Medicaid programs, Aetna, Humana, United HealthCare, Cigna, and BCBS. Our company grew from being licensed in 5 states to 51 states and territories in both branches during my first year of working with contracts.

March 2007- Present: Home Health Care of West TN

POSITION: Field Nurse, High-Tech Nurse, On-Call Nurse; worked part-time and on call since 2007; took full time position in 2012, continuing weekends on-call

RESPONSIBILITIES: All aspects of patient care, coordination of care, communication with physicians, supervisors, and other staff; all oasis reassessments per computer; frequently utilized as a clinical resource for high-tech nursing and complicated patient care; skilled with IV infusions, lab draws, PICC lines, central lines

March 2003-November 2011: PSA then Hemophilia Health Services/Accredo
(status post acquisition)

POSITION: Nurse Manager

RESPONSIBILITIES: Management of nursing team; patient care coordination; scheduling; QI; upkeep of client records; JACHO; state compliance; inservices; patient care; skilled nurse visits; assessments of patients; supervisory visits; computerized documentation; plan of treatments; fostering relationships with patients, staff, insurance case managers, and referral sources

March 2000-2003: Tender Loving Care Staffbuilders

POSITION: Pediatric Care Coordinator, then Director of Clinical Services, then Care Team Manager

RESPONSIBILITIES: Supervising and managing all aspects of the patient care of pediatrics and adults who received intermittent skilled nurse visits, full therapy services, CAN services, and nursing and CAN private duty; duties included maintaining state and JACHO regulations; extensive communication with multiple case managers; liason with hospitals, physicians, and insurance companies; organizing plans of treatment and supervising a multi-disciplinary team to maximize patient care; scheduling of all staff as DCS; management of a team of 70

Dennis Perkins

patients, including scheduling and supervisory visits; multi-team approach with nurses, therapists, and CNAs; all oasis events; frequencies to assist with PPS to obtain best financial reimbursement

1999-March 2000: Medshares Nursing Service

POSITION: Director of Clinical Services (Began as Pediatric Care Coordinator)

RESPONSIBILITIES: Same as listed for Tender Loving Care Staffbuilders

1998-1999: Trinity Home Health

POSITION: High-Tech Visit Nurse

RESPONSIBILITIES: Full range of visit specialties, including pediatrics, geriatrics, high-tech, and extensive wound care; Intermittently worked scheduling desk to coordinate patient care with all disciplines; Intermittently worked orders desk to communicate with hospitals, physicians, and case managers in order to coordinate care

1994-1998: Alverno Home Health

POSITION: High-Tech Skilled Visit Nurse

RESPONSIBILITIES: Similar to Trinity position above

1991-1994: St. Jude Children's Research Hospital

POSITION: ICU Staff Nurse/Charge Nurse

RESPONSIBILITIES: Total patient care of critically ill pediatric oncology patients in a research teaching facility; Experience with administration of neoplastic agents; facilitation of the grieving process of terminally ill patients and their families; experience as charge nurse; overseeing patient care team

1988-1991: Regional Medical Center Trauma ICU

POSITION: Nurse Extern

RESPONSIBILITIES: Performed total patient care of critically ill trauma patients; exposed to the worst of the worst accident victims and other graphic injuries; performed quick decision making in crisis situations; worked in an exciting and challenging environment.

1985-1988: Kord's Ambulance Service, Tucson, AZ

POSITION: EMT/First Responder

RESPONSIBILITIES: First Responder for Emergency 911 calls, hospital based

Job Description

TITLE: PRN Infusion Nurse - Registered Nurse (RN)

REPORTS TO: Regional Nurse Manager

The primary role of the Staff Nurse is to provide infusion nursing services to patients receiving infusion medications from AxelaCare Health Solutions LLC. (AxelaCare) pharmacy and /or provide clinical coordination for infusion services for all AxelaCare's patients. Service delivery will occur in patient's home or alternate site per patient's request. All infusion services and medication delivery will be provided utilizing accepted Infusion therapy clinical technique and AxelaCare's established policy and procedures ordered by a licensed physician or licensed practitioner. All clinical operations will be consistent with established goals, objectives, and policies, and specifically focused on delivery of infusion therapy nursing and medication delivery.

REQUIREMENTS and TRAINING:

- Graduate of an accredited school of nursing.
- Registered Nurse - Licensed in the state of practice.
- Minimum of 3 years' experience and proficiency in infusion therapy. Infusion in home health setting is highly desirable.
- MUST HAVE a high level of proficiency with the use of technology, thru exposure to EMR, use of data phones or tablets with WiFi access, and proficiency in Microsoft Office Suite (Excel and Word).
- Knowledge of the Infusion Nursing standards (INS) and nursing process including assessment, problem identification or nursing diagnosis, outcome identification, planning and communicating, implementation, and evaluation.
- Knowledgeable and/or experience with current state licensure requirements
- Knowledgeable and/or experience in HIPAA and JCAHO; a plus
- Excellent interpersonal, listening, organizational, and critical thinking skills.
- Ability to work with an interdisciplinary team of professionals including clinical, pharmacy, physicians, outside infusion nursing agencies, patients, families, and significant caregivers.
- Professional appearance, and teaching skills

Job Description

- Ability to work independently in home or alternate site settings
 - Ability to work under pressure with clinical emergencies if required
 - Ability to meet attendance, overtime, on-call, and other reliability requirements of the job.
- Comply with nursing professional practice acts or title acts relating to reporting and peer review.

FUNCTIONS AND RESPONSIBILITIES

- Ability to establish and maintain positive clinical rapport with all patients and their families, representing AxelaCare including working directly with patients and their families, maintain contact and clinically monitor all patients providing direct infusion therapy services.
- Infuse medications on a regular basis in patient's home setting including monitoring and tracking vital signs, performing procedures such as IV placement, phlebotomy, and medication administration via peripheral infusion device; or PICC line; Implantable port; and/or Central Venous Catheters and as ordered by a licensed physician or licensed practitioner.
- Assess patient in home environments, including clinical assessment safety of environment, pain assessment, monitor effectiveness of medication treatment, develop plan of care, education for patients and patient's family members, including providing care.
- Establish and maintain all clinical documentation including Plans of Care/Treatment (POC/POT), Clinical Summaries, medication changes and updates for AxelaCare pharmacy.
- Willingness to work with most ages and diagnosis of patients receiving infusion therapy medication.
- May work with numerous infused or injectable medications including orals per AxelaCare protocols
- Clinical oversight of all patient functions provided by AxelaCare Health Solutions, LLC.
- Collaborative relationships involving all agencies delivering services on behalf of/or in conjunction with AxelaCare, including all nursing agencies in a contracted relationship, patient, families, significant caregivers, and other healthcare team members.
- Maintaining current State Nursing licensure, as required by the State Department of Health, is mandatory.

Job Description

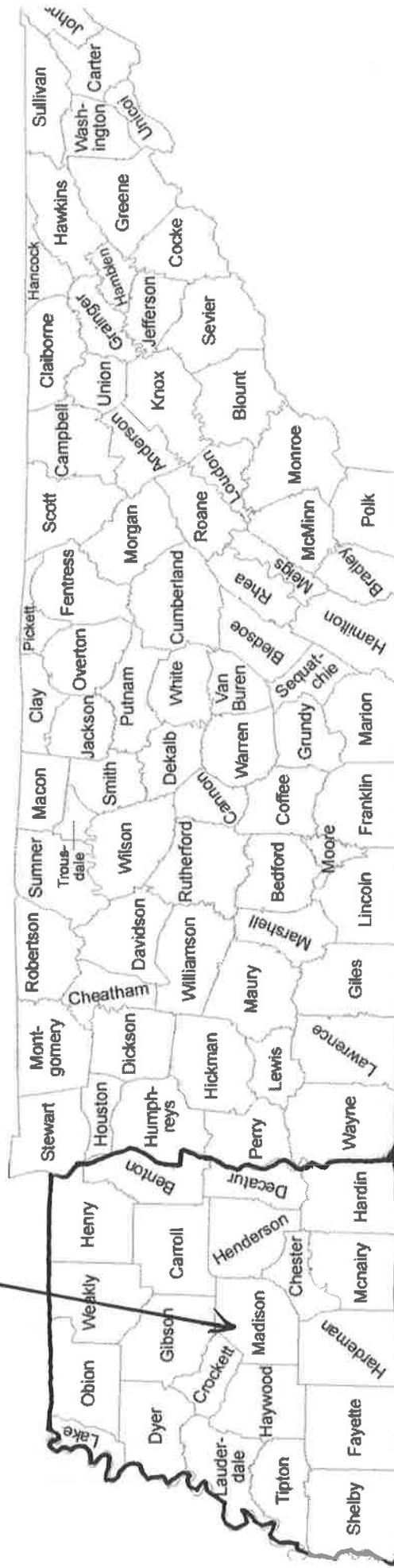
- Assist in securing and maintaining all licensure and accreditations warranted by AxelaCare, including required Home Health Licensure, JCAHO, and any other licensure or credentialing as necessary.
- Compliance and adherence to all State and Federal regulations and laws, JCAHO, OSHA, HIPAA, CPR, all infusion pharmacy and nursing licensure accepted standards of practice.
- Maintain all mandatory education required upon hire and annually per policy.
- May be required to represent the company in clinical interactions as requested.
- May provide education regarding AxelaCare Health Solutions services, for both internally and external customers.
- Function as clinical educator, and resource.
- May work in office or alternate settings including home settings
- Ability to travel on occasion
- Excellent driving record
- Maintains automobile liability insurance
- May be required to work any day or shift as required to accommodate patient schedules in administering medications
- May be required to lift or carry equipment and supplies to patients home
- May be required to participate in afterhours on call responsibilities
- Other duties as requested

Employee Signature

Date

C, Need--3
Service Area Maps

AXELACARE WEST TENNESSEE
PROJECT SERVICE AREA



C, Economic Feasibility--2
Documentation of Availability of Funding



Experience. The Difference.

15529 College Blvd
Lenexa, KS 66219

Toll-free: 877.342.9352
Fax: 877.542.9352

www.AxelaCare.com

June 10, 2016

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application to Establish a Home Health Agency
Shelby County, Tennessee

Dear Mrs. Hill:

AxelaCare Health Solutions, LLC is filing a Certificate of Need application to establish a home health agency in Shelby County, limited to providing home infusion of immune globulin pharmaceuticals.

AxelaCare Health Solutions, LLC is wholly owned through several wholly owned subsidiaries by UnitedHealth Group, Inc., a publicly traded company.

I am writing to confirm that the project's capital cost, estimated at only approximately \$58,000, will be funded by a cash transfer to the applicant through its parent company. As Controller of Axelacare Holdings, Inc., parent company of AxelaCare Health Solutions, LLC, I am authorized to make that commitment. The availability of sufficient cash for the project is shown in financial statements in the Attachments to the application.

Clay Collins
Controller
Axelacare Holdings, Inc.

C, Economic Feasibility--10
Financial Statements

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015 ✓

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 1-10864

UNITEDHEALTH GROUP®

UnitedHealth Group Incorporated

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

41-1321939
(I.R.S. Employer
Identification No.)

UnitedHealth Group Center
9900 Bren Road East
Minnetonka, Minnesota
(Address of principal executive offices)

55343
(Zip Code)

(952) 936-1300

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, \$.01 PAR VALUE
(Title of each class)

NEW YORK STOCK EXCHANGE, INC.
(Name of each exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2015 was \$114,440,856,791 (based on the last reported sale price of \$122.00 per share on June 30, 2015, on the New York Stock Exchange), excluding only shares of voting stock held beneficially by directors, executive officers and subsidiaries of the registrant.

As of January 29, 2016, there were 950,673,998 shares of the registrant's Common Stock, \$.01 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to its 2016 Annual Meeting of Shareholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

UnitedHealth Group
Consolidated Balance Sheets

(in millions, except per share data)	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 10,923	\$ 7,495
Short-term investments	1,988	1,741
Accounts receivable, net of allowances of \$333 and \$260	6,523	4,252
Other current receivables, net of allowances of \$138 and \$156	6,801	5,498
Assets under management	2,998	2,962
Deferred income taxes	860	556
Prepaid expenses and other current assets	1,546	1,052
Total current assets	31,639	23,556
Long-term investments	18,792	18,827
Property, equipment and capitalized software, net of accumulated depreciation and amortization of \$3,173 and \$2,954	4,861	4,418
Goodwill	44,453	32,940
Other intangible assets, net of accumulated amortization of \$3,128 and \$2,685	8,391	3,669
Other assets	3,247	2,972
Total assets	\$ 111,383	\$ 86,382
Liabilities, redeemable noncontrolling interests and equity		
Current liabilities:		
Medical costs payable	\$ 14,330	\$ 12,040
Accounts payable and accrued liabilities	11,994	9,247
Other policy liabilities	7,798	5,965
Commercial paper and current maturities of long-term debt	6,634	1,399
Unearned revenues	2,142	1,972
Total current liabilities	42,898	30,623
Long-term debt, less current maturities	25,460	16,007
Future policy benefits	2,496	2,488
Deferred income taxes	3,587	2,065
Other liabilities	1,481	1,357
Total liabilities	75,922	52,540
Commitments and contingencies (Note 13)		
Redeemable noncontrolling interests	1,736	1,388
Equity:		
Preferred stock, \$0.001 par value — 10 shares authorized; no shares issued or outstanding	—	—
Common stock, \$0.01 par value — 3,000 shares authorized; 953 and 954 issued and outstanding	10	10
Additional paid-in capital	29	—
Retained earnings	37,125	33,836
Accumulated other comprehensive loss	(3,334)	(1,392)
Nonredeemable noncontrolling interest	(105)	—
Total equity	33,725	32,454
Total liabilities, redeemable noncontrolling interests and equity	\$ 111,383	\$ 86,382

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Operations

(in millions, except per share data)	For the Years Ended December 31,		
	2015	2014	2013
Revenues:			
Premiums	\$127,163	\$115,302	\$109,557
Products	17,312	4,242	3,190
Services	11,922	10,151	8,997
Investment and other income	710	779	745
Total revenues	157,107	130,474	122,489
Operating costs:			
Medical costs	103,875	93,633	89,659
Operating costs	24,312	21,263	18,941
Cost of products sold	16,206	3,826	2,891
Depreciation and amortization	1,693	1,478	1,375
Total operating costs	146,086	120,200	112,866
Earnings from operations	11,021	10,274	9,623
Interest expense	(790)	(618)	(708)
Earnings before income taxes	10,231	9,656	8,915
Provision for income taxes	(4,363)	(4,037)	(3,242)
Net earnings	5,868	5,619	5,673
Earnings attributable to noncontrolling interests	(55)	—	(48)
Net earnings attributable to UnitedHealth Group common stockholders	\$ 5,813	\$ 5,619	\$ 5,625
Earnings per share attributable to UnitedHealth Group common stockholders:			
Basic	\$ 6.10	\$ 5.78	\$ 5.59
Diluted	\$ 6.01	\$ 5.70	\$ 5.50
Basic weighted-average number of common shares outstanding	953	972	1,006
Dilutive effect of common share equivalents	14	14	17
Diluted weighted-average number of common shares outstanding	967	986	1,023
Anti-dilutive shares excluded from the calculation of dilutive effect of common share equivalents	8	6	8
Cash dividends declared per common share	\$ 1.8750	\$ 1.4050	\$ 1.0525

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Comprehensive Income

(in millions)	For the Years Ended December 31,		
	2015	2014	2013
Net earnings	<u>\$ 5,868</u>	<u>\$ 5,619</u>	<u>\$ 5,673</u>
Other comprehensive loss:			
Gross unrealized (losses) gains on investment securities during the period	(123)	476	(543)
Income tax effect	44	(173)	196
Total unrealized (losses) gains, net of tax	(79)	303	(347)
Gross reclassification adjustment for net realized gains included in net earnings	(141)	(211)	(181)
Income tax effect	53	77	66
Total reclassification adjustment, net of tax	(88)	(134)	(115)
Total foreign currency translation losses	(1,775)	(653)	(884)
Other comprehensive loss	(1,942)	(484)	(1,346)
Comprehensive income	3,926	5,135	4,327
Comprehensive income attributable to noncontrolling interests	(55)	—	(48)
Comprehensive income attributable to UnitedHealth Group common stockholders	<u>\$ 3,871</u>	<u>\$ 5,135</u>	<u>\$ 4,279</u>

See Notes to the Consolidated Financial Statements

Miscellaneous Information

**AxelaCare Health Solutions--Shelby County
Patient Origin Projection
CY2017-CY2018**

County	Percent of Total Patients	Cumulative Percent of Total Patients	Year One CY2017 Patients	Year Two CY2018 Patients
Shelby	59.2%	59.2%	27	38
Madison	6.4%	65.6%	3	4
Tipton	4.1%	69.7%	2	3
Gibson	3.2%	72.9%	1	2
Fayette	2.8%	75.7%	1	2
Dyer	2.4%	78.1%	1	2
Weakley	2.2%	80.3%	1	1
Henry	2.1%	82.4%	1	1
Obion	2.0%	84.4%	1	1
Henderson	1.8%	86.2%	1	1
Lauderdale	1.8%	88.0%	1	1
Carroll	1.7%	89.7%	1	1
Hardeman	1.7%	91.4%	1	1
McNairy	1.7%	93.1%	1	1
Hardin	1.6%	94.7%	1	1
Chester	1.1%	95.8%	0	1
Haywood	1.1%	96.9%	0	1
Benton	1.0%	97.9%	0	1
Crockett	0.9%	98.8%	0	1
Decatur	0.7%	99.5%	0	0
Lake	0.5%	100.0%	0	0
Service Area Total	100.0%		45	65

Source: Patient projections in proportion to county populations, 2016.

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Benton

(Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	636	100.0	Hamilton	1	
Benton	149	23.4	Geniva Health Services	15	
Tennessee Quality Homecare - Northwest	149		Home Care Solutions	21	
Carroll	21	3.3	Life Care at Home of Tennessee	33	
Baptist Memorial Home Care	21		Memorial Hospital Home Health	1	
Davidson	3	0.5	NHC Homecare	253	51.0
Elk Valley Health Services, LLC	3		Warren	253	
Decatur	2	0.3	Careall Home Care Services		
Tennessee Quality Homecare-Southwest	2				
Gibson	230	36.2			
NHC Homecare	25				
Volunteer Home Care, Inc.	205	1.1			
Henderson	7	6.9			
Regional Home Care, Lexington	7				
Henry	44	21.5			
Henry County Medical Center Home Health	44				
Madison	137				
Amedisys Home Health Care	89				
Extendicare Home Health of West Tennessee	48				
Weakley	43	6.8			
CareAll Homecare Services	43				

Resident County: Bledsoe

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	496	100.0	TOTAL PATIENTS	2,274	100.0
Bradley	40	8.1	Anderson	5	0.2
Home Health Care of East Tennessee, Inc.	40		Professional Case Management of Tennessee	5	49.4
Davidson	1	0.2	Blount	1,124	
Elk Valley Health Services, LLC	1		Blount Memorial Hospital Home Health Services	1,124	
Hamilton	202	40.7	Davidson	14	0.6
Amedisys Home Health	121		Elk Valley Health Services, LLC	5	
Continuicare Healthservices, Inc. - I	10		Home Care Solutions	9	
			Hamilton	1	0.0
			Amedisys Home Health	1	
			Knox	1,128	49.6
			Amedisys Home Health Care	186	
			Camellia Home Health of East Tennessee, LLC	46	
			CareAll Home Care Services	77	
			Covenant Homecare	185	
			East Tennessee Children's Hospital Home Health Care	46	
			Geniva Health Services	194	
			Maxim Healthcare Services, Inc.	9	
			NHC Homecare	43	
			Tennova Home Health	213	
			University of TN Medical Center Home Care Services - Home He	129	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

REPORT 6
 REPORT FOR HOME HEALTH AGENCIES 2014

Resident County: Cannon

Resident County: Carroll

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	543	100.0	TOTAL PATIENTS	1,333	100.0
Coffee	7	1.3	Benton	67	5.0
Suncrest Home Health of Manchester, Inc.	7		Tennessee Quality Homecare - Northwest	67	16.8
Davidson	36	6.6	Carroll	224	
Angel Private Duty and Home Health, Inc.	2		Baptist Memorial Home Care	224	
CareAll Homecare Services	2		Davidson	6	0.5
Home Care Solutions	4		Elk Valley Health Services, LLC	6	
Home Health Care of Middle Tennessee, LLC	20		Decatur	1	0.1
Willowbrook Home Health Care Agency, Inc.	8		Volunteer Homecare of West Tennessee, Inc.	1	
DeKalb	276	50.8	Gibson	366	27.5
Suncrest Home Health	276		NHC Homecare	77	
Franklin	4	0.7	Volunteer Home Care, Inc.	289	
Caresouth HHA Holdings of Winchester, LLC	4		Haywood	2	0.2
Lincoln	2	0.4	CareAll Homecare Services	2	
Elk Valley Home Health Care Agency, LLC	2		Henderson	226	17.0
Rutherford	67	12.3	Regional Home Care, Lexington	226	
Amedisys Home Health	14		Henry	34	2.6
NHC Homecare	53		Henry County Medical Center Home Health	34	
Warren	131	24.1	Madison	207	15.5
Careall Home Care Services	97		Amedisys Home Health Care	93	
Friendship Home Health, Inc.	13		Extendicare Home Health of West Tennessee	61	
Intrepid USA Healthcare Services	21		Intrepid USA Healthcare Services	25	
Williamson	3	0.6	Medical Center Home Health, LLC	25	
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	3		Regional Home Care, Jackson	3	
Wilson	17	3.1	Weakley	200	15.0
Cedar Creek Home Health Care Agency, LLC	12		CareAll Homecare Services	200	
Gentiva Health Services	5				

Resident County: Carter

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,960	100.0
Carter	586	29.9
Amedisys Home Health Care	586	

REPORT 6
 HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

REPORT 6
 HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

Resident County: Carter (Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
Davidson	5	0.3	Davidson (Continued)	3	
Elk Valley Health Services, LLC	5		Maxim Healthcare Services, Inc.	40	
Greene	89	4.5	Vanderbilt Community and Home Services	29	
Procure Home Health Services	89		Vanderbilt Home Care Services	38	
Hamblen	12	0.6	Willowbrook Home Health Care Agency, Inc.	45	5.6
Premier Support Services	12		Franklin	45	
Johnson	8	0.4	Caresouth HHA Holdings of Winchester, LLC	35	4.4
Johnson County Home Health	8		Maury	35	
Sullivan	32	1.6	NHC Homecare	147	18.3
Gentiva Health Services	32		Montgomery	16	
Washington	1,228	62.7	Gateway Home Health, Clarksville	131	
Amedysis Home Health	5		Suncrest Home Health of Nashville, Inc.	114	14.2
Medical Center Homecare Services	1,107		Robertson	7	
Medical Center Homecare, Kingsport	76		Lifeline Home Health Care	107	
NHC Homecare	40		NHC Homecare	1	0.1

Resident County: Cheatham

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	802	100.0
Davidson	422	52.6
Alere Women's and Children's Health, LLC	3	
Amedisys Home Health	56	
Angel Private Duty and Home Health, Inc.	3	
CareAll Homecare Services	1	
Continuous Care Services, LLC	14	
Elk Valley Health Services, LLC	2	
Friendship Home Health Agency LLC	3	
Gentiva Health Services	10	
Home Care Solutions	6	
Home Health Care of Middle Tennessee, LLC	90	
Innovative Senior Care Home Health of Nashville, LLC	1	
Intrepid USA Healthcare Services	123	

Resident County: Cheatham

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	640	100.0
Carroll	4	0.6
Baptist Memorial Home Care	4	
Davidson	1	0.2
Elk Valley Health Services, LLC	1	
Decatur	166	25.9
Tennessee Quality Homecare-Southwest	79	
Volunteer Homecare of West Tennessee, Inc.	87	

Resident County: Chester

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	640	100.0
Carroll	4	0.6
Baptist Memorial Home Care	4	
Davidson	1	0.2
Elk Valley Health Services, LLC	1	
Decatur	166	25.9
Tennessee Quality Homecare-Southwest	79	
Volunteer Homecare of West Tennessee, Inc.	87	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Chester

Resident County:	Facility Location/Name	Patients	Percent	Resident County:	Facility Location/Name	Patients	Percent
Claiborne	Gibson	6	0.9	Claiborne	Hamblen	3	
	NHC Homecare	6			Premier Support Services	1	2.8
	Hardin	139	21.7		University of TN Medical Center Home Health Services	48	
	Gericare, LLC	137			Hancock	48	6.7
	HMC Home Health, LLC	2	21.3		Hancock County Home Health Agency	115	
	Haywood	136			Knox	13	
	CareAll Homecare Services	136	0.3		Camellia Home Health of East Tennessee, LLC	14	
	Henderson	2	29.1		Covenant Homecare	15	
	Regional Home Care, Lexington	2			East Tennessee Children's Hospital Home Health Care	1	
	Madison	186			Gentiva Health Services	3	
	Amedisys Home Health Care	35			Maxim Healthcare Services, Inc.	58	
	Extendicare Home Health of West Tennessee	11			Tennova Home Health	11	0.1
	Intrepid USA Healthcare Services	31			University of TN Medical Center Home Care Services - Home He	1	
	Medical Center Home Health, LLC	60			Out-of-State	1	
	Regional Home Care, Jackson	49			Professional Home Health Care Agency, Inc.	1	

Resident County:	Facility Location/Name	Patients	Percent	Resident County:	Facility Location/Name	Patients	Percent
Claiborne	TOTAL PATIENTS	1,728	100.0	Clay	TOTAL PATIENTS	296	100.0
	Anderson	1	0.1		Clay	144	48.6
	Professional Case Management of Tennessee	1			Cumberland River Homecare	144	
	Campbell	8	0.5		Davidson	90	30.4
	Sunbelt Homecare	8			CareAll Homecare Services	89	
	Claiborne	1,074	62.2		Home Care Solutions	1	10.5
	Amedisys Home Health of Tennessee	786			Overton	31	
	Suncrest Home Health	288			Amedisys Tennessee, L.L.C.	31	4.1
	Cocke	7	0.4		Rutherford	12	
	Smoky Mountain Home Health and Hospice, Inc.	7			NHC Homecare	12	
	Davidson	1	0.1		Wilson	19	6.4
	Elk Valley Health Services, LLC	1			Cedar Creek Home Health Care Agency, LLC	19	
	Hamblen	473	27.4				
	Amedisys Home Health Care	469					

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

REPORT 6
 REPORT FOR HOME HEALTH AGENCIES 2014

Resident County:	Cooke	Coffee
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,280	100.0
Claiborne	50	3.9
Suncrest Home Health	50	30.3
Cooke	388	0.1
Smoky Mountain Home Health and Hospice, Inc.	388	0.1
Davidson	1	0.9
Elk Valley Health Services, LLC	1	16.1
Greene	11	48.8
Advanced Home Care, Inc.	3	
Laughlin Home Health Agency	8	
Hamblen	206	
Premier Support Services	69	
University of TN Medical Center Home Health Services	137	
Knox	624	
Amedisys Home Health Care	454	
Camellia Home Health of East Tennessee, LLC	28	
Covenant Homecare	35	
East Tennessee Children's Hospital Home Health Care	13	
Gentiva Health Services	90	
Maxim Healthcare Services, Inc.	3	
University of TN Medical Center Home Care Services - Home He	1	

Resident County:	Coffee	Percent
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,980	100.0
Bedford	7	0.4
Heritage Home Health	7	1.2
Bradley	23	45.5
Home Health Care of East Tennessee, Inc.	23	
Coffee	900	
Gentiva Health Services	213	
Suncrest Home Health of Manchester, Inc.	687	

Resident County:	Coffee	Percent
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	557	100.0
Carroll	2	0.4
Baptist Memorial Home Care	2	6.1
Dyer	34	21.7
Regional Home Care, Dyersburg	34	
Gibson	121	
NHC Homecare	14	
Volunteer Home Care, Inc.	107	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County:  **Crockett**

(Continued)

Facility Location/Name	Patients	Percent	Resident County:	Cumberland	Facility Location/Name	Patients	Percent
Haywood	153	27.5		Putnam	35	2.0	
CareAll Homecare Services	153			Highland Rim Home Health Agency	5		
Madison	245	44.0		Intrepid USA Healthcare Services	30	2.2	
Amedisys Home Health Care	108			Rutherford	38		
Extendicare Home Health of West Tennessee	17			NHC Homecare	38		
Intrepid USA Healthcare Services	11			Wilson	81	4.6	
Medical Center Home Health, LLC	60			Cedar Creek Home Health Care Agency, LLC	81		
Regional Home Care, Jackson	49						
Weakley	2	0.4		Resident County: Davidson			
CareAll Homecare Services	2						

Resident County: **Cumberland**

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,754	100.0	TOTAL PATIENTS	14,105	100.0
Clay	34	1.9	Davidson	10,963	77.7
Cumberland River Homecare	34		Alere Women's and Children's Health, LLC	64	
Cumberland	350	20.0	Amedisys Home Health	1,591	
C.M.C. Home C.A.R.E.	350		Amedisys Home Health Services	47	
Davidson	314	17.9	Angel Private Duty and Home Health, Inc.	19	
CareAll Homecare Services	305		CareAll Homecare Services	301	
Elk Valley Health Services, LLC	3		Continuous Care Services, LLC	121	
Home Care Solutions	6		Elk Valley Health Services, LLC	30	
Fentress	757	43.2	Friendship Home Health Agency LLC	452	
Quality Home Health	548		Gentiva Health Services	572	
Quality Private Duty Care	209		Home Care Solutions	183	
Hamilton	5	0.3	Home Health Care of Middle Tennessee, LLC	1,154	
Amedisys Home Health	5		Innovative Senior Care Home Health of Nashville, LLC	453	
Knox	128	7.3	Intrepid USA Healthcare Services	724	
Camellia Home Health of East Tennessee, LLC	127		Maxim Healthcare Services, Inc.	21	
Gentiva Health Services	1		Premiere Home Health, Inc.	81	
Overton	12	0.7	Suncrest Home Health	2,666	
Amedisys Tennessee, L.L.C.	12		Vanderbilt Community and Home Services	966	
			Vanderbilt Home Care Services	1,015	
			Willowbrook Home Health Care Agency, Inc.	503	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Davidson (Continued)

Facility Location/Name	Patients	Percent
Franklin	467	3.3
Caresouth HHA Holdings of Winchester, LLC	467	
Maury	1	0.0
CareAll Homecare Services	1	0.0
Montgomery	1	0.0
Gateway Home Health, Clarksville	1	4.3
Robertson	604	
Lifeline Home Health Care	3	
NHC Homecare	601	4.9
Rutherford	685	
Amedisys Home Health	1	
Amedisys Home Health Care	5	
NHC Homecare	679	0.0
Shelby	1	
Intrepid USA Healthcare Services	1	0.6
Sumner	91	
Highpoint Homecare	91	0.0
Warren	5	
Intrepid USA Healthcare Services	5	4.5
Williamson	630	
Guardian Home Care of Nashville	550	
Home Health Care Services LLC	14	
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	66	4.7
Wilson	657	
Cedar Creek Home Health Care Agency, LLC	608	
Gentiva Health Services	49	
Resident County: Decatur		
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	639	100.0
Benton	1	0.2
Tennessee Quality Homecare - Northwest	1	

Resident County: Decatur (Continued)

Facility Location/Name	Patients	Percent
Carroll	2	0.3
Baptist Memorial Home Care	2	
Decatur	523	81.8
Tennessee Quality Homecare-Southwest	132	
Volunteer Homecare of West Tennessee, Inc.	391	
Gibson	3	0.5
NHC Homecare	3	
Hardin	32	5.0
Gericare, LLC	31	
HMC Home Health, LLC	1	
Haywood	6	0.9
CareAll Homecare Services	6	
Henderson	21	3.3
Regional Home Care, Lexington	21	
Madison	39	6.1
Amedisys Home Health Care	14	
Extendicare Home Health of West Tennessee	1	
Intrepid USA Healthcare Services	9	
Medical Center Home Health, LLC	15	
Maury	12	1.9
CareAll Homecare Services	12	
Resident County: DeKalb		
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	673	100.0
Davidson	22	3.3
Amedisys Home Health	1	
Angel Private Duty and Home Health, Inc.	3	
CareAll Homecare Services	8	
Elk Valley Health Services, LLC	2	
Home Care Solutions	2	
Home Health Care of Middle Tennessee, LLC	5	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County:	Dekalb	Dickson			
Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
Davidson (Continued)			Davidson (Continued)		
Intrepid USA Healthcare Services	1		Home Health Care of Middle Tennessee, LLC	91	
DeKalb	410	60.9	Intrepid USA Healthcare Services	17	
Suncrest Home Health	410		Maxim Healthcare Services, Inc.	9	
Franklin	11	1.6	Willowbrook Home Health Care Agency, Inc.	16	0.4
Amedisys Tennessee, L.L.C.	10		Decatur	6	
Caresouth HHA Holdings of Winchester, LLC	1		Volunteer Homecare of West Tennessee, Inc.	6	
Putnam	1	0.1	Franklin	5	0.4
Intrepid USA Healthcare Services	1		Caresouth HHA Holdings of Winchester, LLC	5	
Rutherford	107	15.9	Hickman	38	2.7
NHC Homecare	107		St Thomas Home Health	38	
Smith	9	1.3	Mauzy	170	11.9
Highpoint Homecare	9		NHC Homecare	170	
Warren	67	10.0	Montgomery	285	20.0
Carcall Home Care Services	34		Gateway Home Health, Clarksville	29	
Friendship Home Health, Inc.	20		Suncrest Home Health of Nashville, Inc.	256	
Intrepid USA Healthcare Services	13		Williamson	216	15.2
Wilson	46	6.8	Guardian Home Care of Nashville	211	
Cedar Creek Home Health Care Agency, LLC	34		Vanderbilt HC Affiliated W/Walgreens IV and RT Services	5	
Geniva Health Services	12		Wilson	13	0.9
			Cedar Creek Home Health Care Agency, LLC	13	

Resident County: Dickson

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,424	100.0
Davidson	691	48.5
Alere Women's and Children's Health, LLC	6	
Amedisys Home Health	181	
Angel Private Duty and Home Health, Inc.	2	
Elk Valley Health Services, LLC	2	
Friendship Home Health Agency LLC	3	
Geniva Health Services	10	
Home Care Solutions	354	

Resident County: Dyer

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,064	100.0
Davidson	5	0.2
Elk Valley Health Services, LLC	5	
Dyer	981	47.5
Regional Home Care, Dyersburg	981	
Gibson	469	22.7
NHC Homecare	15	
Volunteer Home Care, Inc.	454	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **Dyer** (Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
Haywood	1	0.0	Shelby	33	
CareAll Homecare Services	1		Home Health Care of West Tennessee, Inc.	260	
Madison	408	19.8	Homechoice Health Services, LLC	3	
Amedisys Home Health Care	275		Maxim Healthcare Services, Inc.	1	
Extendicare Home Health of West Tennessee	129		Meritan, Inc.	45	
Medical Center Home Health, LLC	3		Methodist Alliance Home Care	84	
Regional Home Care, Jackson	1		Willowbrook Visiting Nurse Association, Inc.	2	0.2
Weakley	200	9.7	Tipton	2	
CareAll Homecare Services	200		Baptist Home Care and Hospice - Covington	2	

Resident County: **Fayette** (Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	848	100.0	TOTAL PATIENTS	998	100.0
Fayette	124	14.6	Clay	14	1.4
NHC Homecare	119		Cumberland River Homecare	14	
Where The Heart Is, Inc.	5		Fentress	719	72.0
Haywood	14	1.7	Quality Home Health	488	
CareAll Homecare Services	14		Quality Private Duty Care	231	
Madison	57	6.7	Overton	211	21.1
Amedisys Home Health Care	1		Amedisys Tennessee, L.L.C.	211	
Extendicare Home Health of West Tennessee	10		Putnam	11	1.1
Intrepid USA Healthcare Services	14		Intrepid USA Healthcare Services	11	
Regional Home Care, Jackson	32		Rutherford	8	0.8
Shelby	651	76.8	NHC Homecare	8	
Accredo Health Group, Inc.	2		Scott	35	3.5
Alere Women's and Children's Health	7		Elk Valley Home Health Care Agency, LLC	35	
Amedisys Home Care	2				
Amedisys Home Health	2				
Amedisys Home Health Care	76				
Baptist Trinity Home Care	110				
Extended Health Care, Inc.	1				
Functional Independence Home Care, Inc.	25				

REPORT 6 HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

REPORT FOR HOME HEALTH AGENCIES 2014

(Continued)

Resident County: Franklin

Resident County: Gibson

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,509	100.0	Decatur	1	0.1
Bradley	66	4.4	Tennessee Quality Homecare-Southwest	1	2.1
Home Health Care of East Tennessee, Inc.	66	4.4	Dyer	39	2.1
Coffee	235	15.6	Regional Home Care, Dyersburg	39	42.0
Geniva Health Services	44		Gibson	791	
Suncrest Home Health of Manchester, Inc.	191		NHC Homecare	284	
Davidson	12	0.8	Volunteer Home Care, Inc.	507	4.9
Amedisys Home Health	3		Haywood	92	
Elk Valley Health Services, LLC	3		CareAll Homecare Services	92	
Home Care Solutions	6		Henderson	2	0.1
Franklin	972	64.4	Regional Home Care, Lexington	2	
Amedisys Tennessee, L.L.C.	494		Madison	612	32.5
Caresouth FHA Holdings of Winchester, LLC	478		Amedisys Home Health Care	149	
Lincoln	167	11.1	Extendicare Home Health of West Tennessee	19	
Elk Valley Home Health Care Agency, LLC	167		Intrepid USA Healthcare Services	28	
Maury	38	2.5	Medical Center Home Health, LLC	228	
NHC Homecare	38		Regional Home Care, Jackson	188	
Warren	18	1.2	Obion	3	0.2
Friendship Home Health, Inc.	18		Extendicare Home Health of Western Tennessee	3	
Williamson	1	0.1	Weakley	262	13.9
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1		CareAll Homecare Services	262	

Resident County: Franklin

Resident County: Giles

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,885	100.0	TOTAL PATIENTS	1,019	100.0
Benton	66	3.5	Davidson	7	0.7
Tennessee Quality Homecare - Northwest	66		Elk Valley Health Services, LLC	6	
Carroll	6	0.3	Home Care Solutions	1	
Baptist Memorial Home Care	6		Lincoln	118	11.6
Davidson	11	0.6	Elk Valley Home Health Care Agency, LLC	113	
Elk Valley Health Services, LLC	11		Lincoln Medical Home Health and Hospice	5	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Hamilton

Resident County: Hancock

(Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
Franklin	476	6.0	Knox	4	0.6
Caresouth HHA Holdings of Winchester, LLC	476		Camellia Home Health of East Tennessee, LLC	2	
Hamilton	6,788	85.6	Geniva Health Services	1	
Alere Women's and Children's Health, LLC	15		Tennova Home Health	1	
Amedisys Home Health	1,031				
Continuicare Healthservices, Inc. - I	1,181		Resident County: Hardeman		
Continuicare Healthservices, Inc. - II	6		Facility Location/Name	Patients	Percent
Geniva Health Services	316		TOTAL PATIENTS	898	100.0
Guardian Home Care, LLC	706		Decatur	128	14.3
Home Care Solutions	403		Volunteer Homecare of West Tennessee, Inc.	128	
Life Care at Home of Tennessee	678		Fayette	80	8.9
Maxim Healthcare Services	32		NHC Homecare	80	
Memorial Hospital Home Health	2,062		Hardin	87	9.7
NHC Homecare	358		Gerricare, LLC	87	
Knox	23	0.3	Haywood	164	18.3
Camellia Home Health of East Tennessee, LLC	23		CareAll Homecare Services	164	
			Madison	262	29.2
			Amedisys Home Health Care	41	
Resident County: Hancock			Extendicare Home Health of West Tennessee	3	
Facility Location/Name	Patients	Percent	Intrepid USA Healthcare Services	14	
TOTAL PATIENTS	650	100.0	Medical Center Home Health, LLC	128	
Claborne	20	3.1	Regional Home Care, Jackson	76	
Amedisys Home Health of Tennessee	9		Shelby	177	19.7
Suncrest Home Health	11		Accredo Health Group, Inc.	1	
Hamblen	364	56.0	Alere Women's and Children's Health	2	
Amedisys Home Health Care	351		Homechoice Health Services, LLC	149	
Premier Support Services	12		Maxim Healthcare Services, Inc.	9	
University of TN Medical Center Home Health Services	1		Willowbrook Visiting Nurse Association, Inc.	16	
Hancock	261	40.2			
Hancock County Home Health Agency	261				
Hawkins	1	0.2			
Hometown Home Health Care, Inc.	1				

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **Hardin**

Resident County: **Hawkins**

(Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,221	100.0	Davidson	2	0.1
Davidson	4	0.3	Elk Valley Health Services, LLC	2	11.9
Elk Valley Health Services, LLC	4	9.6	Greene	241	232
Decatur	117	33	Advanced Home Care, Inc.	9	54.1
Tennessee Quality Homecare-Southwest	84	624	Laughlin Home Health Agency	1,098	683
Volunteer Homecare of West Tennessee, Inc.	494	130	Hamblen	251	164
Hardin	6	0.5	Amedisys Home Health Care	102	5.0
Gerticare, LLC	6	0.2	Premier Support Services	87	4.3
HMC Home Health, LLC	2	24.4	University of TN Medical Center Home Health Services	102	1.3
Haywood	298	236	Hancock County Home Health Agency	87	14
CareAll Homecare Services	1	11	Hawkins	27	1.3
Henderson	19	31	Hometown Home Health Care, Inc.	14	1
Regional Home Care, Lexington	164	162	Knox	1	15.1
Madison	2	6	Camellia Home Health of East Tennessee, LLC	306	276
Amedisys Home Health Care	6	13.4	Sullivan	30	3.5
Extendicare Home Health of West Tennessee	2	0.5	Advanced Home Care, Inc.	71	14
Intrepid USA Healthcare Services	6	2	Gentiva Health Services	55	2
Medical Center Home Health, LLC	6	6	Medical Center Homecare, Kingsport	2	
Regional Home Care, Jackson	2	6	NHC Homecare	2	
Maury	2	6			
CareAll Homecare Services	6	6			
NHC Homecare	6	6			
Out-of-State	6	6			
Magnolia Regional Health Center Home Health and Hospice Age	6	6			

Resident County: **Hawkins**

Resident County: **Haywood**

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	2,028	100.0	TOTAL PATIENTS	790	100.0
Claborne	64	3.2	Davidson	4	0.5
Suncrest Home Health	64	1.5	Elk Valley Health Services, LLC	4	1.4
Cocke	30	30	Fayette	11	1.4
Smoky Mountain Home Health and Hospice, Inc.	30	30	NHC Homecare	11	1.4

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

REPORT 6
 REPORT FOR HOME HEALTH AGENCIES 2014

Resident County: **Haywood** (Continued)

Facility Location/Name	Patients	Percent	Resident County: Henderson	Facility Location/Name	Patients	Percent
Hardin	12	1.5		Henderson	290	26.9
Gericare, LLC	12			Regional Home Care, Lexington	290	
Haywood	273	34.6		Madison	197	18.3
CareAll Homecare Services	273			Amedisys Home Health Care	27	
Madison	319	40.4		Extendicare Home Health of West Tennessee	5	
Amedisys Home Health Care	27			Intrepid USA Healthcare Services	101	
Extendicare Home Health of West Tennessee	5			Medical Center Home Health, LLC	62	
Intrepid USA Healthcare Services	41			Regional Home Care, Jackson	2	
Medical Center Home Health, LLC	35					
Regional Home Care, Jackson	211			Resident County: Henry		
Shelby	171	21.6		Facility Location/Name	Patients	Percent
Homechoice Health Services, LLC	160			TOTAL PATIENTS	1,253	100.0
Maxim Healthcare Services, Inc.	10			Benton	132	10.5
Willowbrook Visiting Nurse Association, Inc.	1			Tennessee Quality Homecare - Northwest	132	
				Carroll	3	0.2
				Baptist Memorial Home Care	3	
				Davidson	5	0.4
				Elk Valley Health Services, LLC	5	
				Gibson	296	23.6
				NHC Homecare	22	
				Volunteer Home Care, Inc.	274	
				Henderson	28	2.2
				Regional Home Care, Lexington	28	
				Henry	313	25.0
				Henry County Medical Center Home Health	313	
				Madison	382	30.5
				Amedisys Home Health Care	333	
				Extendicare Home Health of West Tennessee	49	
				Weakley	94	7.5
				CareAll Homecare Services	94	

Resident County: **Henderson**

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,079	100.0
Carroll	5	0.5
Baptist Memorial Home Care	5	
Davidson	3	0.3
Elk Valley Health Services, LLC	3	
Decatur	417	38.6
Tennessee Quality Homecare-Southwest	80	
Volunteer Homecare of West Tennessee, Inc.	337	
Gibson	20	1.9
NHC Homecare	20	
Hardin	92	8.5
Gericare, LLC	92	
Haywood	55	5.1
CareAll Homecare Services	55	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

(Continued)

Resident County: Johnson

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	848	100.0	Knox	7,536	85.6
Carter	330	38.9	Amedisys Home Health Care	1,400	
Greene	330	0.5	Camellia Home Health of East Tennessee, LLC	456	
Johnson	4	56.6	CareAll Home Care Services	343	
Johnson County Home Health	4	0.2	Covenant Homecare	1,632	
Sullivan	480	3.8	East Tennessee Children's Hospital Home Health Care	203	
Washington	480	0.1	Gentiva Health Services	916	
Medical Center Homecare Services	2	0.1	Maxim Healthcare Services, Inc.	31	
Medical Center Homecare, Kingsport	2	0.1	NHC Homecare	563	
	32	0.1	Tennova Home Health	1,646	
	3	0.1	The Home Option By Harden Health Care	27	
	29	0.1	University of TN Medical Center Home Care Services - Home He	319	2.8
			Monroe	244	
			Intrepid USA Healthcare Services	244	

Resident County: Lake

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	8,802	100.0	TOTAL PATIENTS	411	100.0
Anderson	182	2.1	Dyer	134	32.6
Clinch River Home Health	137	0.1	Regional Home Care, Dyersburg	134	14.6
Professional Case Management of Tennessee	45	0.1	Gibson	60	1.5
Blount	9	0.1	Volunteer Home Care, Inc.	60	1.5
Blount Memorial Hospital Home Health Services	9	1.7	Madison	6	2.7
Campbell	6	7.6	Extendicare Home Health of West Tennessee	6	2.7
Sunbelt Homecare	6	0.1	Obion	11	48.7
Davidson	147	0.1	Extendicare Home Health of Western Tennessee	11	48.7
Elk Valley Health Services, LLC	9	0.1	Weakley	200	48.7
Home Care Solutions	138	0.1	CareAll Homecare Services	200	48.7
Fentress	668	0.1			
Quality Home Health	660	0.1			
Quality Private Duty Care	8	0.1			
Hambleton	10	0.1			
Premier Support Services	7	0.1			
University of TN Medical Center Home Health Services	3	0.1			

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

(Continued)

Resident County:	Lawrence	Lawrence	Lawrence	Lawrence	Lawrence
Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name
Patients	Patients	Patients	Patients	Patients	Patients
Percent	Percent	Percent	Percent	Percent	Percent
TOTAL PATIENTS	1,075	100.0	183	10.4	10.4
Davidson	1	0.1	183	0.1	0.1
Elk Valley Health Services, LLC	1	0.1	1	0.1	0.1
Dyer	211	19.6	1	0.1	0.1
Regional Home Care, Dyersburg	211	19.6	1,351	77.1	77.1
Fayette	7	0.7	246	13.6	13.6
NHC Homecare	7	0.7	167	9.0	9.0
Haywood	294	27.3	638	34.6	34.6
CareAll Homecare Services	294	27.3	300	16.3	16.3
Madison	362	33.7	181	10.3	10.3
Amedisys Home Health Care	263	24.5	181	10.3	10.3
Extendicare Home Health of West Tennessee	86	8.0			
Intrepid USA Healthcare Services	11	1.0			
Regional Home Care, Jackson	2	0.2			
Shelby	130	12.1			
Accredo Health Group, Inc.	2	0.2			
Alere Women's and Children's Health	6	0.6			
Home Health Care of West Tennessee, Inc.	41	3.8			
Homechoice Health Services, LLC	81	7.5			
Tipton	70	6.5			
Baptist Home Care and Hospice - Covington	70	6.5			

Resident County:	Lawrence	Lawrence	Lawrence	Lawrence	Lawrence
Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name
Patients	Patients	Patients	Patients	Patients	Patients
Percent	Percent	Percent	Percent	Percent	Percent
TOTAL PATIENTS	1,753	100.0	423	24.1	24.1
Davidson	16	0.9	5	1.2	1.2
Elk Valley Health Services, LLC	14	0.8	5	1.2	1.2
Home Care Solutions	2	0.1	241	13.7	13.7
Decatur	21	1.2	96	5.5	5.5
Tennessee Quality Homecare-Southwest	20	1.1	145	8.3	8.3
Volunteer Homecare of West Tennessee, Inc.	1	0.1	18	1.0	1.0

Resident County:	Lawrence	Lawrence	Lawrence	Lawrence	Lawrence
Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name	Facility Location/Name
Patients	Patients	Patients	Patients	Patients	Patients
Percent	Percent	Percent	Percent	Percent	Percent
TOTAL PATIENTS	1,753	100.0	423	24.1	24.1
Davidson	16	0.9	5	1.2	1.2
Elk Valley Health Services, LLC	14	0.8	5	1.2	1.2
Home Care Solutions	2	0.1	241	13.7	13.7
Decatur	21	1.2	96	5.5	5.5
Tennessee Quality Homecare-Southwest	20	1.1	145	8.3	8.3
Volunteer Homecare of West Tennessee, Inc.	1	0.1	18	1.0	1.0

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: McMinn

(Continued)

Facility Location/Name	Patients	Percent
Bradley	233	15.3
Family Home Care, Cleveland	71	
Home Health Care of East Tennessee, Inc.	162	
Franklin	13	0.9
Amedisys Tennessee, L.L.C.	1	
Caresouth FHA Holdings of Winchester, LLC	12	
Hamilton	710	46.7
Alere Women's and Children's Health, LLC	3	
Amedisys Home Health	542	
Continuicare Healthservices, Inc. - I	12	
Guardian Home Care, LLC	102	
Life Care at Home of Tennessee	37	
Maxim Healthcare Services	4	
Memorial Hospital Home Health	10	
Knox	206	13.6
Camellia Home Health of East Tennessee, LLC	192	
Geniva Health Services	14	
McMinn	250	16.4
Home Care Solutions-Etowah	38	
NHC Homecare	212	
Monroe	107	7.0
Intrepid USA Healthcare Services	18	
Sweetwater Hospital Home Health	89	

Resident County: McNairy

(Continued)

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,354	100.0
Davidson	1	0.1
Elk Valley Health Services, LLC	1	
Decatur	288	21.3
Tennessee Quality Homecare-Southwest	67	
Volunteer Homecare of West Tennessee, Inc.	221	

Resident County: McNairy

(Continued)

Facility Location/Name	Patients	Percent
Fayette	10	0.7
NHC Homecare	10	
Hardin	555	41.0
Gericare, LLC	498	
HMC Home Health, LLC	57	3.8
Haywood	51	
CareAll Homecare Services	51	
Madison	418	30.9
Amedisys Home Health Care	115	
Extendicare Home Health of West Tennessee	10	
Intrepid USA Healthcare Services	24	
Medical Center Home Health, LLC	34	
Regional Home Care, Jackson	235	
Maury	2	0.1
CareAll Homecare Services	2	
Out-of-State	29	2.1
Magnolia Regional Health Center Home Health and Hospice Age	29	

Resident County: Macon

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	940	100.0
Clay	42	4.5
Cumberland River Homecare	42	
Davidson	439	46.7
Amedisys Home Health	55	
Angel Private Duty and Home Health, Inc.	1	
CareAll Homecare Services	87	
Home Care Solutions	22	
Home Health Care of Middle Tennessee, LLC	2	
Suncrest Home Health	272	
Knox	1	0.1
Amedisys Home Health Care	1	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

(Continued)

Resident County: **Macon**

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
Overton	5	0.5	Henderson	2	0.1
Amedisys Tennessee, L.L.C.	5		Regional Home Care, Lexington	2	
Rutherford	14	1.5	Madison	1,600	49.4
NHC Homecare	14		Amedisys Home Health Care	384	
Smith	66	7.0	Extendicare Home Health of West Tennessee	78	
Highpoint Homecare	66		Intrepid USA Healthcare Services	152	
Sumner	8	0.9	Medical Center Home Health, LLC	427	
Highpoint Homecare	8		Regional Home Care, Jackson	559	
Warren	277	29.5	Shelby	46	1.4
Friendship Home Health, Inc.	277		Alere Women's and Children's Health	4	
Wilson	88	9.4	Maxim Healthcare Services, Inc.	42	
American National Home Health	17		Weakley	1	0.0
Cedar Creek Home Health Care Agency, LLC	5		CareAll Homecare Services	1	
Geniva Health Services	66				

Resident County: **Marion**

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	3,238	100.0	TOTAL PATIENTS	745	100.0
Carroll	6	0.2	Bradley	367	49.3
Baptist Memorial Home Care	6		Home Health Care of East Tennessee, Inc.	367	
Davidson	6	0.2	Coffee	21	2.8
Elk Valley Health Services, LLC	6		Suncrest Home Health of Manchester, Inc.	21	
Decatur	239	7.4	Davidson	2	0.3
Tennessee Quality Homecare-Southwest	239		Elk Valley Health Services, LLC	2	
Gibson	893	27.6	Franklin	16	2.1
NHC Homecare	149		Amedisys Tennessee, L.L.C.	5	
Volunteer Home Care, Inc.	744		Caresouth HHA Holdings of Winchester, LLC	11	
Hardin	127	3.9	Hamilton	337	45.2
Genicare, LLC	127		Amedisys Home Health	75	
Haywood	318	9.8	Continuicare Healthservices, Inc. - I	58	
CareAll Homecare Services	318		Geniva Health Services	8	
			Guardian Home Care, LLC	1	
			Home Care Solutions	38	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County:	Morgan	Obion			
Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	561	100.0	TOTAL PATIENTS	1,220	100.0
Anderson	21	3.7	Benton	62	5.1
Clinch River Home Health	19		Tennessee Quality Homecare - Northwest	62	
Professional Case Management of Tennessee	2		Davidson	6	0.5
Bradley	4	0.7	Elk Valley Health Services, LLC	6	
Home Health Care of East Tennessee, Inc.	4		Dyer	53	4.3
Campbell	1	0.2	Regional Home Care, Dyersburg	53	
Sunbelt Homecare	1		Gibson	237	19.4
Davidson	7	1.2	NHC Homecare	13	
Elk Valley Health Services, LLC	3		Volunteer Home Care, Inc.	224	
Home Care Solutions	4		Madison	350	28.7
Fentress	244	43.5	Amedisys Home Health Care	268	
Quality Home Health	191		Regional Home Care, Jackson	82	
Quality Private Duty Care	53		Obion	85	7.0
Knox	222	39.6	Extendicare Home Health of Western Tennessee	85	
Amedisys Home Health Care	35		Weakley	388	31.8
Camellia Home Health of East Tennessee, LLC	4		CareAll Homecare Services	388	
CareAll Home Care Services	38		Out-of-State	39	3.2
Covenant Homecare	118		Regional Home Care Parkway	39	
East Tennessee Children's Hospital Home Health Care	5		Resident County: Overton		
Geniva Health Services	17		Facility Location/Name	Patients	Percent
Maxim Healthcare Services, Inc.	5		TOTAL PATIENTS	845	100.0
Overton	27	4.8	Clay	37	4.4
Amedisys Tennessee, L.L.C.	27		Cumberland River Homecare	37	
Rutherford	2	0.4	Davidson	32	3.8
NHC Homecare	2		CareAll Homecare Services	31	
Scott	33	5.9	Home Care Solutions	1	
Elk Valley Home Health Care Agency, LLC	33		Fentress	403	47.7
			Quality Home Health	278	
			Quality Private Duty Care	125	

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
 PATIENT ORIGIN BY BASE COUNTY

REPORT 6
 REPORT FOR HOME HEALTH AGENCIES 2014

Resident County:	Sequitahie	Sevier
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	514	100.0
Bradley	52	10.1
Home Health Care of East Tennessee, Inc.	52	5.1
Coffee	26	0.6
Suncrest Home Health of Manchester, Inc.	26	48.4
Franklin	3	
Caresouth HHA Holdings of Winchester, LLC	3	
Hamilton	249	
Amedisys Home Health	32	
Continuicare Healthservices, Inc. - I	12	
Gentiva Health Services	3	
Guardian Home Care, LLC	53	
Home Care Solutions	24	
Life Care at Home of Tennessee	8	
Maxim Healthcare Services	4	
Memorial Hospital Home Health	92	
NHC Homecare	21	
Warren	184	35.8
Careall Home Care Services	184	

Resident County:	Sevier	
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	17,601	100.0
Davidson	10	0.1
Elk Valley Health Services, LLC	10	0.9
Fayette	165	
NHC Homecare	73	
Where The Heart Is, Inc.	92	
Madison	265	1.5
Amedisys Home Health Care	4	
Extendicare Home Health of West Tennessee	261	
Shelby	17,157	97.5
Accredo Health Group, Inc.	16	
Alere Women's and Children's Health	301	
Amedisys Home Care	1,067	
Amedisys Home Health	1,500	
Amedisys Home Health Care	760	
Americare Home Health Agency, Inc.	1,288	

Resident County:	Sequitahie	Sevier
Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,956	100.0
Anderson	1	0.1
Professional Case Management of Tennessee	1	0.9
Blount	17	
Blount Memorial Hospital Home Health Services	17	0.2
Cocke	4	0.4
Smoky Mountain Home Health and Hospice, Inc.	4	
Davidson	7	
Elk Valley Health Services, LLC	1	
Home Care Solutions	6	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: **Shelby**

(Continued)

(Continued)

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
Shelby (Continued)			Franklin	2	0.3
Baptist Trinity Home Care	3,126		Amedisys Tennessee, L.L.C.	1	
Baptist Trinity Home Care - Private Pay Division	1		Caresouth HHA Holdings of Winchester, LLC	1	0.5
Best Nurses, Inc.	176		Punnam	3	
Extended Health Care, Inc.	201		Highland Rim Home Health Agency	2	
Family Home Health Agency	428		Intrepid USA Healthcare Services	1	6.5
Functional Independence Home Care, Inc.	1,427		Rutherford	41	
Home Health Care of West Tennessee, Inc.	572		NHC Homecare	41	
Homechoice Health Services, LLC	1,593		Smith	188	30.0
Intrepid USA Healthcare Services	521		Highpoint Homecare	188	
Maxim Healthcare Services, Inc.	104		Warren	85	13.6
Meritan, Inc.	631		Friendship Home Health, Inc.	85	
Methodist Alliance Home Care	2,913		Wilson	110	17.6
No Place Like Home, Inc.	77		American National Home Health	34	
Still Waters Home Health Agency	71		Cedar Creek Home Health Care Agency, LLC	18	
Willowbrook Visiting Nurse Association, Inc.	384		Geniva Health Services	58	
Tipton	4	0.0			
Baptist Home Care and Hospice - Covington	4				

Resident County: **Smith**

Resident County: **Stewart**

Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	626	100.0	TOTAL PATIENTS	367	100.0
Davidson	113	18.1	Benton	176	48.0
Amedisys Home Health	84		Tennessee Quality Homecare - Northwest	176	11.2
Angel Private Duty and Home Health, Inc.	3		Davidson	41	
CareAll Homecare Services	19		Amedisys Home Health	37	
Elk Valley Health Services, LLC	1		Elk Valley Health Services, LLC	2	0.3
Home Care Solutions	3		Home Care Solutions	2	
Intrepid USA Healthcare Services	3		Gibson	1	
DeKalb	84	13.4	Volunteer Home Care, Inc.	1	
Suncrest Home Health	84		Henry	2	0.5
			Henry County Medical Center Home Health	2	
			Maury	7	1.9
			NHC Homecare	7	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County: Sumner (Continued)

Facility Location/Name	Patients	Percent
Williamson	80	2.2
Guardian Home Care of Nashville	73	
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	7	
Wilson	197	5.3
American National Home Health	73	
Cedar Creek Home Health Care Agency, LLC	29	
Gentiva Health Services	95	

Resident County: Tipton

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	1,317	100.0
Davidson	1	0.1
Elk Valley Health Services, LLC	1	
Fayette	8	0.6
NHC Homecare	1	
Where The Heart Is, Inc.	7	
Haywood	159	12.1
CareAll Homecare Services	159	6.3
Madison	83	
Extendicare Home Health of West Tennessee	29	
Intrepid USA Healthcare Services	29	
Regional Home Care, Jackson	25	
Shelby	819	62.2
Alerte Women's and Children's Health	15	
Amedisys Home Health	353	
Americare Home Health Agency, Inc.	7	
Extended Health Care, Inc.	2	
Functional Independence Home Care, Inc.	42	
Home Health Care of West Tennessee, Inc.	108	
Homechoice Health Services, LLC	79	
Maxim Healthcare Services, Inc.	5	
Methodist Alliance Home Care	191	

Resident County: Tipton (Continued)

Facility Location/Name	Patients	Percent
Shelby	3	
No Place Like Home, Inc.	14	
Willowbrook Visiting Nurse Association, Inc.	247	18.8
Tipton	247	
Baptist Home Care and Hospice - Covington		

Resident County: Trousdale

Facility Location/Name	Patients	Percent
TOTAL PATIENTS	350	100.0
Davidson	138	39.4
Amedisys Home Health	67	
CareAll Homecare Services	12	
Home Care Solutions	7	
Home Health Care of Middle Tennessee, LLC	4	
Intrepid USA Healthcare Services	1	
Suncrest Home Health	46	
Willowbrook Home Health Care Agency, Inc.	1	2.0
Rutherford	7	
NHC Homecare	7	
Shelby	1	0.3
Amedisys Home Health Care	1	
Smith	3	0.9
Highpoint Homecare	3	
Sumner	39	11.1
Highpoint Homecare	39	34.0
Warren	119	
Friendship Home Health, Inc.	119	
Williamson	1	0.3
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1	
Wilson	42	12.0
American National Home Health	26	
Gentiva Health Services	16	

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

Resident County:	Unicoi	Resident County:	Union	(Continued)	
Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent
TOTAL PATIENTS	516	100.0	Knox	24	
Cooke	3	0.6	Covenant Homecare	10	
Smoky Mountain Home Health and Hospice, Inc.	3		East Tennessee Children's Hospital Home Health Care	9	
Davidson	2	0.4	Gentiva Health Services	10	
Elk Valley Health Services, LLC	2		NHC Homecare	116	
Greene	15	2.9	Tennova Home Health	7	
Procare Home Health Services	15		University of TN Medical Center Home Care Services - Home He		
Hamblen	9	1.7			
Premier Support Services	9		Resident County: Van Buren		
Sullivan	67	13.0	Facility Location/Name	Patients	Percent
Gentiva Health Services	67		TOTAL PATIENTS	230	100.0
Washington	420	81.4	Bradley	2	0.9
Amedisys Home Health	93		Home Health Care of East Tennessee, Inc.	2	
Medical Center Homecare Services	291		Coffee	37	16.1
Medical Center Homecare, Kingsport	11		Suncrest Home Health of Manchester, Inc.	37	
NHC Homecare	25		Davidson	6	2.6
			Angel Private Duty and Home Health, Inc.	1	
Resident County: Union			CareAll Homecare Services	3	
Facility Location/Name	Patients	Percent	Elk Valley Health Services, LLC	2	
TOTAL PATIENTS	418	100.0	Franklin	1	0.4
Anderson	4	1.0	Amedisys Tennessee, L.L.C.	1	
Clinch River Home Health	3		Hamilton	12	5.2
Professional Case Management of Tennessee	1		Amedisys Home Health	12	
Claborne	224	53.6	Rutherford	42	18.3
Amedisys Home Health of Tennessee	172		NHC Homecare	42	
Suncrest Home Health	52		Warren	130	56.5
Hamblen	2	0.5	CareAll Home Care Services	43	
Amedisys Home Health Care	1		Friendship Home Health, Inc.	78	
Premier Support Services	1		Intrepid USA Healthcare Services	9	
Knox	188	45.0			
Amedisys Home Health Care	3				
Camellia Home Health of East Tennessee, LLC	9				

HOME HEALTH AGENCIES LICENSED IN TENNESSEE
PATIENT ORIGIN BY BASE COUNTY

REPORT 6
REPORT FOR HOME HEALTH AGENCIES 2014

Resident County:	Wayne	(Continued)		Resident County:	Weakley	(Continued)	
Facility Location/Name	Patients	Percent	Facility Location/Name	Patients	Percent	Facility Location/Name	Patients
Hardin	449	54.9	Obion	20	1.5		
Gericare, LLC	434		Extendicare Home Health of Western Tennessee	20			
HMC Home Health, LLC	15		Weakley	735	53.8		
Maury	72	8.8	CareAll Homecare Services	735			
CareAll Homecare Services	44						
Maury Regional Home Services	11						
NHC Homecare	17		Resident County: White				
Williamson	1	0.1	Facility Location/Name	Patients	Percent		
Vanderbilt HC Affiliated W/Walgreens IV and RT Services	1		TOTAL PATIENTS	1,052	100.0		
			Clay	3	0.3		
			Cumberland River Homecare	3	0.3		
			Coffee	3			
			Suncrest Home Health of Manchester, Inc.	3	3.7		
Resident County: Weakley			Davidson	39			
Facility Location/Name	Patients	Percent	Davidson	34			
TOTAL PATIENTS	1,366	100.0	CareAll Homecare Services	2			
Benton	80	5.9	Elk Valley Health Services, LLC	3	30.3		
Tennessee Quality Homecare - Northwest	80		Home Care Solutions	319			
Carroll	4	0.3	DeKalb	319	4.4		
Baptist Memorial Home Care	4		Suncrest Home Health	46			
Davidson	1	0.1	Overton	46	4.8		
Elk Valley Health Services, LLC	1		Amedisys Tennessee, L.L.C.	50			
Gibson	105	7.7	Putnam	21			
NHC Homecare	27		Highland Rim Home Health Agency	29			
Volunteer Home Care, Inc.	78		Intrepid USA Healthcare Services	437	41.5		
Henderson	1	0.1	Rutherford	437			
Regional Home Care, Lexington	1	1.1	NHC Homecare	116	11.0		
Henry	15		Warren	116			
Henry County Medical Center Home Health	15		Careall Home Care Services	39	3.7		
Madison	405	29.6	Wilson	39			
Amedisys Home Health Care	77		Cedar Creek Home Health Care Agency, LLC	39			
Extendicare Home Health of West Tennessee	3						
Intrepid USA Healthcare Services	6						
Medical Center Home Health, LLC	2						
Regional Home Care, Jackson	317						



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About URAC



For 25 years, URAC has been the independent leader in promoting health care quality through accreditation, education, and measurement. URAC offers a wide range of quality benchmarking products that reflect the latest changes in health care and provide a symbol of excellence for organizations to showcase their validated commitment to quality and accountability. URAC's evidence-based measures and standards are developed through inclusive engagement with a broad range of stakeholders committed to improving the quality of health care.

Our History

In the late 1980's, concerns grew over the lack of uniform standards for utilization review (UR) services. UR is the process where organizations determine whether health care is medically necessary for a patient or an insured individual. As a result, URAC's first mission was to improve the quality and accountability of health care organizations using UR programs. In later years, URAC's mission expanded to cover a larger range of service functions found in various health care settings, including the accreditation of integrated systems such as accountable care organizations and health plans to smaller organizations offering specialty services. Formally incorporated in 1990, URAC has more than 30 accreditation and certification programs.

From conception, URAC's founders recognized that an accreditation organization would not be accepted by regulators, health care providers, and consumers if controlled by industry interests. Therefore, several operating principles were incorporated into URAC's structure and bylaws. First, URAC was set up as an organization independent of any particular stakeholder group. Second, the governing board of directors was established with representatives from all affected constituencies: consumers, providers, employers, regulators, and industry experts.

URAC is one of the fastest growing health care accreditation agencies in the world. It will continue to develop new standards for the health care system and revise existing ones to promote national standards and to ensure that all stakeholders, including consumers and providers, are protected.

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What is Accreditation?

Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an impartial external organization (accrediting body) to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards.

What is Measurement?

Measurement facilitates quality improvement and enables more meaningful comparisons among accredited organizations. Beginning with measures concepts familiar to the industry, URAC is adding quantitative measures to our accreditation programs. URAC is committed to aligning and harmonizing its performance measures with the national quality endeavors of the federal, state, and local governments to address key health issues of the population.

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Accreditation adds value to organizations that receive it by providing an external, independent seal of approval and by promoting quality improvement within the organization as part of the accreditation review. URAC accredits many types of health care organizations depending on the specific functions they carry out and has a portfolio of programs that spans the health care industry. URAC accreditations, certifications, and designations address health care management, health care operations, health plans, pharmacy quality management, and providers.

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Does URAC offer an accreditation or certification for compounding pharmacies?

No, URAC does not accredit or certify the work done in compounding pharmacies or compounding functions. URAC's Pharmacy Quality Management® accreditation programs include Specialty Pharmacy, Community Pharmacy, Mail Service Pharmacy, Drug Therapy Management, Pharmacy Benefit Management, and Workers' Compensation Pharmacy Benefit Management. URAC defines Specialty Pharmacy as a full service pharmacy that specializes in filling prescriptions for patients who need certain high-cost biotech and injectable medications. These specialty medications help patients with complex conditions including multiple sclerosis, rheumatoid arthritis, certain types of cancer, solid organ transplant, and hemophilia. These drugs can be injected, infused or taken orally, and typically require special handling and other specialty expertise.

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What are the general eligibility requirements for all URAC programs?

To apply for URAC accreditation and certification, the potential applicant organization must:

1. Be an established legal entity in the United States (U.S.) including U.S. Territories.
2. Operate under a unique Employer Identification Number assigned by the Internal Revenue Service.
3. Have the ability to produce a Certificate of Good Standing from the U.S. State or Territory where the entity is domiciled.
4. Have the ability to provide proof of having filed applicable federal and state taxes.
5. Sign the URAC contract and pay all fees within the assigned due dates.
6. Be in compliance with applicable U.S. federal, state, and local laws and regulations.
7. Operate under active business and clinical permits, licenses, registrations, or charters, within the scope of accreditation function, that have been legally issued by U.S. federal, state, or local agencies.
8. Perform all clinical services and denials, within the scope of accreditation function, within the U.S. – this includes U.S. territories.
9. Be able to document all non-clinical services, within the scope of accreditation function, that operate outside of the U.S.
10. Perform health care services that can be evaluated, relevant to the URAC program standards applied.
11. Not delegate or outsource to another entity more than 50 percent of the standards within the scope of accreditation function.
12. Operate under the same policies and procedures at all locations covered within the scope of accreditation function.
13. Provide complete and accurate information to URAC during the application process and during the term of the accreditation.
14. Have the ability to report required measurement data.
15. Demonstrate that it continually assesses and acts to improve the quality of its services that are within the scope of accreditation function.
16. Identify any excluded business or customers from the scope of the accreditation function.
17. Not exclude functions for which URAC is recognized by the federal government or state governments.
18. Have less than six months of operations if seeking provisional accreditation.

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How many organizations hold URAC accreditation?

URAC-accredited organizations are listed in the URAC Directory of Accredited Organizations. It can be searched by a specific program or by organization name.

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Who recognizes URAC accreditation?

URAC's accreditation is recognized nationwide by state and federal regulators. URAC accreditation standards appear in legislation and regulation at the state and federal government. URAC has deemed status for various state and federal programs and is authorized by the U.S. Department of Health and Human Services as an accreditor for Qualified Health Plans in the Health Insurance Marketplace. URAC's health plan accreditation standards are approved by the U.S. Department of Health and Human Services (HHS) and are valid for health plans in all 50 states as well as the District of Columbia. URAC has recognition of our Health Plan Accreditation from the Center for Consumer Information and Insurance Oversight for Qualified Health Plans being offered on Health Insurance Marketplaces and deeming recognition from the Centers for Medicare and Medicaid Services (CMS) for Medicare Advantage plans (which does not include Part D plans).

TennCare Enrollment Report for April 2016

MCO	REGION	Total
AMERIGROUP COMMUNITY CARE		443,496
BLUECARE	East Tennessee	208,420
BLUECARE	Middle Tennessee	171,846
BLUECARE	West Tennessee	152,513
UnitedHealthcare Community Plan	East Tennessee	168,706
UnitedHealthcare Community Plan	Middle Tennessee	172,258
UnitedHealthcare Community Plan	West Tennessee	141,714
TENNCARE SELECT HIGH	All	52,874
TENNCARE SELECT LOW	All	22,239
PACE		268
Awaiting MCO assignment		33
Grand Total		1,534,367

COUNTY	Female			Male			Grand Total				
	0 - 18	19 - 20	21 - 64	65 ->	Female						
					Total	0 - 18		19 - 20	21 - 64	65 ->	Male Total
ANDERSON	4,217	387	4,555	629	9,788	4,508	321	2,178	280	7,287	17,075
BEDFORD	3,880	282	3,244	257	7,663	4,040	257	1,339	126	5,762	13,425
BENTON	1,047	108	1,188	146	2,489	1,098	93	633	72	1,896	4,385
BLED SOE	809	78	870	117	1,874	901	82	508	58	1,549	3,423
BLOUNT	6,084	552	6,412	671	13,719	6,171	429	2,874	321	9,795	23,514
BRADLEY	6,028	497	6,244	694	13,463	6,333	398	2,718	289	9,738	23,201
CAMPBELL	2,965	314	3,866	677	7,822	3,126	244	2,165	378	5,913	13,735
CANNON	769	78	884	135	1,866	801	65	407	52	1,325	3,191
CARROLL	1,856	183	2,246	336	4,621	2,046	179	1,152	126	3,503	8,124
CARTER	3,188	293	3,683	709	7,873	3,377	243	1,910	276	5,806	13,679
CHEATHAM	2,039	198	2,074	159	4,470	2,167	168	960	91	3,386	7,856
CHESTER	1,042	104	1,087	150	2,383	1,061	72	466	71	1,670	4,053
CLAIBORNE	2,072	226	2,565	554	5,417	2,193	194	1,555	253	4,195	9,612
CLAY	540	50	569	120	1,279	559	39	371	68	1,037	2,316
COCKE	2,808	268	3,275	468	6,819	2,930	231	1,775	235	5,171	11,990
COFFE	3,676	306	3,772	403	8,157	3,805	246	1,678	166	5,895	14,052
CROCKETT	1,114	82	1,032	207	2,435	1,073	73	494	82	1,722	4,157
CUMBERLAND	3,308	317	3,506	505	7,636	3,481	235	1,729	240	5,685	13,321
DAVIDSON	43,096	2,927	38,186	3,402	87,611	44,267	2,536	15,981	1,799	64,583	152,194
DECATUR	672	75	792	201	1,740	770	54	439	66	1,329	3,069
DEKALB	1,369	121	1,406	197	3,093	1,467	110	740	107	2,424	5,517
DICKSON	2,994	263	3,121	319	6,687	3,183	224	1,353	133	4,893	11,580
DYER	2,769	271	3,159	437	6,636	2,894	253	1,377	155	4,679	11,315
FAYETTE	1,839	169	1,868	294	4,170	1,968	138	782	144	3,032	7,202
FENTRESS	1,359	140	1,610	367	3,476	1,480	138	1,068	194	2,880	6,356
FRANKLIN	2,028	204	2,232	263	4,727	2,171	177	1,071	114	3,533	8,260
GIBSON	3,347	316	3,746	588	7,997	3,558	288	1,727	261	5,834	13,831
GILES	1,703	159	1,795	239	3,896	1,655	136	859	118	2,768	6,664
GRAINGER	1,507	146	1,603	311	3,567	1,500	126	945	151	2,722	6,289

COUNTY	Female				Male				Male Total	Grand Total	
	0 - 18	19 - 20	21 - 64	65 ->	Female Total	0 - 18	19 - 20	21 - 64			65 ->
GREENE	3,732	364	4,523	723	9,342	4,004	282	2,199	375	6,860	16,202
GRUNDY	1,066	132	1,318	217	2,733	1,203	111	766	122	2,202	4,935
HAMBLEN	4,681	307	3,998	537	9,523	4,785	309	1,813	221	7,128	16,651
HAMILTON	18,399	1,370	18,984	2,381	41,134	19,291	1,196	7,850	1,054	29,391	70,525
HANCOCK	519	67	641	144	1,371	564	49	382	69	1,064	2,435
HARDEMAN	1,841	179	2,055	334	4,409	1,809	150	970	160	3,089	7,498
HARDIN	1,754	170	2,078	377	4,379	1,843	168	1,033	197	3,241	7,620
HAWKINS	3,460	292	3,900	593	8,245	3,599	277	1,988	297	6,161	14,406
HAYWOOD	1,493	148	1,735	254	3,630	1,646	124	630	102	2,502	6,132
HENDERSON	1,849	173	2,061	267	4,350	2,008	141	936	103	3,188	7,538
HENRY	2,063	189	2,315	287	4,854	2,240	193	1,135	89	3,657	8,511
HICKMAN	1,556	149	1,719	187	3,611	1,783	148	920	96	2,947	6,558
HOUSTON	493	41	562	114	1,210	531	36	274	74	915	2,125
HUMPHREYS	1,122	97	1,227	155	2,601	1,151	64	593	57	1,865	4,466
JACKSON	660	60	787	135	1,642	755	66	448	94	1,363	3,005
JEFFERSON	3,315	295	3,334	491	7,435	3,483	263	1,687	200	5,633	13,068
JOHNSON	1,060	98	1,206	270	2,634	1,128	81	763	147	2,119	4,753
KNOX	20,669	1,707	21,779	2,466	46,621	21,695	1,456	9,635	1,150	33,936	80,557
LAKE	475	44	671	157	1,347	560	46	299	78	983	2,330
LAUDERDALE	2,066	207	2,285	302	4,860	2,166	180	1,004	125	3,475	8,335
LAWRENCE	2,838	241	2,938	403	6,420	3,013	188	1,474	144	4,819	11,239
LEWIS	804	70	811	126	1,811	791	71	402	58	1,322	3,133
LINCOLN	2,092	176	2,003	273	4,544	2,158	138	989	102	3,387	7,931
LOUDON	2,598	221	2,436	271	5,526	2,675	163	1,124	114	4,076	9,602
MACON	1,885	173	1,763	241	4,062	2,000	134	884	115	3,133	7,195
MADISON	6,875	553	7,232	844	15,504	6,985	461	2,670	359	10,475	25,979
MARION	1,841	171	2,122	236	4,370	1,870	162	933	131	3,096	7,466
MARSHALL	1,906	142	1,870	179	4,097	2,032	136	790	73	3,031	7,128
MAURY	5,277	370	5,143	533	11,323	5,579	322	2,097	194	8,192	19,515
MCMINN	3,181	292	3,483	506	7,462	3,444	235	1,607	231	5,517	12,979
MCNAIRY	1,799	180	2,182	360	4,521	1,989	156	1,213	183	3,541	8,062
MEIGS	844	78	916	79	1,917	883	72	463	38	1,456	3,373
MONROE	2,938	282	3,206	491	6,917	3,225	244	1,662	249	5,380	12,297
MONTGOMERY	9,853	684	9,816	687	21,040	10,185	523	3,472	246	14,426	35,466
MOORE	221	20	203	48	492	254	25	105	16	400	892
MORGAN	1,237	116	1,291	208	2,852	1,284	127	676	101	2,188	5,040
OBION	2,128	202	2,334	294	4,958	2,213	150	992	125	3,480	8,438
OVERTON	1,271	145	1,379	280	3,075	1,352	121	764	132	2,369	5,444
PERRY	567	49	534	89	1,239	553	59	311	34	957	2,196
PICKETT	259	31	317	79	686	285	36	162	45	528	1,214
POLK	1,071	114	1,197	155	2,537	1,099	82	637	79	1,897	4,434
PUTNAM	4,451	386	4,698	737	10,272	4,690	313	2,481	321	7,805	18,077
RHEA	2,470	224	2,436	352	5,482	2,554	184	1,227	141	4,106	9,588
ROANE	2,780	245	3,351	517	6,893	3,109	250	1,741	231	5,331	12,224
ROBERTSON	4,044	309	3,521	379	8,253	4,276	257	1,436	160	6,129	14,382
RUTHERFORD	14,662	1,122	13,074	984	29,842	15,290	862	4,813	433	21,398	51,240
SCOTT	1,943	175	2,224	369	4,711	2,056	161	1,210	183	3,610	8,321
SEQUATCHIE	1,031	97	1,110	149	2,387	1,058	86	595	53	1,792	4,179
SEVIER	5,851	493	5,393	467	12,204	6,281	386	2,301	170	9,138	21,342

COUNTY	Female				Male				Grand Total		
	0 - 18	19 - 20	21 - 64	65 ->	Female Total	0 - 18	19 - 20	21 - 64		65 ->	
SHELBY	77,825	6,173	73,263	6,843	164,104	79,630	5,604	25,278	3,017	113,529	277,633
SMITH	1,147	109	1,222	162	2,640	1,175	83	570	63	1,891	4,531
STEWART	746	63	850	113	1,772	798	71	431	58	1,358	3,130
SULLIVAN	8,298	743	9,734	1,296	20,071	8,741	648	4,889	589	14,867	34,938
SUMNER	8,312	694	8,027	803	17,836	8,750	592	3,224	301	12,867	30,703
TIPTON	3,782	336	3,822	366	8,306	3,982	315	1,538	139	5,974	14,280
TROUSDALE	553	68	570	75	1,266	530	38	274	35	877	2,143
UNICOI	949	103	1,136	249	2,437	1,071	84	563	125	1,843	4,280
UNION	1,423	135	1,374	161	3,093	1,361	108	744	90	2,303	5,396
VAN BUREN	335	31	357	58	781	370	28	201	47	646	1,427
WARREN	2,995	248	3,074	434	6,751	3,113	213	1,492	203	5,021	11,772
WASHINGTON	6,149	510	7,059	963	14,681	6,300	441	3,414	426	10,581	25,262
WAYNE	861	70	945	170	2,046	902	78	474	73	1,527	3,573
WEAKLEY	1,874	183	2,175	319	4,551	1,950	157	1,028	115	3,250	7,801
WHITE	1,790	172	1,954	293	4,209	1,929	139	1,089	122	3,279	7,488
WILLIAMSON	3,512	265	3,041	360	7,178	3,759	277	1,272	141	5,449	12,627
WILSON	5,351	456	5,191	467	11,465	5,602	314	2,076	193	8,185	19,650
Other	4,519	410	5,700	170	10,799	4,927	344	2,147	104	7,522	18,321
Grand Total	401,536	33,323	406,245	47,584	888,688	418,900	28,727	176,514	21,538	645,679	1,534,367

Reports include some membership additions that are the result of retroactivity; however, additional retroactivity may still occur. The "Other" county category reflects recipients who are Tennessee residents for which their domicile is temporarily located outside of the state.

CHEYENNE JOHNSON

Assessor of Property

Property Location and Owner Information	2015 Appraisal and Assessment Information
<p>Parcel ID: 056033 00237</p> <p>Property Address: 5100 POPLAR AVE ✓</p> <p>Municipal Jurisdiction: MEMPHIS</p> <p>Neighborhood Number: 00712E56</p> <p>Tax Map Page: 154E</p> <p>Land Square Footage:</p> <p>Acres: 7.7900 ✓</p> <p>Lot Dimensions: 139.71 X 237.97 IRR</p> <p>Subdivision Name: CLARK TOWER SD RESUB OF LOT 2</p> <p>Subdivision Lot Number: 2A</p> <p>Plat Book and Page: 216-030</p> <p>Number of Improvements: 1</p> <p>Owner Name: CLARK TOWER LLC</p> <p>In Care Of:</p> <p>Owner Address: 2328 10TH AVE N STE 401</p> <p>Owner City/State/Zip: LAKE WORTH, FL 33461 6606</p>	<p>Class: COMMERCIAL</p> <p>Land Appraisal: \$ 5,155,600</p> <p>Building Appraisal: \$ 16,854,700</p> <p>✓ <u>Total Appraisal:</u> \$ <u>22,010,300</u></p> <p>✓ <u>Total Assessment:</u> \$ 8,804,120</p> <p>Greenbelt Land: \$ 0</p> <p>Homesite Land: \$ 0</p> <p>Homesite Building: \$ 0</p> <p>Greenbelt Appraisal: \$ 0</p> <p>Greenbelt Assessment: \$ 0</p> <p>Click Here for 2014 Values</p> <p>View: Assessor's GIS Map</p> <p>View: GIS Parcel Map</p>

Commercial Structure Information

Land Use:	- OFFICE HIGH
Total Living Units:	
Structure Type:	OFFICE BLDG H-R 5ST
Year Built:	1973
Investment Grade:	B
<u>Building Square Footage:</u>	<u>1172656</u> ✓

Other Buildings on Site for this Property
See Permits Filed for this Property
See Sales Data for this Property

Disclaimer: The information presented on this web site is based on the inventory of real property found within the jurisdiction of the county of Shelby in the State of Tennessee. Shelby County assumes no legal responsibility for the information contained within this web site. This is not a bill and does not serve as a notice or invoice for payment of taxes nor does it replace scheduled notices mailed to property owners.

SUPPORT LETTERS

Wesley Neurology Clinic

Center for the Diagnosis, Treatment and Research of Neurological Disorders

~~Bolin Adumolekun, M.D.~~

May 26, 2016

~~Tullo E. Bectorini, M.D.~~

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

~~Yaohui Chai, M.D.~~

~~Gregory J. Condon, M.D.~~

~~Hafiz A. Elahi, M.D.~~

~~Nada El Audary, M.D.~~

~~Mark LeDoux, M.D.~~

~~Jesus F. Martinez, M.D.~~

~~Rekha Pillal, M.D.~~

Re: Axelacare Health Solutions LLC--Certificate of Need Application

~~Nancy E. Baker
Administrator~~

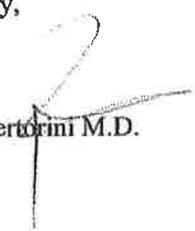
Dear Ms. Hill:

Wesley Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system--some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

Having companies like AxelaCare that specialize in pharmacy and IgG infusion nursing in the home setting provides a great alternative to treat these patients. Identifying companies that can provide home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

I support Axelacare's application for a Certificate of Need to provide these specialized services. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,


Tulio Bectorini M.D.

Central Office
1211 Union Ave
Suite 400
Memphis, TN 38104
(901) 725-8920

East Office
8000 Centerview Pkwy
Suite 305
Memphis, TN 38018
(901) 624-2960

MRI Center
8000 Centerview Pkwy
Suite 101
Memphis, TN 38018
(901) 624-0384

North Office
3950 New Covington Pike
Suite 270
Memphis, TN 38128
(901) 387-2120

June 9, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

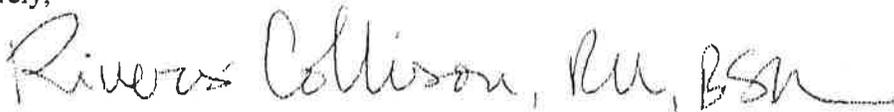
I am a Registered Nurse working for Memphis Neurology. We are a multi-physician specialty medical practice in Memphis treating patients with disorders related to the nervous system. We see patients from Memphis and several counties surrounding Shelby County.

In the past, we have attempted to identify home health agencies that will treat our patients requiring immune globulin (IvIg) therapy in the home. This is an infused therapy given by IV which requires specially trained skilled nurses to administer. The RN goes to the home, starts an IV, administers the drug and monitors the patient throughout the infusion. Due to the nature of the drug and the dose given, this can often require the infusion to last 4-8 hours and must be given over consecutive days. Consequently, many home health agencies decline these patients because they do not have the trained staff or the number of nurses available to service.

Recently, I have had patients that should have received this therapy in the home but I could not identify an agency in West Tennessee that could service this type of patient.

I am requesting that you approve Axelacare's request for CON to provide services for our patients. There is an unmet need in our area and having Axelacare as an option to provide these services could improve the quality and timeliness of care our patients receive.

Sincerely,



Rivers Collison, RN

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

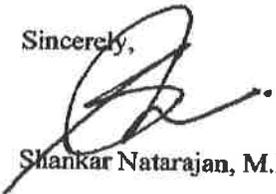
Dear Ms. Hill:

Memphis Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system—some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

For these reasons, we support Axelacare's application for a Certificate of Need. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,


Shankar Natarajan, M.D.

Rahul Sonone, M.D.

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

Memphis Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system, some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

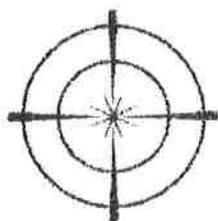
For these reasons, we support Axelacare's application for a Certificate of Need. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Shankar Natarajan, M.D.



Rahul Sonone, M.D.



INTERNATIONAL
PRECISION MEDICINE
ASSOCIATES

2200 Pennsylvania Avenue NW
4th Floor East Tower
Washington, DC 20037
888-727-6910
Fax 202-765-2456

May 17, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

The physicians at International Precision Medicine Associates want to express our support for Axelacare Health Solutions LLC's Certificate of Need application to expand its services to West Tennessee. There is a significant need for access to the valuable services that Axelacare provides, and we are confident that the approval of this project will assist both in improving patient care and the orderly development of healthcare in the region. We urge you to give Axelacare's application your approval. While our physician practice is not in Tennessee, we have a patient who resides in West Tennessee.

International Precision Medicine Associates is a specialty medical practice of two physicians, one naturopathic physician, and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in West Tennessee. Many of our patients are afflicted with challenging medical conditions – such as Primary Immune Deficiency, Selective Ig Deficiency, Common Variable Immune Deficiency – that defy conventional forms of therapy. In such cases, immune globulin infusion (IgG) therapy is often the best, and sometimes, the only, treatment alternative. A treatment regimen can take several days to administer; so it is a burden for many rural patients to have to travel long distances to receive infusions in institutional settings.

The addition of Axelacare home infusion nursing to the West Tennessee region will be a real improvement in our options. Axelacare specializes in IgG home infusion therapy and has been recognized by The Joint Commission for meeting exemplary clinical standards. It has a proven track record of success of delivering IgG therapy in many other states, using its in-house specialty pharmacy and nursing resources, and we would welcome the opportunity to have access to its integrated services (both nursing and pharmaceuticals) for the benefit of our patients. We also value AxelaCare's advanced *CareExchange* technology, which allows us to collect assessment and outcome data on our patients remotely and in real-time--and feel that it is best operated by AxelaCare's own experienced infusion nurses, as proposed in this application. Knowing our patient will receive the same standard of care and clinical outcomes data collection in Tennessee allows us to effectively manage the patient from afar.

For all of these reasons, we enthusiastically endorse Axelacare's application for a Certificate of Need. Axelacare's home infusion nursing services are needed throughout the West Tennessee region, and will improve the quality of care for our patient.

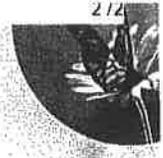
Respectfully submitted,

A handwritten signature in black ink, appearing to read "C. Gant", with a long horizontal flourish extending to the right.

Charles Gant, M.D., Ph.D.



National Integrated Health Associates
Leaders in Integrative Medicine and Biological Dentistry



5/16/16

Melanie M. Hill
 Health Services & Development Agency
 Andrew Jackson Bldg., 9th Floor
 502 Deaderick Street
 Nashville, Tennessee 37243

Dear Ms. Hill:

The physicians at National Integrated Health Associates want to express our support for Axelacare Health Solutions LLC's Certificate of Need application to expand its services to West Tennessee. There is a significant need for access to the valuable services that Axelacare provides, and we are confident that the approval of this project will assist both in improving patient care and the orderly development of healthcare in the region. We urge you to give Axelacare's application your approval. While our physician practice is not in Tennessee, we have a patient who resides in Arlington, TN.

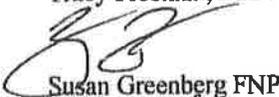
National Integrated Health Associates is a specialty medical practice of six physicians and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in Shelby County. Many of our patients are afflicted with challenging medical conditions – such as Primary Immune Deficiency, Selective Ig Deficiency, Common Variable Immune Deficiency – that defy conventional forms of therapy. In such cases, immune globulin infusion (IgG) therapy is often the best, and sometimes, the only, treatment alternative. A treatment regimen can take several days to administer; so it is a burden for many rural patients to have to travel long distances to receive infusions in institutional settings.

The addition of Axelacare home infusion nursing to the West Tennessee region will be a real improvement in our options. Axelacare specializes in IgG home infusion therapy and has been recognized by The Joint Commission for meeting exemplary clinical standards. It has a proven track record of success of delivering IgG therapy in many other states, using its in-house specialty pharmacy and nursing resources, and we would welcome the opportunity to have access to its integrated services (both nursing and pharmaceuticals) for the benefit of our patients. We also value AxelaCare's advanced *CareExchange* technology, which allows us to collect assessment and outcome data on our patients remotely and in real-time—and feel that it is best operated by AxelaCare's own experienced infusion nurses, as proposed in this application. Knowing our patient will receive the same standard of care and clinical outcomes data collection in Tennessee allows us to effectively manage the patient from afar.

For all of these reasons, we enthusiastically endorse Axelacare's application for a Certificate of Need. Axelacare's home infusion nursing services are needed throughout the West Tennessee region, and will improve the quality of care for our patient.

Respectfully submitted,

Tracy Freeman, M.D.


 Susan Greenberg FNP



5225 Wisconsin Avenue, Suite 402 • Washington, D.C. 20015

(202) 237-7000

www.NIHAdc.com

Fax (202) 237-0011

EMAILED SUPPORT STATEMENT

NOTE: Mr. Hartman, a Pharmacist, resides in Hamilton County.

From: Steven Hartman <chadrx2005@gmail.com>

Date: June 10, 2016 at 8:46:23 AM CDT

To: Derrek Blake <dblake@axelacare.com>

Subject: Re: AxelaCare Health Solutions TN Letter (Derrek Blake)

To Whom It May Concern:

I would like to express my professional and personal opinions regarding the arrangement of nursing home care for HyQvia infusion treatment. As a pharmacist I have seen the benefits of streamlining any treatment for patients. The least complex process is always the most advantageous for the patient and usually leads to a higher patient compliance rate. I believe reducing the number of patient contacts by the ability to schedule nursing care through a single contact at AxelaCare will help patients. From a personal/patient point of view I found myself engaging in some phone tag when scheduling my initial nursing care visit. This seems to have pushed back my start date a few days. Not a problem for me personally, but could be a potential issue for some patients in the future. Thank you for your time and attention to my viewpoints. I hope this helps in the decision making process and advances patient care to the very best it can be.

Sincerely,
Chad Hartman, PharmD

JUN 24 15:54:15

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

JOHN WELLBORN, being first duly sworn, says that he is the lawful agent of the applicant named in this application, that this project will be completed in accordance with the application to the best of the agent's knowledge, that the agent has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of the agent's knowledge.

John L. Wellborn
SIGNATURE/TITLE

Sworn to and subscribed before me this 13th day of June, 2016 a Notary
(Month) (Year)

Public in and for the County/State of DAVIDSON



[Signature]
NOTARY PUBLIC

My commission expires July 2, 2018
(Month/Day) (Year)

JUN 10 10:56 AM '16

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published on or before June 10, 2016, for one day, in the following newspapers:

(a) The *Commercial Appeal*, which is a newspaper of general circulation in *Crockett, Fayette, Hardeman, Hardin, Haywood, Lake, Lauderdale, McNairy, Obion, Shelby, Tipton and Weakley Counties*;

(b) The *Jackson Sun*, which is a newspaper of general circulation in *Carroll, Chester, Decatur, Gibson, Henderson and Madison Counties*;

(c) The *Paris Post-Intelligencer*, which is a newspaper of general circulation in *Benton and Henry Counties*; and

(d) The *Dyersburg State Gazette*, which is a newspaper of general circulation in *Dyer County*.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at \$69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

The applicant seeks licensure as a Home Health Agency (limited as described above) by the Board for Licensing Health Care facilities. The applicant's principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

John Wellborn 6-9-16
(Signature) (Date)

jwdsg@comcast.net
(E-mail Address)



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

July 1, 2016

John Wellborn
Development Support Group
4219 Hillsboro Road, Suite 210
Nashville, TN 37215

RE: Certificate of Need Application -- AxelaCare Health Solutions LLC. - CN1606-022
The establishment of a home care organization and the initiation of home health services limited to the home infusion of immune globulin pharmaceuticals in 21 West Tennessee counties. The principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis (Shelby County) Tennessee. The service area includes Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton, and Weakley Counties. The estimated project cost is \$69,628.

Dear Mr. Wellborn:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised that your application is now considered to be complete by this office.

Your application is being forwarded to Trent Sansing at the Tennessee Department of Health for Certificate of Need review by the Division of Policy, Planning and Assessment. You may be contacted by Mr. Sansing or someone from his office for additional clarification while the application is under review by the Department. Mr. Sansing's contact information is Trent.Sansing@tn.gov or 615-253-4702.

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on July 1, 2016. The first 60 days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the 60-day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review. You will receive a copy of their findings. The Health Services and Development Agency will review your application on October 26, 2016.

Mr. Wellborn
July 1, 2016
Page 2

Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

- (3) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.
- (4) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,



Melanie M. Hill
Executive Director

cc: Trent Sansing, TDH/Health Statistics, PPA



State of Tennessee

Health Services and Development Agency

Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: 
Melanie M. Hill
Executive Director

DATE: July 1, 2016

RE: Certificate of Need Application
AxelaCare Health Solutions LLC. - CN1606-022

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a 60-day review period to begin on July 1, 2016 and end on September 1, 2016.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: John Wellborn

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published on or before June 10, 2016, for one day, in the following newspapers:

(a) The *Commercial Appeal*, which is a newspaper of general circulation in *Crockett, Fayette, Hardeman, Hardin, Haywood, Lake, Lauderdale, McNairy, Obion, Shelby, Tipton and Weakley Counties*;

(b) The *Jackson Sun*, which is a newspaper of general circulation in *Carroll, Chester, Decatur, Gibson, Henderson and Madison Counties*;

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This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at \$69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

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The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

John Wellborn 6-9-16
(Signature) (Date)

jwdsg@comcast.net
(E-mail Address)

Supplemental #1
-ORIGINAL-

AxelaCare Health
Solutions, LLC

CN1606-022

June 22, 2016

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1606-022
AxelaCare Health Solutions, LLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section A. Applicant Profile, Item 1

a. The Letter of Intent notes the applicant's proposed site is located on the 27th floor at 5100 Poplar Avenue, Memphis, TN. Please revise.

Attached after this page is revised page 1R, adding "Suite 2739" to the address for the site, so it exactly agrees with the Letter of Intent.

b. The applicant notes the proposed site is located in Johnson (Kansas) County. Please revise to reflect Shelby County, TN.

Revised page 1R following this page corrects that county name.

June 23, 2016**12:14 pm*****PART A******1. Name of Facility, Agency, or Institution***

AxelaCare Health Solutions		
<i>Name</i>		
5100 Poplar Avenue, 27 th Floor, Suite 2739		Shelby
<i>Street or Route</i>		<i>County</i>
Memphis	TN	38137
<i>City</i>	<i>State</i>	<i>Zip Code</i>

2. Contact Person Available for Responses to Questions

John Wellborn		Consultant	
<i>Name</i>		<i>Title</i>	
Development Support Group		jwdsg@comcast.net	
<i>Company Name</i>		<i>E-Mail Address</i>	
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
<i>Street or Route</i>	<i>City</i>	<i>State</i>	<i>Zip Code</i>
CON Consultant	615-665-2022	615-665-2042	
<i>Association With Owner</i>	<i>Phone Number</i>	<i>Fax Number</i>	

3. Owner of the Facility, Agency, or Institution

AxelaCare Health Solutions, LLC		913-747-3717	
<i>Name</i>		<i>Phone Number</i>	
c/o Office of General Counsel, AxelaCare, 15529 College Blvd		Johnson (KS)	
<i>Street or Route</i>		<i>County</i>	
Lenexa	Kansas	66219	
<i>City</i>	<i>State</i>	<i>Zip Code</i>	

4. Type of Ownership or Control (Check One)

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	x
D. Corporation (For-Profit)		I. Other (Specify):	
E. Corporation (Not-for-Profit)			

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS

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2. Section A, Applicant Profile, Item 12 and 13

a. If the applicant does not plan to provide home health infusion nursing services to TennCare/Medicare enrollees, where would enrollees be referred for those services? If a home health provider is not located, would an enrollee be required to travel on-site for infusion services? Please be specific.

Medicare patients must meet strict Federal guidelines -- "Conditions of Participation" -- to qualify for home infusion nursing. The most difficult of these to meet is being "homebound". The few patients who meet that and the other criteria can only receive home nursing from a Medicare-certified home health agency. AxelaCare is not such an agency and cannot serve Medicare or TennCare referrals. The applicant's survey of existing agencies (Table One in the application) identified only three area agencies that are currently able and prepared to infuse patients with IVIG at home--and two of them are limited to six (6) counties out of the twenty-one (21)-county service area.

Because very few TennCare/Medicare patients qualify under reimbursement rules for home infusion of IVIG products, and because many agencies do not do home infusion of IVIG products, the applicant believes that most TennCare/Medicare patients needing IVIG therapy are being referred by their physicians to hospital outpatient infusion centers, to freestanding infusion centers, or to physician practices that provide such infusions.

b. Please clarify if the applicant's licensed home infusion pharmacy serves non-TennCare/Medicare patients in the proposed 21 County service area.

Yes; the AxelaCare regional pharmacy in Kansas has a Tennessee non-resident pharmacy license that allows it to ship immune globulin product to patient homes in any Tennessee county, when prescribed by patients' physicians.

c. What is the Medicare Intravenous Immune Globulin (IVIG) Demonstration Project? Does the applicant plan to participate?

Attached at the end of this letter is a short report to Congress from the Medicare program, describing that project. It was mandated by 2012 Federal legislation. It establishes a test program for reimbursing IVIG in any setting including the home setting. After the project was designed, HHS began soliciting Medicare patient (not provider) enrollment in 2014. The project is ongoing. The applicant will not accept Medicare patients, so none of the applicant's patients will be participating in that project.

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3. Section B, Project Description, Item I

a. Please provide an overview of how home health infusion staff will be distributed in the 21 proposed county service area.

AxelaCare will employ nurses who have a reasonable drive time from their homes to the patients' homes, in each nurse's own judgment. The drive time from Memphis to all area counties is within norms for home health agencies (see Table Two on page 27 in the application). However, AxelaCare's priority will be to employ at least one nurse who lives in the Jackson area, in addition to having nursing staff who live in the Memphis area. This distribution will shorten nurse drive time to rural counties in the central and eastern parts of the service area.

b. If approved, please clarify if the applicant will subcontract any home health services associated with this application.

No. If approved, AxelaCare intends to deliver IVIG home nursing services to all area patients for whom AxelaCare immune globulin pharmaceuticals are prescribed by referring physicians.

c. What are the risks of a patient experiencing a reaction to a medication as a result of a first dose administered by a home health agency in the home?

The risks are the same wherever IVIG administration occurs. Please see "Side Effects of Intravenous Immune Globulins" (authored by Duhejk, Dicato, and Ries), attached at the end of this response letter. This clinical paper describes reported risks of IG therapy and how potential side effects are managed or avoided.

d. If a patient is new, typically are the first infusion doses administered in a controlled setting such as a hospital, MD office, clinic, etc.?

No. AxelaCare performs a pre-dose screening to determine if each patient is clinically appropriate to receive a first dose at home. AxelaCare's experience is that the majority of patients do qualify as low-risk, appropriate for the home setting. Patients who do not qualify receive a first dose in a monitored setting, rather than in their homes.

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e. If RNs are needed to be specially trained in starting and managing home infusions, why does the applicant not require a nurse to have the Certified Registered Nurse Infusion Designation (CRNI) prior to employment?

AxelaCare uses only nurses who are highly skilled in infusion care before joining AxelaCare. Their skills are validated by AxelaCare's internal assessment program prior to their employment and deployment in the field. Many qualified nurses have never sought CRNI designation because it is very expensive and time-consuming to complete CRNI coursework and testing. However, once with AxelaCare, our nurses receive financial support from the company to seek and obtain CRNI designation.

f. Please provide an overview of the care exchange software and how is it different from other home health provider software.

The CareExchange technology and its uses and advantages were summarized on pages 14 and 15 of the application. For additional details, the applicant is attaching after this page an additional description of its advantages over other provider software, and copies of materials that are distributed to physicians and insurers describing some of its features.

g. It is noted the applicant appears to rely heavily on Axelacare's CareExchange Software to communicate real time with other providers while in the patient's home. Please indicate if rural internet coverage is adequate in all the proposed 21 Counties to use the web-based software.

The applicant cannot provide an analysis of rural internet coverage across every home in West Tennessee. But the applicant believes that internet is accessible in almost all parts of the service area. It is possible that there are a very small number of spots lacking coverage, and there is a possibility that a patient's home may be in such a spot. To allow for this, AxelaCare's CareExchange technology allows the RN to plan for it in advance. The forms and response sheets that would be downloaded "on site" in areas that are covered can be downloaded to the nurse's iPad before the home visit, from any spot where there is coverage. Forms and reports would then be completed manually in the patient's home, and would reside on the iPad until the nurse enters a covered zone on the return trip. At that point the iPad program would automatically upload all data, where it will be accessible to the referring physician 24/7.

June 23, 2016**12:14 pm****CareExchange--The AxelaCare Advantage**

After extended research, AxelaCare introduced its nurse-managed, iPad-based CareExchange technology in 2012. It was the first such system developed for physicians and their patients, and for the research community. As described in the CON application (pgs 14-15), this is an iPad-based software tool that the infusion nurse uses to:

- (a) record critically important patient treatment and response data, including patient input, during the dosing session, and to
- (b) make that data available via internet connection to the patient's physician in graphics, tables, and text formats both during and after the treatment session, and to
- (c) create a growing database of significant importance to research studies.

The system is superior to that of other agencies known to the applicant; and the differences are significant.

First, the CareExchange software's data-gathering instruments were developed, and are maintained, using "best data" recommendations and requests from nationally recognized physician leaders and researchers in this complex field. AxelaCare believes that no other home health infusion company is as deeply involved with those clinical experts on an ongoing basis.

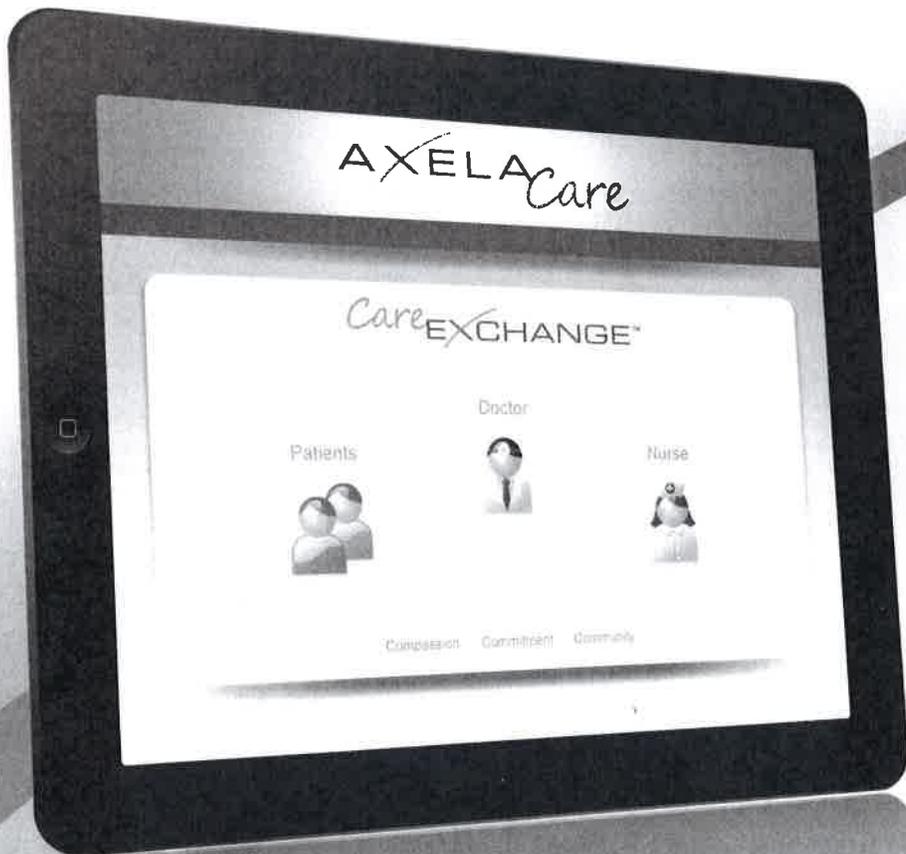
Second, the iPad-based information-gathering process is managed by a trained nurse, working on-site at the time of treatment, to gather important patient response data directly from the patient as well as from nursing observations. This real-time approach that incorporates both nurse and patient input, about measurable and felt responses to infusion, is more accurate, informative, and comprehensive than the old way -- which consisted of the team pharmacist interviewing the patient by telephone some time after the infusion visit, and the infusion nurse writing nursing reports from notes at some time after leaving the patient. This real-time, on-site, comprehensive information gathering and communication system is unique to CareExchange. The referring physician can access relevant data--both quantitative and "soft" information--in highly usable formats, at any time day or night, including during the infusion session itself.

Third, CareExchange captures data from a set of physical assessments of the patient at the time of the infusion session. The patient is asked to perform a set of simple physical tasks that have clinical meaning to reviewing physicians; and their performance of those tasks is quantified, recorded, and put into the physician's hands immediately to help inform treatment decisions. To AxelaCare's knowledge, only CareExchange has this important capability. It provides much-needed information for the physician.

For much more detail on the CareExchange technology and data sets, please review the additional CareExchange materials attached at the end of this response letter.

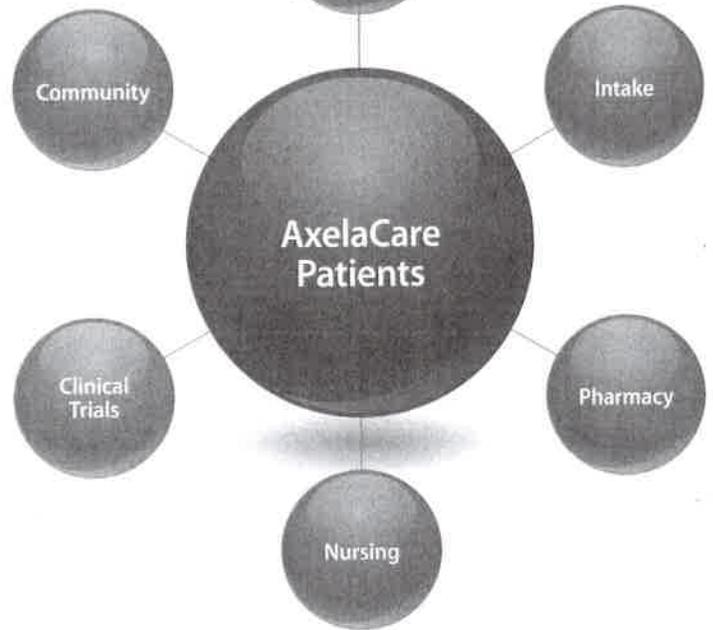
Care EXCHANGE[®]

Outcome Assessment Technology



June 23, 2016

12:14 pm
Practicing
Clinicians



Introducing CareExchange®: Innovation in Patient-Centered Care

The new technology-driven solution from AxelaCare®, called CareExchange®, allows physicians and nurses to easily capture information about the treatments of rare and complex diseases and patients' responses to them – ultimately improving patient outcomes and reducing costs. CareExchange gives physicians the ability to optimize dosing, determine the best therapy strategies and identify natural and non-responders.

The features of CareExchange® innovation include:

- Infusion nurse data collection
- iPad data entry tool
- Validated outcomes assessments
- Web-based physician data access
- Dose vs. outcomes analysis and graphs

CareExchange® Database Architecture

CareExchange is a SQL database that ties all collected outcomes data to AxelaCare's foundational CareLink database. CareLink integrates pharmacy, prescriptions and operations with all patient, history, diagnostics and insurance information, providing an unparalleled ability to correlate and data mine across care elements.

CareExchange® Database Design

AxelaCare built and designed CareExchange with expert input from thought leaders in CIDP, Immuno Globulin, pharmacy and nursing, peripheral neuropathy, neurology, immunology and many others. AxelaCare sought guidance from these experts on outcomes measurements and their applicability from a research and clinical trial setting into an infusion nurse driven scenario. The data collection and validation process is intended to give the most practical and insightful data to practicing clinicians as well as build data sets with specific research objectives in mind. AxelaCare welcomes feedback and collaboration on the design, implementation and research objectives of CareExchange. If you are interested in being a part of the process, please don't hesitate to contact us.

How CareExchange® Works

Employing the latest technology including wireless internet access and iPads, CareExchange tracks data collected through standard studies and practices. The iPad outcomes assessment is nurse-administered during home infusions, and is a patient management tool that optimizes data collection. The resulting data reports are simple to view and easily available to physicians who are creating treatment plans for patients.

Features include:

- Web-based, wireless connectivity for immediate data upload
- Simple touch pad for nurse and patient ease-of-use
- Outcome measures, including:

Physical Assessments

- Timed Up and Go (TUGS), Grip Strength (Jamar)

Disability Scores

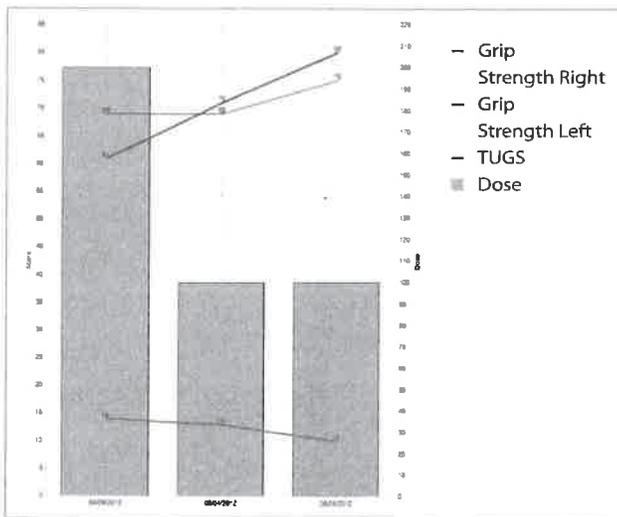
- RODS, ONLS, mFSS (Fatigue), VAS (Pain)

Quality of Life Measures

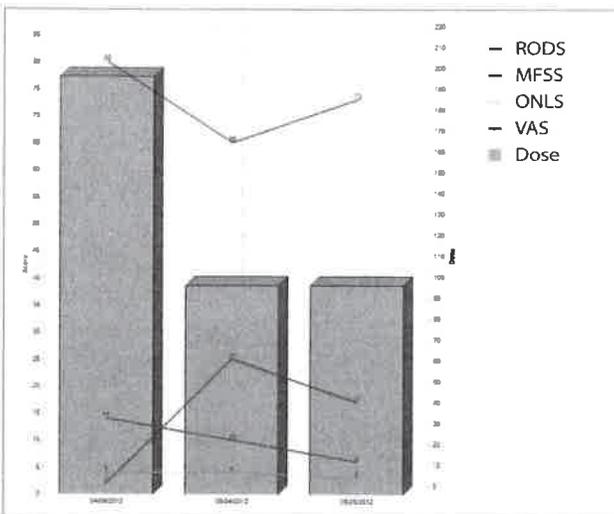
- SF-36

Patient Test

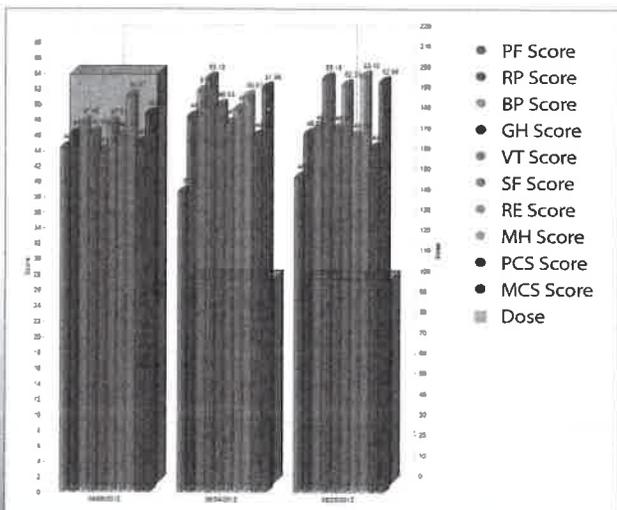
Physical Assessments



Disability Scores



Quality of Life Measures



What is the CareExchange® Outcome?

CareExchange allows physicians and nurses to track patients' progress and optimize therapy. This type of data tracking and management improves:

- Physician access to data and communications
- Physician's understanding of how a therapy is working, and how it might work for other patients with similar conditions
- Physician's ability to adjust therapy to find the most effective dose
- Access to real-time information between office visits to help manage a patient's condition
- Quality and continuity of care
- Nurse productivity
- Research data collection
- Identifying natural responders and non-responders
- Patient care outcomes for those suffering from many rare diseases such as:

- CIDP
- Peripheral Neuropathy
- MGUSP

Future tests may include:

- MMN
- Small Fiber Neuropathy
- MG
- MS
- PIDD
- Stiff-Person Syndrome



Clinical Care Research Overview

Many rare and complex diseases, and the medicines that treat them, lack robust bodies of research to support physicians in designing the most effective care plans. By better understanding these conditions and the way they are treated, we can offer new hope to people facing serious long-term medical challenges.

AxelaCare's clinical care research programs monitor numerous aspects of a patient's treatment and track outcomes on a large scale, helping us to understand the applications of infusion medicine in greater depth and breadth more than ever before and providing new tools for physicians and nurses in managing care.

Clinical care research initiatives include:

- Dose optimization
- Patient outcomes measurement and reporting
- Quality of Life (QOL) measures
- Biomarker development
- Digital recordkeeping and physician collaboration tools
- New therapeutic and patient management strategies
- Supporting clinical research protocols and investigator-initiated studies
- Treatment algorithms
- Natural responders
- Patient education

If you are a physician or research organization interested in participating in AxelaCare's clinical care research initiatives, please contact us at research@axelacare.com.

How can I enroll my patients in CareExchange®?

Simply complete the CareExchange Enrollment Form and provide any of the appropriate items listed below:

- Copy of patient's insurance card
- H & P (History & Physical) or letter to referring MD
- EMG/NCS results
- Nerve biopsy (if done)
- CSF – Cerebral Spinal Fluid (if done)
- Tried and failed therapies

Is the patient data safe?

Yes. The system is a HIPPA compliant electronic medical record database with HTTPS encryption. Patient data is only shared with their physicians and caregivers. Research information is not connected in any way to any Personal Health Information (PHI).

Will patients sign an Informed Consent?

Yes, all patients will get an Informed Consent Form. The AxelaCare team will guide them through everything that CareExchange entails.

How do I learn more?

For additional information regarding CareExchange and AxelaCare, please contact your AxelaCare representative at 877.342.9352 or visit us at www.axelacare.com.



CareEXCHANGE™

for Primary Immune (PID) | IVIg and SCIG

Test Menu

Physical Assessments (Physical Testing)

- Spirometry FEV1/PEF

Disability Scores (Questionnaires)

- AxelaCare Touch™ Patient Self Assessment
- Energy Level/mFSS (modified Fatigue Severity Score)
- Breathing Ability
- Infections
- Work/School/Activities
- Pain

Quality of Life Measures (Assessment)

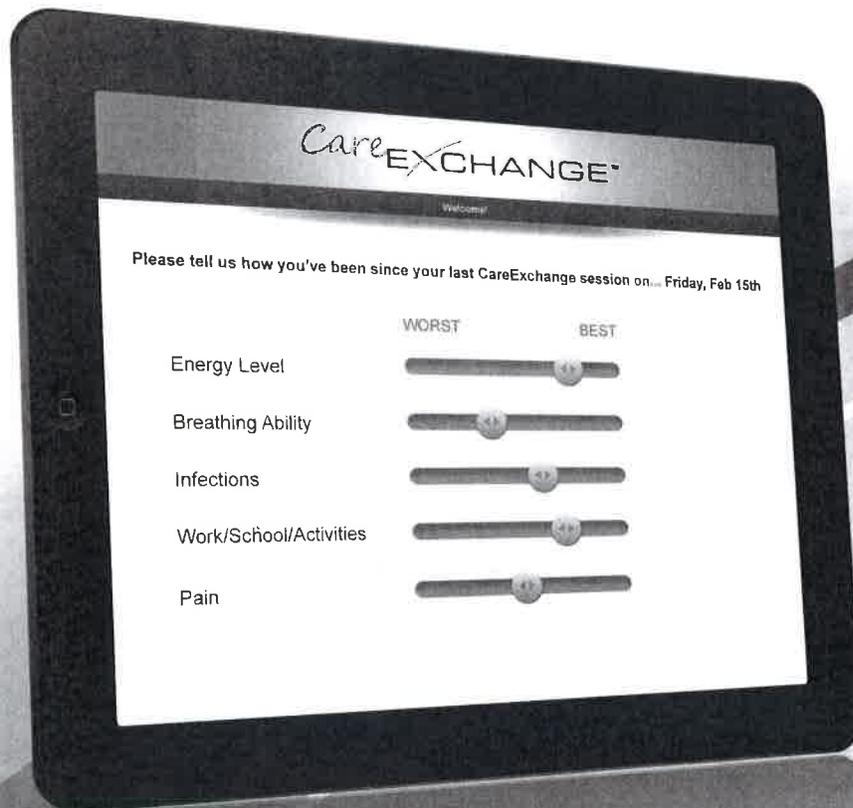
- SF-36 (Adult)
- CHQ-28 (Pediatric)

References

van Nes, Sonja I, et al. (2009). Improving fatigue assessment in immune-mediated neuropathies: the modified Rasch-built fatigue severity scale. *Journal of the Peripheral Nervous System*. 14, 268-278.

Ware Jr., John E. (2000). SF-36® Health Survey Update. *SPINE*. 25 (24), 3130-3139.

Landgraf, J.M., Abetz, L., & Ware Jr., J.E. (1996). *Child Health Questionnaire (CHQ): A User's Manual. First Edition*. Boston, MA: The Health Institute, New England Medical Center.



Patient Assessments

Energy Level

Tap for instructions...

Modified Fatigue Severity Scale

Rasch-built 7-item modified fatigue survey scale: "The higher the score you choose, the more you agree with the question (the lower the score the less you agree)"

Exercise brings on my fatigue

0 DISAGREE

1

2

3 AGREE

I am easily fatigued

0 DISAGREE

1

2

3 AGREE

0 DISAGREE

Infections

Tap for instructions...

1) Since your last infusion...

a. Do you think you have an infection in the?

i) Head

Yes

No

ii) Sinus

Yes

No

iii) Lung

Yes

No

Activities

Tap for instructions...

1) Since your last infusion, due to your condition...

a. Have you missed any work(days)?

1/2

1

2

3

4

5

>5

None

NA

b. Have you missed any school/daycare/activities(days)?

1/2

N

Breathing

Tap for instructions...

Since your last infusion...

Has difficulty in breathing prevented you from performing any activities?

Yes

No

Have you experienced any shortness of breath, coughing or wheezing?

Yes

No

Have you used any rescue inhalers or nebulizers in addition to any regularly prescribed medications you take for your breathing?

Yes

No

Yes

Spirometry

FEV1 and PEF

Spirometry

Forced Expiratory Volume at 1 Second

FEV1 1:

FEV1 2:

FEV1 3:

Peak Expiratory Flow

PEF 1:

PEF 2:

PEF 3:

Finalize Spirometry on Save Save Spirometry



Infusion

Medication Administration and Reactions

Immunoglobulin Liquid | Route: IV

Start Time:

End Time:

Lot # / Expiration Date:

Dose:

Dose UOM: gm

Amount Infused:

Amount Infused UOM: ml

Selected Lot(s): No lots selected

Adverse Reaction(s): Chills, Headache, Migraine, Diarrhea

Selected Adverse Reaction(s): No adverse reactions selected

Comments:

To Learn More
www.axelacare.com

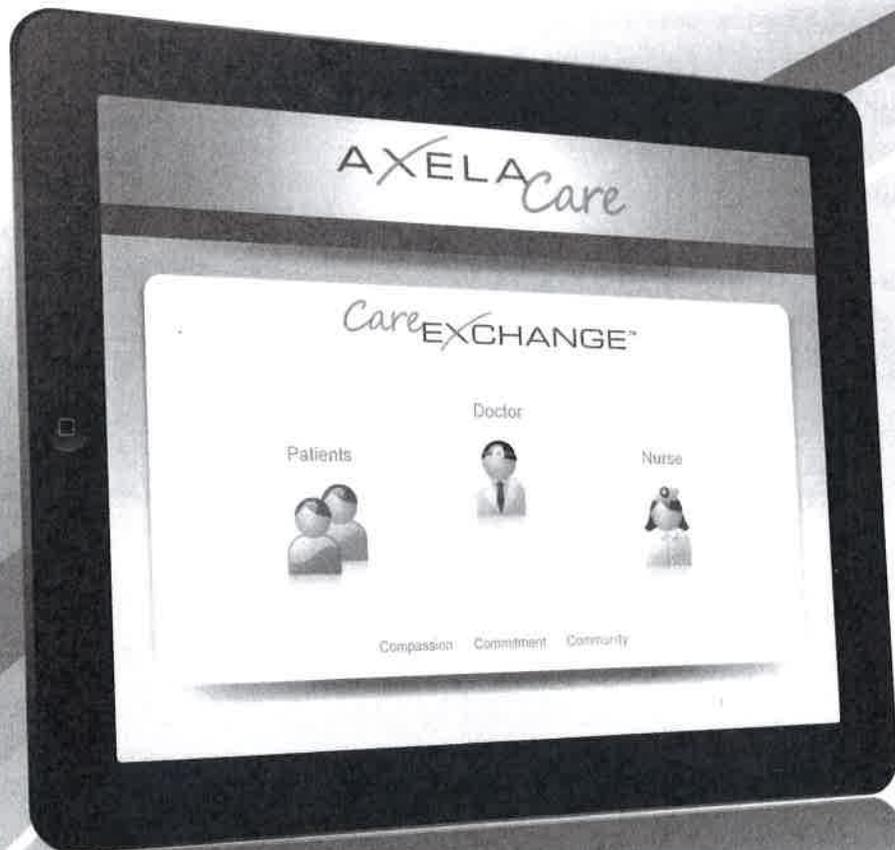


Home Infusion Specialists

CareExchange™ for Managed Care

Better...

- Patient Outcomes
- Drug Optimization
- Cost Savings



Experience. The Difference.

June 23, 2016

12:14 pm

Who We Are

AxelaCare is a patient-focused, in-home provider of Immune Globulin (IgG) and other specialized intravenous infusion medicines. We provide comprehensive service and support for people with complex and chronic medical needs including medications, pharmacy services, treatment management, insurance support, home infusion nursing and patient advocacy. Our team strives to make the treatment process as affordable, comfortable, convenient and personal as possible, with the ultimate goal of improving our patients overall quality of life.

AxelaCare Home Infusion Service and Support includes:

- Specialized Home Infusion
- Pharmacy and Nursing
- Patient Advocacy and Reimbursement Support
- Home Infusion - Antibiotics, Etc.
- Total Parenteral Nutrition
- Immune Globulin (IgG) Therapy
- Administrative Services
- Treatment Management
- Patient Education
- Care Provider Resources
- Clinical Care Research Initiatives

CareExchange™.. Immune Therapy Monitoring System

AxelaCare is entirely focused on improving patient outcomes and helping them to achieve a better quality of life. CareExchange™ a new technology-driven research tool, ensures our success in this critical area.

CareExchange was built and designed with expert input from thought leaders in, Immune Globulin, pharmacy, nursing, peripheral neuropathy, neurology, immunology and many others. This outcomes management tool captures and tracks data about the treatment of rare and complex diseases and patients' responses to them.

*Ultimately, our main goal is simple:
We strive every day to achieve better
outcomes for our patients.*



Cost vs. Benefit Analysis

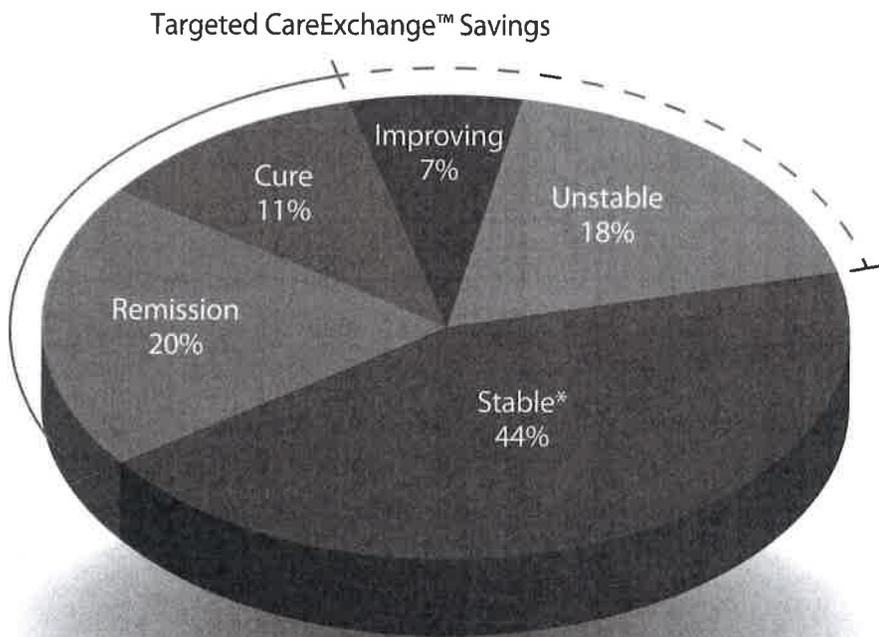
Published data has shown a significant number of IVIg patients (natural responders) can come off of therapy and retain the treatment benefits. Identifying these patients is only possible by diligently tracking patient outcomes.

We can help you manage costly infusion medications while providing optimal patient outcomes.

Partnership with AxelaCare also gives your members access to the CareExchange home infusion outcomes management tool, a bedside, patient reporting treatment resource that provides:

- Tenured and educated professional infusion nurses
- Proven compliance (JCAHO Gold Seal of Approval)
- Higher patient and physician satisfaction and performance
- Better patient outcomes resulting in lower expected ancillary costs
- Data for physicians to more quickly identify natural and non-responders

CIDP (Peripheral Neuropathy Example) - Long-Term Response to IVIg Therapy (2010 U.S. Data)



- Cure > 5 years 11%
- Remission < 5 years 20%
- Stable, Active 44%
- Improving 7%
- Unstable Active Disease 18%
 - Treatment Naive 6%
 - Off Treatment 7%
 - On Treatment 5%

* Stable: Patients on long-term IVIg Therapy

*CareExchange™ savings effects **total** volume of drug, not incremental price concessions.*

Just like other home infusion providers, AxelaCare has all of these strategies at our disposal. However, we are the only company that has CareExchange. CareExchange is the cost-savings strategy that has the most profound impact on the **total** cost of home infusion therapy.

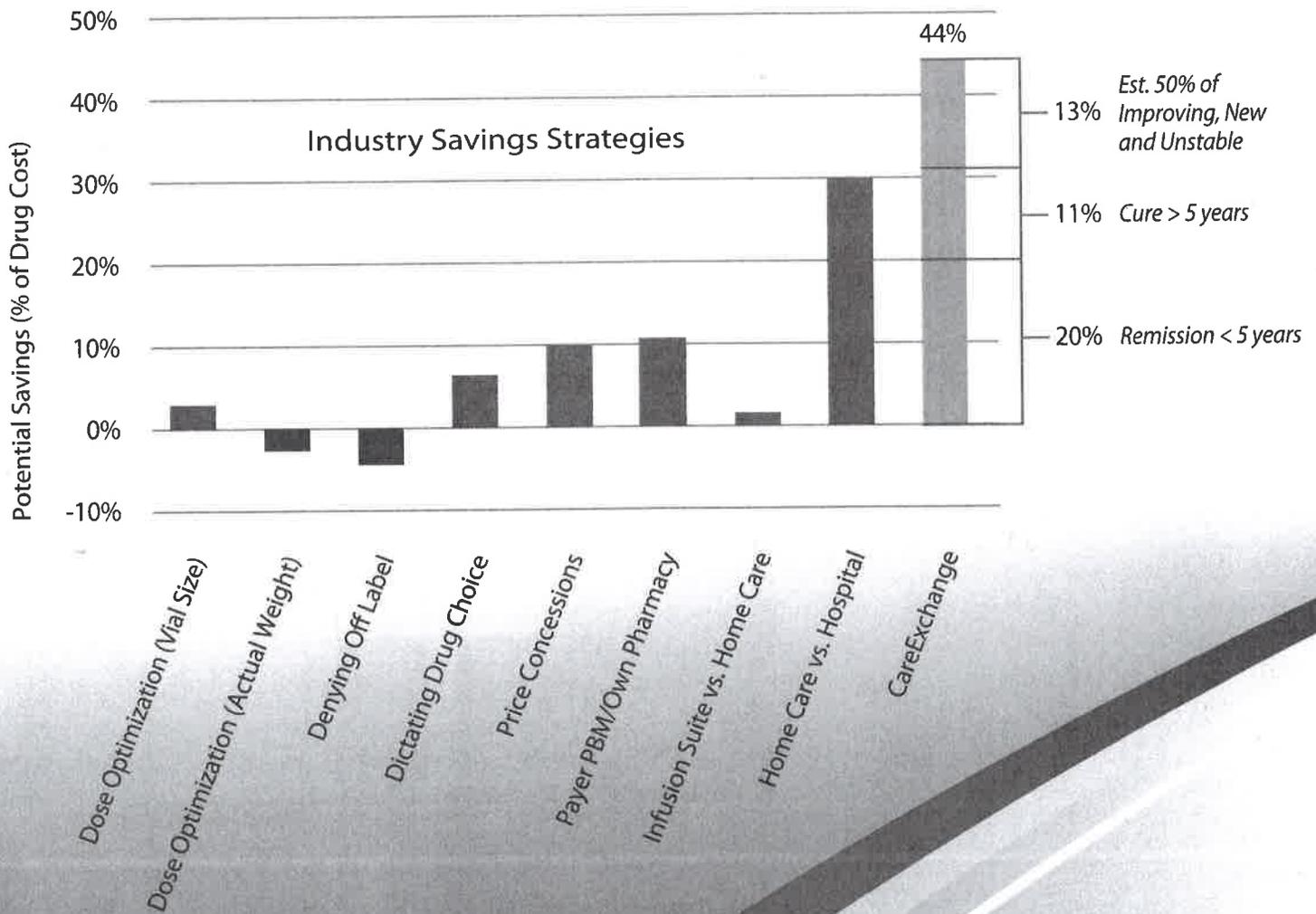
CareExchange has the inherent ability to identify patients who are not responding to IgG therapy and enhance the treatment for those who do need it.

CareExchange outcomes management technology provides the right patients, the right dose at the right frequency, for the right treatment length.

We believe a reduction in the cost of care should not have to result in a reduction in quality and service. The patient is at the heart of all we do and CareExchange was designed with the patient in mind. CareExchange is an extension of the compassionate care AxelaCare is known for.

IVIg Estimated Cost Savings* - Strategies Comparison

Potential CareExchange™ Savings



* Based on published costs and AxelaCare analysis of market prices for IgG, nursing and pharmacy services.

The features of CareExchange™ innovation include:

- Web-based, wireless connectivity for immediate data upload and access
- Simple iPad data collection tool for nurse and patient ease-of-use
- Dose vs. outcomes analysis and graphs
- Validated outcomes assessments, including:

Physical Assessments

- Timed Up and Go (TUGS), Grip Strength (Jamar)

Disability Scores

- RODS, ONLS, mFSS (Fatigue), VAS (Pain)

Quality of Life Measures

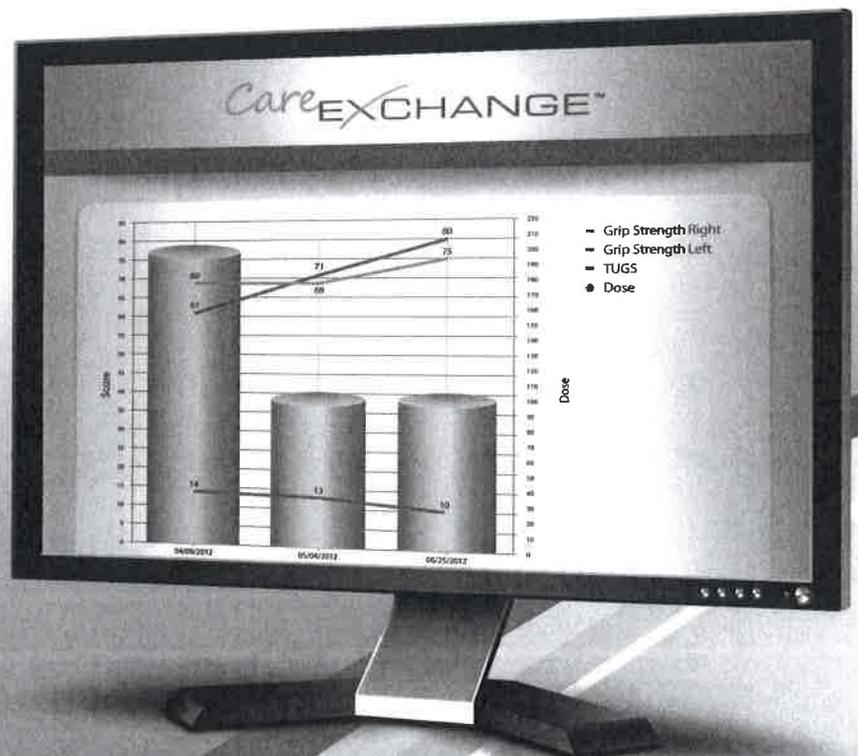
- SF-36



At-home infusion costs are typically 30% less than in-hospital treatments, as a result lowering the financial burden while providing convenience and comfort for the patient.

CareExchange makes home infusion an even more desirable treatment option, as the resulting data empowers physicians with the information needed to optimize dosing, determine the best therapy strategies, and identify natural and non-responders.

*Superior care at a lower cost.
CareExchange™ creates a win-win-win
for patients, healthcare professionals
and Managed Care companies.*



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h. What diseases are currently approved by the FDA to be treated with IVIG?

Infusion products have different FDA-approved indications. Please see the chart below for some major examples. *See Supplemental Attachment 3i (especially pages 25-26) for a summary of eight clinical indications for which IVIG has been licensed by the FDA.*

Product	Manufacturer	Indications
Gammagard Liquid	Baxter Healthcare Corporation	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency • Multifocal Motor Neuropathy
Gammagard S/D	Baxter Healthcare Corporation	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency • B-cell Chronic Lymphocytic Leukemia • Immune Thrombocytopenic Purpura • Kawasaki syndrome
Gammaplex	Bio Products Laboratory	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Bivigam	Biotest Pharmaceuticals Corporation	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency
Carimune NF	CSL Behring AG	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Privigen	CSL Behring AG	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Gamunex-C Gammaked (Distributed by: Kedrion Biopharma)	Grifols Therapeutics, Inc.	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura • Chronic Inflammatory Demyelinating Polyneuropathy
Flebogamma DIF 5% & 10%	Instituto Grifols, SA	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency
Octagam	Octapharma Pharmazeutika Produktionsges.m.b.H	<ul style="list-style-type: none"> • Primary Humoral Immunodeficiency

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i. Are there any IVIG infusion therapies that are considered investigational by the FDA or commercial insurance carriers?

The applicant is not involved with any investigational studies. The applicant fulfills physician prescription of the infusion pharmaceuticals when a referral is made. Physicians currently prescribe IG (immune globulin) for both FDA-approved uses and “off-label” indications, which is both commonplace and desirable. Please refer to the excerpt below from another publication, and see the UnitedHealth IVIG Policy document at the end of this letter, which governs AxelaCare’s use of IVIG for various complex patient conditions.

“Off-Label Indications:

The number of off-label uses for IG far exceeds that of labeled indications. Although IG has been proven useful for many disease states, the likelihood of manufacturers pursuing FDA approval for already treated indications is remote given the high cost of conducting trials without the benefit of increased marketing advantages. The sometimes tenuous and limited supply of IG, combined with the high costs of treatment, require best practice standards be used when deciding to treat with IG. Some diseases commonly treated off label with IVIG are Guillain-Barré syndrome, polymyositis, dermatomyositis, multifocal motor neuropathy, stiff person syndrome, relapsing-remitting multiple sclerosis and pemphigus.² Anecdotal reports suggest IVIG is effective in treating autoimmune neutropenia, autoimmune hemolytic anemia, Evans syndrome and acquired hemophilia, especially when other therapeutic modalities fail.³

Indications Under Current Research

Many studies are currently being conducted to look at the efficacy of IG in non-FDA-approved indications. Three specific areas that are being explored, for which IG is not used as a standard of care, include Alzheimer’s, secondary recurrent miscarriage and chronic regional pain syndrome.

Alzheimer’s. IVIG appears to have promising effects for both reducing the risk of developing Alzheimer’s, as well as improving the cognitive ability of those suffering from it. Results of a study presented at the International Alzheimer’s Symposium in 2008 showed that the risk of developing Alzheimer’s disease and related disorders (ARD) may be reduced by about 40 percent in patients previously treated with IVIG.⁴

As of early 2009, several small clinical trials have shown promising results for treating Alzheimer’s with IVIG.⁵ In March 2010, results of a Phase 2 clinical trial suggests that treatment with IVIG is associated with a reduction in ventricular enlargement rates and cognitive decline in patients with mild to moderate Alzheimer’s. In the study, uninterrupted treatment with IVIG for 18 months was associated with about half the rate of ventricular enlargement

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reflecting brain atrophy versus a placebo, along with better scores on neuropsychological testing. A pivotal Phase 3 study is now enrolling patients from 35 sites throughout the United States.⁶

Secondary recurrent miscarriage. Several clinical trials have been conducted to determine whether IVIG is an effective treatment for recurrent miscarriage. While clinical trials are still ongoing, one particular study consisted of a systematic review of randomized controlled trials, comparing all dosages of IVIG to a placebo or an active control. The study looked at eight trials involving 442 women that evaluated IVIG therapy used to treat recurrent miscarriage. The findings showed that, overall, IVIG did not significantly increase the odds ratio of live birth when compared with a placebo for treatment of recurrent miscarriage. However, there was a significant increase in live births following IVIG use in women with secondary recurrent miscarriage, while those with primary miscarriage did not experience the same benefit.⁷

Chronic regional pain syndrome (CRPS). Most recently, a small study found IVIG effective for alleviating CRPS, which causes chronic and often intractable pain, usually in the arm or leg, long after recovery from an illness. Researchers at the Pain Research Institute at the University of Liverpool in England administered a half gram of IVIG per kilogram of body weight to 13 people who had been suffering from CRPS between six and 30 months and who reported pain intensity of at least five on an 11-point scale for seven consecutive months. All had failed to achieve significant relief from other conventional treatments. After being treated with IVIG, five of the 12 subjects reported median pain scores at least two points lower, and three of the five reported pain scores at least 50 percent lower.⁸

Other diseases. There also are case reports and open label trials that show IVIG benefits some patients with rheumatoid arthritis, anti-neutrophil cytoplasmic antibody disorders, systemic sclerosis/scleroderma and Still's disease.³

j. Please clarify if this proposed project involves any pain management infusion therapies.

The proposed agency will not serve diagnosed chronic pain patients. They are not IVIG cases. Minor pain management pharmaceuticals such as Tordol (a non-steroidal anti-inflammatory (NSAID) may on occasion be administered prior to administering IVIG, if the referring physician deems it to be needed; but this would be incidental to the IVIG therapy for which the patient was referred. AxelaCare is not a pain management provider and does not administer opioids.

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4. Section B, Project Description, Item II.A

a. Please indicate the shelf life of the infusion dosages.

IG shelf live varies between manufacturers based on FDA approval; but it typically is between 24 and 36 months.

b. Does the applicant use common overnight carriers to deliver the product to patient homes?

In Tennessee, AxelaCare uses FedEx to deliver the product to patient homes.

c. Does the infusion patient sign for the delivery of the infusion dosage? If the patient is not available, what happens to the infusion dosage package?

AxelaCare requires proof of delivery by signature, either by the patient or a person designated by the patient. Some patients authorize the package to be left in the event no one is at home to sign for it; but this is strongly discouraged and rarely used.

d. How does the infusion nurse time patient visits to coincide with the infusion dose delivery?

Patients are ordered to receive the infusion at a set interval. When the nurse completes the current visit an approximate date is determined for the next infusion. Several days (4-7 days) prior to the tentative date, the pharmacy calls the patient and confirms/modifies the visit date and medication delivery date with the patient. The complete delivery should occur one to two days before the infusion. Once the delivery date is confirmed it is communicated to the nurse. The nurse verifies with the patient the day before the infusion that the delivery has occurred.

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5. Section B, Project Description, Item II.C

a. Do commercial insurance carriers reimburse for non-FDA approved indications for IVIG?

Yes they do. Each commercial carrier does so in compliance with its corporate medical policies for approval and use of IG, based on diagnosis and supporting documentation. As an example, the applicant has attached UnitedHealth's policy document at the end of this response letter.

b. Table One on page 22 is noted. However, please provide the name of the West Tennessee Counties IVIG services are provided, and the subcontractor that Homechoice Health Services and Maxim Healthcare Services, Inc. contracts with.

Table Six-B in the application lists the counties that agencies are licensed to serve in the 21-county service area. Coram is licensed for all 21 counties. HomeChoice is licensed for Fayette, Hardeman, Haywood, Lauderdale, Shelby, and Tipton Counties (6). Maxim is licensed for Fayette, Hardeman, Haywood, Madison, Shelby, and Tipton Counties (6). Page 21 of the submitted application states correctly that both these agencies serve 6 counties; but Table One on page 22 mistakenly indicated that HomeChoice serves 4 counties. Attached following this page is a revised page 22R correcting that typographical error in Table One.

Maxim subcontracts with AxelaCare, for its home infusion patients. The applicant does not currently contract with HomeChoice and has no information on what agency contracts with HomeChoice.

c. When the applicant conducted the telephone survey of home health agencies in the proposed service area, did the applicant ask how many IVIG patients were being served by the three agencies listed in the table as being IVIG providers? If so, please provide.

This was not requested. Home health providers hold this level of information to be confidential and proprietary. It is not available to the applicant. Nor is it reported in the Joint Annual Reports. Even if an agency were willing to share this information, patient numbers would vary over time and would not be meaningful if provided on a "snapshot" basis at the time of a phone survey.

Table One: AxelaCare Telephone Survey of Home Health Agencies in Project Service Area

Health Statistics ID	Agency County	Agency	Are you staffed at this time, or do you have a staffing subcontract in place, to provide IV infusion of immune globulin (IVIG) upon request?		
			NO	YES, WITH OWN STAFF	YES, WITH SUBCONTRACTED STAFF
79456	Shelby	Accredo Health Group, Inc.	X		
79146	Shelby	Amedisys Home Care	X*		
33103	Hamilton	Amedisys Home Health	X*		
57075	Madison	Amedisys Home Health Care	X		
79246	Shelby	Amedisys Home Health Care	X		
79386	Shelby	Amedisys Tennessee, LLC (D/B/A Amedisys HH)	X		
79256	Shelby	Americare Home Health Agency, Inc	X		
09065	Carroll	Baptist Memorial Home Care & Hospice	X		
79276	Shelby	Baptist Trinity Home Care	X		
79446	Shelby	Baptist Trinity Home Care - Private Pay	X		
79546	Shelby	Best Nurses, Inc.	X		
38015	Haywood	Careall Homecare Services	X		
92025	Weakley	Careall Homecare Services (University HH, LLC)	X		
79556	Shelby	Coram/CVS Specialty Infusion Service		(IN 21 WEST TN COUNTIES)	
36025	Hardin	Deaconess Homecare	X		
19494	Davidson	Elk Valley Health Services Inc	X		
57095	Madison	Extencicare Home Health of West Tennessee	X		
66035	Obion	Extencicare Home Health of Western Tennessee	X		
79206	Shelby	Family Home Health Agency	X		
79496	Shelby	Functional Independence Home Care, Inc	X		
36035	Hardin	Hardin Medical Center Home Health (HMC HH)	NR		
unassigned on 6/10	Shelby	Hemophilia Preferred Care of Memphis	x		
40075	Henry	Henry County Medical Center Home Health	X		
19544	Davidson	Home Care Solutions, Inc	X		
79486	Shelby	Home Health Care of West Tennessee, Inc	X		
79376	Shelby	Homechoice Health Services			(IN 6 WEST TN COUNTIES)
79226	Shelby	Intrepid USA Healthcare Services	X		
57165	Madison	Intrepid USA Healthcare Services (F.C. of TN)	X		
79536	Shelby	Maxim Healthcare Services, Inc.			(IN 6 WEST TN COUNTIES)
57055	Madison	Medical Center Home Health	X		
79106	Shelby	Meritan, Inc.	X		
79316	Shelby	Methodist Alliance Home Care	X		
24026	Fayette	NHC Homecare	X		
27025	Gibson	NHC Homecare	X		
79506	Shelby	No Place Like Home, Inc	X		
79136	Shelby	Quality Home Health Service	X		
23035	Dyer	Regional Home Care - Dyersburg	NR		
57085	Madison	Regional Home Care - Jackson	NR		
39035	Henderson	Regional Home Care - Lexington	NR		
79526	Shelby	Still Waters Home Health Agency	X		
03025	Benton	Tennessee Quality Homecare - Northwest	X		
20045	Decatur	Tennessee Quality Homecare - Southwest	NR		
27085	Gibson	Volunteer Home Care, Inc	X		
20055	Decatur	Volunteer Homecare of West Tennessee	X		
24036	Fayette	Where The Heart Is	X		
79236	Shelby	Willowbrook Visiting Nurse Association	X		

Notes: 1. Excludes 5 agencies that do not serve the Memphis MSA, or more than 2 rural counties in the project service area. Excludes Alere (serves only pregnant women).
 2. Asterisks denote 2 of Amedisys' 5 area agencies who were not surveyed but are assumed to not offer IVIG based on responses of 3 sister Amedisys agencies.
 3. NR indicates that agency did not respond to multiple phone requests for information.

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6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
- a. The average cost per visit by service category shall be listed.
 - b. The average cost per patient based upon the projected number of visits per patients shall be listed.

As explained in Section C.II.6.A below, AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a “gross charge” that is discounted by “contractual adjustments” to yield “net revenue”. The revenue figures shown in Section B of the Projected Data Charts are the billed or “expected” revenues, i.e., the projected receipts based on pre-negotiated reimbursement contracts before deductions for charity and bad debt.

The table below shows the average expected charge/revenue data per patient and per visit for AxelaCare’s nursing services (home office and field staff) in West Tennessee. That is what AxelaCare is applying to add to its ongoing pharmaceutical distributions in Tennessee.

Table Three: Axela Health Solutions, West Tennessee Nursing and Home Office (Excluding Pharmaceuticals)		
	Year One--CY2017	Year Two--CY2018
Expected Nursing Revenue	\$259,200	\$374,400
Visits	1,080 visits	1,560 visits
Expected Average Revenue/Visit	\$240	\$240
Patients (Cases)	45	65
Expected Average Revenue/Patient	\$5,760	\$5,760

Table Four on the second following page provides available charge and cost information filed by area home health agencies in their most recent 2015 Joint Annual Reports. The data is for skilled nursing only, which is the only home health service proposed in this application. The data do not allow a meaningful comparison to AxelaCare’s very different pricing structure.

AxelaCare pays its infusion nurses between \$37 and \$45 per hour; an average is approximately \$40 per hour. AxelaCare projects Year One (2017) average expected nursing revenues of \$240 per visit.

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C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

There are no current charges because the home nursing service is proposed, not operational. There are no current charges to be impacted or adjusted as a result of this project.

AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a “gross charge” that is discounted by “contractual adjustments” to yield “net revenue”. The revenue figures shown in Section B of the Projected Data Charts are the billed or “expected” revenues, i.e., the projected receipts based on pre-negotiated reimbursement contracts, before deductions for charity and bad debt.

The table below (repeated from a prior section of the application) shows the average expected charge/revenue data per patient and per visit for AxelaCare’s nursing services (home office and field staff) in West Tennessee. That is what AxelaCare is applying to add to its ongoing pharmaceutical distributions in Tennessee.

Table Three (Repeated): AxelaCare Healthcare Solutions, West Tennessee Nursing and Home Office (Excluding Pharmaceuticals)		
	Year One--CY2017	Year Two-CY2018
Expected Nursing Revenue	\$259,200	\$374,400
Visits	1,080 visits	1,560 visits
Expected Average Revenue/Visit	\$240	\$240
Patients (Cases)	45	65
Expected Average Revenue/Patient	\$5,760	\$5,760

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**6. Section B, Project Description, Item V (Home Health Agency)
Does the applicant propose any branch offices?**

No.

7. Section C. Need, Item 1 (Specific Criteria: Home Health Services)

It is noted the applicant addressed the Project Specific Criteria using the Guidelines for Growth, 2000 Edition. Please address the Project Specific Home Health Criteria according to the Tennessee State Health Plan 2014 Update. The update may be found at the following web-site:

http://www.tennessee.gov/assets/entities/hsda/attachments/FINAL_2014_SHP_Home_Health_Services_Criteria.pdf

Please see the attachment at the end of this supplemental response letter.

8. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

Please indicate the physician referred projected number of cases by service category to be provided in the initial year of operation.

This is unavailable to the applicant. Physicians who have written letters of support for this project are not willing to project their potential IVIG referrals to AxelaCare, or the number of such patients they refer to other agencies or infusion sites. All patients served by AxelaCare will be solely for IVIG care. As you can see from UnitedHealth's clinically complex IG Policy document attached to this letter, it is not feasible to estimate cases by service category beyond the single category of IVIG.

9. Section C. Need, Item 1 (Specific Criteria: Home Health)- Item 6a & 6b

Your response in Table Three is noted. However, the expected Average Revenue/Patient of \$5,750 in Year Two (2018) appears to be incorrect. Please revise.

This was a typographical error. The correct amount is \$5,760, the same as stated in Year One of that Table Three. Attached following this page are revised pages 32R and 56R, both of which include Table Three.

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10. Section C, Need, Item 6

The methodology of projecting the number of patients in Year One is unclear in the application. Please provide a brief simplified overview of the calculations, assumptions, referrals, etc. to project 45 patients in Year One.

Axelacare reviewed their Tennessee referrals and identified 127 referred IVIG patients Statewide. It was assumed that at least this level of referrals will continue, in an area of care with steeply increasing demand nationwide.* One-third of that number (43 patients) were projected to be coming from West Tennessee if this proposal is approved; and that was simply rounded up to 45 patients to allow for annual increases in demand. For the second year, a growth to 65 patients was assumed because where local marketing and community linkages are in place, AxelaCare typically sees a minimum of 5 to 6 new referrals per month.

**For example, the attached HHS report to Congress identifies (p. 7) a 55% increase in PIDD incidence -- a condition treated with IVIG -- with their Medicare enrollees over just a five-year period.)*

11. Section C. Economic Feasibility Item 1 (Project Cost Chart)

a. Your response is noted. However, please clarify if laptops, electronic record system, office equipment, portable electronic equipment, etc. has been accounted for in the Project Costs Chart.

The laptops are leased to AxelaCare and are shown in the Projected Data Chart's other expenses as a rental item. Office equipment and furnishings are provided in the Executive Suite lease arrangement. There is no other portable electronic equipment other than the I-pads.

b. Please clarify where \$1,938.00 standard service fee retainer in the lease is accounted in the Project Costs Chart.

This retainer is two months' rent in advance. The lease agreement is year to year, so the Project Cost Chart was based on 12 months' rent at \$969 per month. If the applicant moves to another Shelby County location (which requires no CON approval for a headquarters office) after one year, that retainer of two months' rent in advance is offset by no need to pay the last two months' rent. So the applicant requests that the Project Cost Chart not have to be revised to add \$1,938 to Section B's lease outlay line.

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12. Section C. Economic Feasibility Item 2 (Funding) and Item 10

a. It is noted the proposed project will be funded by the applicant's parent company. However, the financial balance sheets of UnitedHealth Group ending December 31, 2015 reflects total current assets of \$21,639,000,000 and current liabilities of \$42,898,000,000, and a current ratio of .50 to 1. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities. Please clarify if the applicant has the cash available to fund the proposed project. If so, please document.

Yes, as a Fortune 6 company with annual revenues that are projected to be in excess of \$182 billion in 2016, AxelaCare's corporate parent -- United Health Group -- clearly has sufficient cash to cover the small, approximately \$60,000 implementation costs associated with this application. Indeed, in the first quarter of 2016 alone, UHG and its corporate affiliates generated \$3 billion in earnings from operations. For more information on UHG's financial wherewithal, please see the UHG earnings report attached at the end of this application.

b. The funding letter from AxelaCare Holding Inc. is noted. However, please clarify if the proposed project will be funded through a cash transfer through UnitedHealth Group Inc. or AxelaCare Holdings, Inc. If the proposed project will be funded through AxelaCare Holdings, Inc. please provide copies of the balance sheet and income statement from the most recent reporting period.

I think that the confusion is caused by the use of the term "parent company" in Mr. Collins' funding letter. AxelaCare Holdings, Inc. is the applicant's *immediate* parent company, but UnitedHealth Group Inc. is the applicant's *ultimate* parent company. The project funding will come from the ultimate parent company to the applicant *through* the immediate parent entity. Mr. Collins was authorized to affirm that. UnitedHealth Group's financial statements were provided in the application so it should not be necessary to submit additional financial statements for AxelaCare Holdings, Inc.

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13. Section C. Economic Feasibility Item 4. (Historical Data Chart and Projected Data Chart)

a. Please clarify where the \$99.00 monthly telecom/internet services as listed in the lease is accounted for in the Projected Data Chart for AxelaCare West Tennessee Nursing and Home office only.

Those are options in the lease. AxelaCare will not need the connectivity but is budgeting for phone service at \$75 per month (based on company experience), as shown in the itemization of Other Expenses following the three Projected Data Charts.

b. The provision for charity care is noted at \$5,184 in Year One in the Projected Data Chart for AxelaCare West Tennessee Nursing and Home office only. This is less than the average gross patient charge of \$5,760. Please clarify why the applicant will not at a minimum cover the average charge for one charity patient.

The charity care has been budgeted at the company average of 2% of gross revenues, which far exceeds the average of most home health agencies. This is a substantial commitment for a proposed nursing service that will operate at a loss. Please note that the 2015 JAR's of all three other agencies that provide home infusion care report zero ("0") charity care.

In addition, consider that the average charge of \$5,760 will be the aggregation of many cases, some higher and some lower in gross charges. In practice, the charity care will cover charges for one or more of the lower-cost infusion cases.

c. The financial Assistance Program protocol in the attachment is noted. Please clarify if all charity care associated with this project must apply through the applicant's Financial Assistance Program.

Yes.

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d. Please clarify if charity care entails only the waiver of co-insurance and/or deductible amounts.

No. A patient with drug coverage but not nursing coverage is eligible for discounts on nursing coverage as well as copays and deductibles.

e. Please clarify where the cost of automobiles, cell phones, and mileage are accounted for in the Projected Data Chart for Axelacare West Tennessee Nursing and Home office only.

Automobiles and cell phones are not provided by the applicant. Nurses use their own vehicles and are reimbursed for mileage. The latter was erroneously omitted from the "other costs" of the project; an estimate for that expense has been included in the revised Projected Data Charts and Other Expenses tables submitted in response to question 13f below.

f. The tables for "D9-Other Expenses" on page 54 are noted. However, the categories do not match the categories as listed in the three submitted Projected Data Charts. Please revise.

The categories you reference on the three Projected Data Charts are in fine print below the line D9. They are typographical errors, artifacts from a prior form, and should have been deleted before submittal. Attached after this page are revised pages 51R-53R, with those words removed from the three Charts, and revised page 54 with titles more closely matching the titles on the three Charts.

g. The Projected Data Chart-"Axelacare West Tennessee Pharmaceuticals Only" is noted. However, please clarify what the 10% in Year One and Year Two represents under F. Capital Expenditures.

That is also an artifact from a prior template that should not appear on the Chart. Revised page 53R submitted following this page corrects that typographical error.

h. The provision for charity care of \$91,584 in Year One in the Projected Data Chart for Axelacare West Tennessee Consolidated is noted. However, this is less than the average gross patient charge of \$101,760. Please clarify why the applicant will not at a minimum cover the average charge for one charity patient.

PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE
NURSING AND HOME OFFICE ONLY--PHARMACEUTICALS EXCLUDED

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Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2017	CY 2018
	PATIENTS	<u>45</u>	<u>65</u>
	VISITS	<u>1,080</u>	<u>1,560</u>
A.	Utilization Data		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u> </u>	\$ <u> </u>
2.	Outpatient Services-home health nursing visits	<u>259,200</u>	<u>374,400</u>
3.	Emergency Services	<u> </u>	<u> </u>
4.	Other Operating Revenue (Specify) <u>See notes page</u>	<u> </u>	<u> </u>
	Gross Operating Revenue	\$ <u>259,200</u>	\$ <u>374,400</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u> </u>	\$ <u> </u>
2.	Provision for Charity Care	<u>5,184</u>	<u>7,488</u>
3.	Provisions for Bad Debt	<u>2,592</u>	<u>3,744</u>
	Total Deductions	\$ <u>7,776</u>	\$ <u>11,232</u>
	NET OPERATING REVENUE	\$ <u>251,424</u>	\$ <u>363,168</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>369,840</u>	\$ <u>483,605</u>
2.	Physicians Salaries and Wages	<u> </u>	<u> </u>
3.	Supplies	<u>12,571</u>	<u>18,158</u>
4.	Taxes	<u> </u>	<u> </u>
5.	Depreciation	<u> </u>	<u> </u>
6.	Rent	<u>11,628</u>	<u>12,209</u>
7.	Interest, other than Capital	<u> </u>	<u> </u>
8.	Management Fees	<u> </u>	<u> </u>
	a. Fees to Affiliates	<u> </u>	<u> </u>
	b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9.	Other Expenses (Specify) <u>See notes page</u>	<u>7,798</u>	<u>10,873</u>
	Total Operating Expenses	\$ <u>401,837</u>	\$ <u>524,845</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u> </u>	\$ <u> </u>
	NET OPERATING INCOME (LOSS)	\$ <u>(150,413)</u>	\$ <u>(161,677)</u>
F.	Capital Expenditures		
1.	Retirement of Principal	\$ <u> </u>	\$ <u> </u>
2.	Interest	<u> </u>	<u> </u>
	Total Capital Expenditures	\$ <u>0</u>	\$ <u>0</u>
	NET OPERATING INCOME (LOSS)	\$ <u>(150,413)</u>	\$ <u>(161,677)</u>
	LESS CAPITAL EXPENDITURES	\$ <u>(150,413)</u>	\$ <u>(161,677)</u>

SUPPLEMENTAL #1**June 23, 2016****12:14 pm****PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE
PHARMACEUTICALS ONLY (FROM REGIONAL PHARMACY IN LENEXA, KANSAS)**

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2017	CY 2018
	PATIENTS	<u>45</u>	<u>65</u>
A.	Utilization Data	<u>1,080</u>	<u>1,560</u>
	VISITS		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u> </u>	\$ <u> </u>
2.	Outpatient Services	<u>4,320,000</u>	<u>6,240,000</u>
3.	Emergency Services	<u> </u>	<u> </u>
4.	Other Operating Revenue (Specify) <u>See notes page</u>	<u> </u>	<u> </u>
	Gross Operating Revenue	\$ <u>4,320,000</u>	\$ <u>6,240,000</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u> </u>	\$ <u> </u>
2.	Provision for Charity Care	<u>86,400</u>	<u>124,800</u>
3.	Provisions for Bad Debt	<u>43,200</u>	<u>62,400</u>
	Total Deductions	\$ <u>129,600</u>	\$ <u>187,200</u>
	NET OPERATING REVENUE	\$ <u>4,190,400</u>	\$ <u>6,052,800</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>333,500</u>	\$ <u>390,885</u>
2.	Physicians Salaries and Wages	<u>0</u>	<u>0</u>
3.	Supplies	<u>2,514,240</u>	<u>3,631,680</u>
4.	Taxes	<u>400,000</u>	<u>600,000</u>
5.	Depreciation	<u>3,333</u>	<u>7,500</u>
6.	Rent	<u>36,000</u>	<u>36,000</u>
7.	Interest, other than Capital	<u> </u>	<u> </u>
8.	Management Fees	<u> </u>	<u> </u>
	a. Fees to Affiliates	<u> </u>	<u> </u>
	b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9.	Other Expenses (Specify) <u>See notes page</u>	<u>33,600</u>	<u>48,000</u>
	Total Operating Expenses	\$ <u>3,320,673</u>	\$ <u>4,714,065</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u> </u>	\$ <u> </u>
	NET OPERATING INCOME (LOSS)	\$ <u>869,727</u>	\$ <u>1,338,735</u>
F.	Capital Expenditures		
1.	Equipment	\$ <u>200,000</u>	\$ <u>250,000</u>
2.	Interest	<u> </u>	<u> </u>
	Total Capital Expenditures	\$ <u>200,000</u>	\$ <u>250,000</u>
	NET OPERATING INCOME (LOSS)		
	LESS CAPITAL EXPENDITURES	\$ <u>669,727</u>	\$ <u>1,088,735</u>

CONSOLIDATED OPERATIONS: NURSING, HOME OFFICE, & PHARMACEUTICALS

Give information for the two (2) years following the completion of this proposal. **12:14 pm**

The fiscal year begins in January.

	CY 2017	CY 2018
PATIENTS	<u>45</u>	<u>65</u>
VISITS	<u>1,080</u>	<u>1,560</u>
A. Utilization Data		
B. Revenue from Services to Patients		
1. Inpatient Services	\$ <u> </u>	\$ <u> </u>
2. Outpatient Services-home health nursing visits	<u>4,579,200</u>	<u>6,614,400</u>
3. Emergency Services	<u> 0</u>	<u> 0</u>
4. Other Operating Revenue (Specify) <u>See notes page</u>	<u> 0</u>	<u> 0</u>
Gross Operating Revenue	<u>\$ 4,579,200</u>	<u>\$ 6,614,400</u>
C. Deductions for Operating Revenue		
1. Contractual Adjustments	\$ <u> 0</u>	\$ <u> 0</u>
2. Provision for Charity Care	<u>91,584</u>	<u>132,288</u>
3. Provisions for Bad Debt	<u>45,792</u>	<u>66,144</u>
Total Deductions	<u>\$ 137,376</u>	<u>\$ 198,432</u>
NET OPERATING REVENUE	<u>\$ 4,441,824</u>	<u>\$ 6,415,968</u>
D. Operating Expenses		
1. Salaries and Wages	\$ <u>703,340</u>	\$ <u>874,490</u>
2. Physicians Salaries and Wages	<u> 0</u>	<u> 0</u>
3. Supplies	<u>2,526,811</u>	<u>3,649,838</u>
4. Taxes	<u>400,000</u>	<u>600,000</u>
5. Depreciation	<u>3,333</u>	<u>7,500</u>
6. Rent	<u>47,628</u>	<u>48,209</u>
7. Interest, other than Capital	<u> 0</u>	<u> 0</u>
8. Management Fees		
a. Fees to Affiliates	<u> 0</u>	<u> 0</u>
b. Fees to Non-Affiliates	<u> 0</u>	<u> 0</u>
9. Other Expenses (Specify) <u>See notes page</u>	<u>41,398</u>	<u>58,783</u>
Total Operating Expenses	<u>\$ 3,722,511</u>	<u>\$ 5,238,820</u>
E. Other Revenue (Expenses) -- Net (Specify)	<u>\$ 0</u>	<u>\$ 0</u>
NET OPERATING INCOME (LOSS)	<u>\$ 719,313</u>	<u>\$ 1,177,148</u>
F. Capital Expenditures		
1. Equipment	\$ <u>200,000</u>	\$ <u>250,000</u>
2. Interest	<u> 0</u>	<u> 0</u>
Total Capital Expenditures	<u>\$ 200,000</u>	<u>\$ 250,000</u>
NET OPERATING INCOME (LOSS)		
LESS CAPITAL EXPENDITURES	<u>\$ 519,313</u>	<u>\$ 927,148</u>

D9--OTHER EXPENSESNURSING AND HOME OFFICE CHART

	2017	2018
Postage	300	300
RN mileage	5638	8143
office phone	900	900
i-pad use fee	960	1440
	7798	10783

PHARMACEUTICALS/SERVICES CHART

	2017	2018
Postage	300	300
office phone	900	900
Pharma/Shipping	32400	46800
	33600	48000

CONSOLIDATED OPERATIONS CHART

	2017	2018
Postage	600	600
RN mileage	5638	8143
office phone	1800	1800
iPad Use Fee	960	1440
Pharma/Shipping	32400	46800
	41398	58783

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That charity care has been budgeted at the company average of 2% of gross revenues, which far exceeds the average of most home health agencies. This is a substantial commitment by agency standards. Please note that the 2015 JAR's of all three other agencies that provide home infusion care report zero ("0") charity care.

In addition, the average charge will be the aggregation of many cases, some higher and some lower in gross charges. In practice, the charity care will cover charges for one or more of the lower-cost infusion cases.

14. Section C, Economic Feasibility, Item 5

Table Eleven-A on page 55 is noted. However, the average net operating income after expenses per patients of -\$3,217 and average net operating income after expenses, per visits of -\$134.00 appears to be incorrect. Please revise.

Revised page 55R is attached following this page, with corrected and updated data.

15. Section C, Economic Feasibility, Item 6. A

Table Three on page 56 is noted. However, the expected Average Revenue/Patient of \$5,750 appears to be incorrect. Please revise.

Please see the response to your question #9 above, and the revised page attached in response to that question.

16. Section C, Contribution to Orderly Development, Item 3

Please clarify if an RN/patient ratio of 2.5 RNs to 45 patients in Year One is adequate for a 21 County service area covering a geographical area of all of West Tennessee.

Such an RN/patient ratio is adequate. The projection of patients amounts to approximately 4 patients per month. With nurses based in Memphis and Jackson, this is a very reasonable expectation for nurse drive times, and the projected staffing is sufficient to serve those patients.

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Eleven-A: Average Charges, Deductions, Net Charges, Net Operating Income West Tennessee Nursing Operations Only		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$5,760	\$5,760
Average Expected Revenue Per Visit	\$240	\$240
Average Deduction from Operating Revenue per Patient	\$173	\$173
Average Deduction from Operating Revenue per Visit	\$7	\$7
Average Net Charge (Net Operating Revenue) Per Patient	\$5,587	\$5,587
Average Net Charge (Net Operating Revenue) Per Visit	\$233	\$233
Average Net Operating Income after Expenses, Per Patient	-\$3,343	-\$2,487
Average Net Operating Income after Expenses, Per Visit	-\$139	-\$104

Table Eleven-B: Average Charges, Deductions, Net Charges, Net Operating Income Combined W. TN Nursing and Out of State Pharmaceutical Operations		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$101,760	\$101,760
Average Expected Revenue Per Visit	\$4,240	\$4,240
Average Deduction from Operating Revenue per Patient	\$3,053	\$3,053
Average Deduction from Operating Revenue per Visit	\$127	\$127
Average Net Charge (Net Operating Revenue) Per Patient	\$98,707	\$98,707
Average Net Charge (Net Operating Revenue) Per Visit	\$4,113	\$4,113
Average Net Operating Income after Expenses, Per Patient	\$15,985	\$18,110
Average Net Operating Income after Expenses, Per Visit	\$666	\$755

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17. Section C, Contribution to Orderly Development, Item 7d

a. If possible, please provide the latest copy of the Axelacare's Specialty Pharmacy Program Inc.'s licensure survey and approved plans of correction.

Copies of the license and inspection survey are attached after this page.

b. The applicant is accredited by The Joint Commission. If approved, will this accreditation also include home health services?

Yes; once the applicant is licensed, the Joint Commission will be notified, and Tennessee will be added as an accredited site under the existing accreditation.

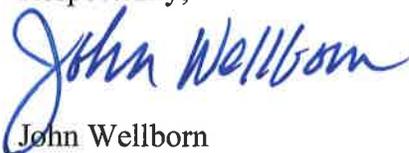
18. Proof of Publication

Please provide copies of the publication of intent of the required 4 newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 21 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication have not all been received from the newspapers. They will be submitted under separate cover.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email me at jwdsg@comcast.net or telephone me at 615-665-2022, so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

SUPPLEMENTAL ATTACHMENTS

<u>Question</u>	<u>Attachment</u>
2e.	HHS Report to Congress on IVIG Demonstration Project
3c.	Side Effects of Intravenous Immune Globulin
3i.	UnitedHealth IVIG Policy Document
7.	Response to State Health Plan's Current CON Criteria for Home Health Agencies
12.	UnitedHealth Group Earnings Report, Q1 2016
17.	AxelaCare Health Solutions -- Licensure Information

**2e. HHS Report to Congress on IVIG Demonstration
Project**

Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration Project:
Interim Report to Congress

U.S. Department of Health and Human Services

Introduction

Section 101 of H.R. 1845 Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Medicare IVIG Access Act), Public Law 112-242, mandates the establishment, implementation, and evaluation of a three-year Medicare Patient Intravenous Immunoglobulin (IVIG) Access Demonstration Project under Part B of title XVIII of the Social Security Act. The demonstration project will voluntarily enroll up to 4,000 Medicare beneficiaries who have been diagnosed with Primary Immunodeficiency Diseases. Under the demonstration, Medicare will provide to suppliers of IVIG a bundled payment under Part B for items and services necessary to administer IVIG in-home to enrolled beneficiaries who are not otherwise homebound or receiving home health care benefits.

The Act also requires a report to Congress that provides interim evaluation findings on the impact of the demonstration project on Medicare beneficiaries' access to items and services needed for the in-home administration of IVIG. This interim report fulfills the statutory requirement.

Background

Primary Immunodeficiency Diseases (PIDD) are a group of conditions that are triggered by genetic defects which cause a lack of and/or impairment of antibody function, resulting in the body's immune system not being able to function effectively. Immunoglobulin (IG) therapy is used to temporarily replace some of the antibodies (immunoglobulins) that are missing or not working properly in people with PIDD, and it is the treatment of choice for Medicare beneficiaries with this diagnosis. The goal of IG therapy is to use IG obtained from normal donor plasma to keep enough antibodies in the blood of patients with PIDD to fight off bacteria and viruses. There are two forms of IG therapy: intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG).

In 2006, the U.S. Food and Drug Administration (FDA) approved an SCIG product for the treatment of patients with PIDD. Patients may self-administer this product at home using an infusion pump. Traditional fee-for-service (FFS) Medicare covers the SCIG product and the infusion pump needed at home under the Medicare durable medical equipment (DME) benefit. Section 642 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, amended section 1861 of the Social Security Act, to require Medicare Part B coverage of IVIG for the treatment of PIDD in the home. The statute only covers IVIG and did not cover any of the items and services needed to administer the drug. The specific items and services are the supplies and in-home nursing services necessary to inject the drug intravenously. These items and services for administering the drug may be covered if the person is homebound or otherwise receiving services under a Medicare home health episode of care. As a result, many beneficiaries receive IVIG at their doctor's office or in an outpatient hospital setting, or they elect to receive the IG therapy subcutaneously because the items needed to administer SCIG in-home are covered by Medicare.

Under the Medicare Patient IVIG Access Demonstration, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option that is most appropriate for the

beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration.

Implementation of the Medicare Patient IVIG Demonstration Project

The Centers for Medicare & Medicaid Services (CMS) developed, as required by the Medicare IVIG Access Act, a bundled per-visit amount to be paid to any Medicare supplier that is able to provide the IVIG drug and the professional services needed for administration. The supplier is also able to provide the professional services either using their own staff or through a separate contract. All staff administering the drug must meet their licensure requirements.

Eligible suppliers who submit claims for the drug and administration of the drug on a single claim form to a Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) will receive the bundled payment for the supplies and services to administer the drug in addition to the payment for the drug which is currently covered under the Medicare benefit. Home health agencies are not eligible to be paid under the demonstration for the administration of the IVIG although they may contract with suppliers in their area to provide professional services. In such situations, the supplier would receive the demonstration payment and reimburse the home health agency directly in accordance with their contract.

Per the Act, the bundled payment amount for items and services needed for the in-home administration of intravenous immunoglobulin was based on the national per visit low-utilization payment (LUPA) amount under the prospective payment system for home health services established under section 1895 of the Social Security Act. The demonstration bundled payment that covers medically necessary items and services needed for the in-home administration of IVIG is based on the LUPA rate used in the Medicare Home Health Prospective Payment System. The LUPA rate is made for beneficiaries who require four or fewer visits during a 60-day home health episode.

A home health episode with four or fewer visits is paid the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage-adjusted per visit amount for each of the visits rendered instead of the full episode amount. The national per visit amounts by discipline (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services) are updated and published annually by the applicable market basket for each visit type.

Per the Act, the bundled payment amount for items and services needed for the in-home administration of IVIG includes infusion services provided by a skilled nurse. Therefore, the bundled payment is based on the LUPA for skilled nursing only because the services of the other LUPA disciplines are not required for this demonstration. A total per-visit bundled payment of \$300 in 2014 was initially calculated. This payment rate is based on the full skilled nursing LUPA for the first 90 minutes of the infusion (\$120) and 50% of the LUPA for each hour thereafter for an average 4.5 hour infusion $[(100\% \times \$120) + (50\% \times 3 \text{ hours} \times \$120)]$. The payment rate is to be revised and updated annually based on the LUPA rate. The payment rate is also subject to

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sequestration. In 2015, the bundled payment rate was \$319.23. This service is subject to coinsurance and deductibles similar to other Part B services provided in the doctor's office.

Prior to finalizing the design of the demonstration, CMS reached out to relevant stakeholders, including beneficiary advocacy groups, suppliers, and professional societies among others. In addition to in-person meetings, CMS hosted several Open Door conference calls and webinars to increase awareness of, and obtain input on, the demonstration project.

CMS contracted with NHIC, Corp., one of the Medicare Administrative Contractors, to perform the demonstration implementation activities. Tasks included outreach and education, enrollment application processing, handling the demonstration hotline, resolving denied demonstration claims, and reporting. Demonstration claims are payable if the demonstration code (Q2052) is billed with the drug (J code) on the same claim. There are also requirements related to dates for each of the line items on the claim. When claims are not submitted in accordance with the specified requirements, claims may be denied. NHIC Corp. reviews all denied claims and if needed, works with the supplier to resolve any problems. Claims that are denied due to submission errors may be resubmitted. NHIC engaged in targeted outreach to physicians who treat PIDD beneficiaries, beneficiary advocacy groups and IG suppliers. NHIC conducted public dissemination activities to increase awareness and facilitate demonstration enrollment.

To be eligible to enroll in the demonstration project, traditional Medicare must be the beneficiaries' primary insurance, thereby excluding beneficiaries (e.g. some working aged beneficiaries) for whom alternative insurance is the primary payer. Beneficiaries must also: a) have current coverage under the Medicare fee-for-service program; b) have coverage under Medicare Part B; c) have a diagnosis of PIDD; d) submit a completed application with physician approval; and e) not be currently receiving Medicare home health services. For the purposes of the demonstration, the following Medicare covered PIDD diagnoses were included: common variable immunodeficiency, selective immunoglobulin M (IgM) deficiency, Wiskott-Aldrich syndrome, congenital hypogammaglobulemia, and immunodeficiency with increased IgM.

NHIC conducted an analysis of Medicare claims to identify all Medicare fee-for-service beneficiaries with a PIDD diagnosis who had been treated with IVIG across the country. Based on this analysis, information about the demonstration and application letters were mailed out to 9,216 potentially eligible beneficiaries with PIDD who had claims for IG treatment in August, 2014 and, again, in January 2015. Letters were also sent to professional societies and providers treating beneficiaries for PIDD.

The Medicare Patient IVIG Demonstration Project was announced via twitter and on the CMS website. CMS sent out the following tweet on August 5, 2014 announcing the demonstration 'Interested in #IVIG? Announced #Medicare Intravenous Immune Globulin Demonstration 8/5, info: <http://go.cms.gov/1s838K2> #careinnovation'. CMS also posted information about the demonstration on the CMS website at <https://innovation.cms.gov/initiatives/IVIG/>.

The beneficiary application mailings began August 8, 2014 with an initial September 15, 2014 deadline. Bundled payment for approved beneficiary IVIG services started on October 1, 2014. Beneficiary applications are now accepted on a rolling basis as long as space is available.

In October 2014, 352 beneficiaries had enrolled in the program. Due to the low initial enrollment in the demonstration project, targeted outreach was done in order to increase enrollment. In January 2015, NHIC mailed out a second letter and application to beneficiaries who had not applied to inform them that there were still openings in the demonstration. This targeted mailing resulted in an increase in the number of inquiries to the designated demonstration hotline number and an increase in enrollment. By August 1, 2015, the demonstration project enrollment had increased to 872 beneficiaries.

As of August 1, 2015, 9.5 percent (n=872) of the 9,216 eligible Medicare beneficiaries had submitted completed application forms and were enrolled in the demonstration project. Monthly growth has averaged around 44 new enrollees per month (range 30-84) reflecting a mix of those new to the Medicare program, beneficiaries newly diagnosed with PIDD, and those just learning about the demonstration or only now interested in possibly switching to in-home administration of the IVIG drug. Among those enrolled, about fifty percent (449 beneficiaries) have used the demonstration benefit based on the claims submitted and paid under the demonstration through August 7, 2015. Additionally, 235 suppliers have submitted demonstration claims.

Evaluation of the Medicare Patient IVIG Demonstration Project

The Medicare IVIG Access Act requires an interim and a final evaluation report due no later than one year after the demonstration project ends, to be submitted to Congress. The interim report is to contain an evaluation of the impact of the demonstration on access for Medicare beneficiaries to items and services needed for the in-home administration of IVIG. The final report will contain a final evaluation of the impact on access to IVIG items and services, as well as an analysis of the appropriateness of implementing a new methodology for payment for IVIG in all care settings, and an update to the 2007 report by the Assistant Secretary for Planning and Evaluation (ASPE) of the Department of Health and Human Services (HHS), entitled *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immunoglobulin Intravenous*.

CMS awarded a contract to Dobson, DaVanzo & Associates, LLC, to conduct the evaluation activities. The assessment of the impact on access to IVIG items and services, as well as the analysis of the appropriateness of implementing a new payment methodology, will include both a qualitative (beneficiary surveys and provider interviews) and a quantitative (Medicare claims) analytic approach. The update of the ASPE report will also include both qualitative and quantitative research activities. These analyses will be described in the final report.

Because the demonstration has operated for less than a year, there is insufficient demonstration claims experience available to date for analysis, thus, analytic findings concerning the demonstration's impact on Medicare beneficiary access to items and services needed for the in-home administration of IVIG are not included in the interim report. However, this report provides information on the implementation experience to date and a descriptive analysis of Medicare claims information for the demonstration baseline in 2014. Medicare Part A and B claims for beneficiaries with a PIDD diagnosis (consistent with the ICD-9 codes eligible for demonstration enrollment) and the receipt of IVIG (drug code and infusion administration) on the same day for the year 2014 were used for the baseline analysis. The demonstration claims for the

three months (October-December, 2014) showed low demonstration enrollment, and with the claims lag time provided insufficient information to draw preliminary conclusions.

The implementation experience findings were based on the review and analysis of NHIC's reports and hotline logs. Beneficiary surveys and supplier interviews were not included in this interim RTC. The evaluation plan does include conducting and reporting findings from beneficiary surveys (targeting both beneficiaries who are enrolled in the demonstration and those who are not enrolled), suppliers, and other stakeholders in the final RTC. These activities are expected to be initiated in 2016.

The purpose of the baseline analysis is to describe the demographics and patterns of IVIG utilization among beneficiaries with PIDD prior to the demonstration project.

Key findings related to implementation experience indicate that:

- Enrollment in the demonstration is lower than anticipated with 872 enrolled as of August 01, 2015;
- Claims submitted for demonstration services by enrolled participants (n=449) are lower than anticipated as of August 01, 2015;
- Some beneficiaries appear to be enrolling in the demonstration just to reserve spots "in case" they want it—concerned about potential future limits;
- It has not been difficult to find suppliers nationwide; and
- Some beneficiaries are confused about the demonstration benefit offered.

Key findings from the baseline analyses illustrated in Tables 1 and 2 below include:

- There was approximately a 60 percent growth rate in Medicare beneficiaries with PIDD receiving IVIG treatment over the past 5 years;
- The average age of Medicare beneficiaries with PIDD who received IVIG was 68 years old in the year 2014, with over half (59 percent) aged 65 to 79 years;
- Twenty-five percent of the Medicare beneficiaries with PIDD in the year 2014 were beneficiaries younger than 65 years old;
- In 2014, the majority of the PIDD population who received IVIG was white (95 percent) and female (68 percent); and
- In 2014, most of the Medicare beneficiaries with PIDD who were treated with IVIG received their IG treatment in an outpatient facility setting including hospitals, outpatient departments, and infusion suites (66 percent). The rest received IVIG services in a doctor's office.

Table 1. Medicare PIDD growth from 2010 through 2014

Year	2010	2011	2012	2013	2014
Medicare beneficiaries with PIDD	15,473	17,579	20,097	22,755	23,970
Medicare beneficiaries with PIDD receiving IVIG treatment	5,723	6,468	7,496	8,483	9,150

Table 2. Demographics in baseline year 2014.

Variables	Medicare beneficiaries with PIDD on IVIG in 2014	
	Beneficiaries	Percent
Age		
<65	2,303	25%
65-69	2,046	22%
70-74	2,010	22%
75-79	1,361	15%
80-84	815	9%
85+	615	7%
Total	9,150	100%
Gender		
Male	2,953	32%
Female	6,197	68%
Total	9,150	100%
Race		
Unknown	104	1%
White	8,684	95%
Black	164	2%
Other	92	1%
Asian	31	0%
Hispanic	53	1%
North American Native	22	0%
Total	9,150	100%
Original reason for Medicare Entitlement - Disability benefit		
Age less than 65 years	2,262	24.7%
Age 65 and older	1,329	14.5%
Total	3,591	39.2%

Overall, the baseline data show that the Medicare beneficiaries with PIDD on IVIG are more likely to be younger (66% younger than 74 years of age), female (68%), white (95%) and non-disabled (75%).

Limitations of the Evaluation

This interim report has several limitations. The low initial enrollment of beneficiaries into the demonstration project makes it difficult to present any findings at this time. Additionally, Medicare claims data for the time period covered in the report (the first ten months of the demonstration) are not yet available due to the lag in obtaining claims data, so an analysis based on demonstration Medicare claims could not be included.

Conclusion

In summary, the demonstration enrollment is voluntary. Presently, beneficiaries have the option to receive the IVIG drug and services in an outpatient setting, a physician's office, an infusion center, or an in-home setting. Given the limited 10-month demonstration experience and low enrollment uptake to date, the interim report does not include an assessment of the impact of the demonstration on beneficiaries' access to items and services needed for the in-home administration of IVIG. The evaluation plan does include conducting and reporting findings from beneficiary surveys (targeting both beneficiaries who are enrolled in the demonstration and those who are not enrolled).

Future recommendations on beneficiaries' access to items and services for in home administration of IVIG will be provided in the final evaluation report. In the meantime, CMS will continue its outreach efforts to beneficiaries and suppliers about the demonstration. This will include targeted outreach focused on non-enrolled beneficiaries eligible for the demonstration via mailings (i.e., a personal letter informing them about the demonstration on an annual basis). The final report to Congress will provide findings based on the full three years of the demonstration project.

3c. Side Effects of Intravenous Immune Globulin

Side-effects of intravenous immune globulins

C. DUHEM, M. A. DICATO & F. RIES *Centre Hospitalier de Luxembourg, Luxembourg*

SUMMARY

Intravenous immune globulin (IVIG) preparations are efficacious and safe products in use worldwide. Although rare, side-effects of IVIG may be serious, even life-threatening, and clinicians should be aware of their potential occurrence. This article summarizes most of the adverse experiences with IVIG reported in the literature since its introduction into clinical practice almost 15 years ago.

Keywords IVIG side-effects management prevention

INTRODUCTION

The clinical benefit of immune globulin prophylaxis in patients with primary antibody deficiency syndromes has been clearly established. In the past, replacement therapy was provided through intramuscular injections. In the early 1980s, highly purified monomeric suspensions of IgG for intravenous use became available and more than 10 commercial preparations of intravenous immune globulin (IVIG) are now at the disposal of the clinician. The indications for administration of IVIG have been enlarged to include transitory primary antibody deficiencies (such as low birth-weight premature babies), secondary hypogammaglobulinaemic states [as in chronic lymphatic leukaemia (CLL) or multiple myeloma], and conditions with increased susceptibility to infections (such as bone marrow transplant or the post-surgery period). In addition to its efficacy as replacement therapy, IVIG now has well-established therapeutic applications in some haematological and autoimmune diseases: IVIG preparations are used successfully in immune thrombocytopenic purpura (ITP), in Kawasaki disease, and for some desperate diseases for which there is no other efficient treatment [reviewed in refs 1 and 2]. The mechanisms of action of IVIG in these conditions, although not yet fully determined, include a reticulo-endothelial blockade, an immunomodulatory effect (by supplying anti-idiotypic antibodies), and an anti-inflammatory action.

This growing usage has increased the need for high quality immune globulin products and, indeed, high-dose IVIG can be administered with only mild, self-limited side-effects. This paper reviews the most frequent adverse reactions reported with IVIG therapy from the time of its introduction into the clinic. Possible underlying causes of these reactions and their current management are described briefly.

SIDE-EFFECTS OF IVIG

The side-effects of IVIG can be separated into adverse reactions due to the relative 'impurity' of the commercial preparations

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(viruses, soluble substances or immunoglobulins other than IgG) and undesirable effects of their active component, the IgG. However, some of the mechanisms underlying these side-effects are speculative and probably complex. The side-effects are enumerated here according to their major manifestations, irrespective of their putative cause.

Generalized reactions

The incidence of generalized reactions occurring during and/or after the administration of IVIG is reported to be in the range of 1–15 % (usually less than 5%). Most of them begin 30–60 min after the onset of the infusion; they are often mild, self-limited and include the following: pyrogenic reactions; minor systemic reactions such as headache, myalgia, fever, chills, low back pain, nausea and/or vomiting; vasomotor and cardiovascular manifestations marked by changes in blood pressure and tachycardia—these may be related to occasional reports of shortness of breath and chest tightness.

These reactions are generally considered to be due to aggregated immunoglobulin molecules which cause the complement system to be activated. They may be due to antigen-antibody reactions as well, or to possible contaminants or even stabilizers that may have been used during the manufacturing process. Frequently, these manifestations can be managed quite easily, sometimes just by reducing the rate of IVIG infusion or stopping it.

Far less frequently, the onset of symptoms of a generalized reaction is delayed until a few days after IVIG infusion, suggesting a type III allergic reaction [3].

Hypersensitivity and anaphylactic reactions

Severe and even fatal anaphylactoid reactions [4,5] may occur during IVIG treatment in patients with IgA deficiency; the appearance of anaphylactic shock is correlated with the presence of anti-IgA antibodies of the IgG and IgE isotypes in the patient's serum [5]. Among hypogammaglobulinaemic patients, those with combined subclass deficiency (for example, IgG2 and IgA deficiency) are more likely to develop this complication. Patients with autoimmune diseases have an increased prevalence of selective IgA deficiency when compared to normal blood donors (1/50 in systemic lupus erythematosus

versus 1/700 in a normal Caucasian population). Furthermore, anti-IgA antibodies seem to be more frequent in those IgA-deficient subjects with autoimmune diseases [6].

Seriously ill patients with a compromised cardiac function may be at increased risk of vasomotor cardiac complications, manifested by elevated blood pressure and/or cardiac failure. The kallikrein activity of some IVIG preparations has been incriminated as contributing to these adverse vasomotor reactions. Moreover, the volume of fluid delivered with IVIG (700 ml with standard preparations) is intolerable in a subset of fluid-restricted patients with congestive disease, especially at a high infusion rate.

Haemolytic anaemia

Two cases of acute Coombs-positive haemolytic anaemia developing during IVIG treatment have been published. The patients, a 30-year-old man and a 9-month-old child, were treated for ITP and Kawasaki disease, respectively [7,8]. In both cases, haemolysis mediated by antibodies to blood-group antigen could be demonstrated. When high doses of IVIG are infused, their isoagglutinin content can be sufficient to explain a Coombs-positive haemolytic anaemia. Furthermore, decreased haptoglobin levels and mild reticulocytosis have been described in normal volunteers receiving IVIG, but without any change in haemoglobin level, suggesting that clinically insignificant, well-compensated haemolysis may occur during IVIG treatment [9].

Viral contamination

Several papers published between 1983 and 1987 reported clusters of non-A, non-B hepatitis after IVIG treatment [10–13]. Hepatitis seemed to run a more severe course in hypogammaglobulinaemic patients with cirrhosis, and death by hepatic failure resulted in some of them. The mechanisms whereby some preparations (and not others during the same period) could be infectious remain unclear. They could include problems with the method of manufacture, either an isolated error in production or a basic defect in the manufacturing procedure, or an insufficient level of specific neutralizing antibody in the source plasma, allowing the presence of an excessive amount of virus. Finally, there is the possibility that the infection could be the result of non-parenteral transmission of the so-called non-A, non-B hepatitis [14].

It now appears clear that anti-hepatitis C positivity of blood products varies, depending on the country of origin of plasma donation [15]. Donors that test antibody-positive are systematically excluded. In February 1994, Baxter Healthcare Corporation, Glendale, California, USA instituted a worldwide recall of Gammagard[®], its brand of IVIG, because of reports of some ten cases of possible transmission of hepatitis C. The coming months should clarify this issue and its extent. The production process for this IVIG preparation includes a chromatography procedure without any further chemical step of inactivation. As of this writing, other IVIG products currently in use have not been incriminated in hepatitis C transmission. Additional steps used in the production process of most other IVIG preparations include adjustment to pH 4, or the use of propionic acid or solvent detergent. At present, it seems cautious to use only IVIG products that have been prepared with an additional inactivation procedure.

No case of human immunodeficiency virus (HIV) seroconversion has yet been ascribed to the administration of IVIG. Furthermore, experiments in which large amounts of HIV were added to plasma before fractionation indicate that HIV is successfully eliminated during IVIG preparation.

Hepatitis B virus has not been detected in IVIG batches and the risk of its transmission is also considered negligible.

Neurological complications

As noted previously, headache is commonly reported by patients receiving IVIG; this symptom is efficiently palliated by antalgic and/or anti-histaminic drugs. Acute aseptic meningitis has been reported as a cause of recurrent IVIG-associated headaches. A 7-year-old boy treated for ITP presented with severe headache, vomiting, fever and meningism a few hours after his second infusion of IVIG [16]. A similar episode has been reported in a 2-year-old Japanese girl also treated for ITP. Seven days after IVIG infusions she experienced the same symptoms as the child just described, which were also attributed to an aseptic meningitis [17]. Two other cases have been reported in the literature [18,19]. The mechanism of this reaction remains unclear; several cases of aseptic meningitis have been associated with the use of drugs such as isoniazid and sulphamethizole or in patients with systemic lupus erythematosus taking anti-inflammatory agents.

Recently, a case of recurrent migraine after IVIG therapy has been described, suggested by the typical symptoms at presentation and the efficient prevention by propranolol before subsequent IVIG infusions. Again, the mechanism is difficult to explain [20].

Stroke as a side-effect of IVIG treatment will be discussed later.

Renal complications

Renal failure related to IVIG treatment has been reported in eight cases [21–24]. When it occurred, the best evidence for a cause–effect relationship was the close temporal association between infusion of the drug and the onset of clinical (oliguria) and biological symptoms, as well as the patients' return to pretreatment creatinine levels after stopping the drug, with the exception of a young woman who was haemodialysed and subsequently received a transplant. Renal biopsy was performed in four patients and some pathological features in three of the cases suggested a high solute load-induced damage of the proximal tubule, similar to that associated with the use of dextran or mannitol. Immunoglobulins themselves (especially large aggregates), or more likely, some component of the preparations (such as sucrose) could be responsible for this injury. The fourth case was a 39-year-old woman with mixed cryoglobulinaemia associated with a lymphoma, who had been treated specifically for hypogammaglobulinaemia and recurrent infections. The mechanism of renal damage in this case differs from the previous cases: this patient developed acute, severe, mixed cryoglobulinaemic nephropathy with evidence of antigen–antibody complex deposition after a single infusion of IVIG [24]. However, most of these patients presented with impairment of their renal function before the episode of acute degradation; IVIG treatment probably just contributed to the deterioration in renal function. Support for this conclusion comes from observations that elevated serum creatinine levels occur in patients with glomerulonephritis who receive IVIG for nephrotic syndromes

[25]. This should draw attention to the importance of screening for impaired renal function before IVIG therapy is initiated. In addition, the report of the case of acute cryoglobulinaemic renal failure after IVIG can serve as a caution against this potential complication in patients with B cell neoplasm and demonstrable serum rheumatoid factor activity.

Thrombotic events

Woodruff *et al.* reported four cases of fatal stroke in elderly patients (62–83 years old), all receiving IVIG for ITP [26]. The authors postulated that IVIG infusion could be responsible for an enhancement of adenosine triphosphate release from platelets, favouring their aggregation, as suggested by *in vitro* aggregometry studies, but these data were not confirmed by another group [27]. In those cases with ITP, the rise in platelet count during IVIG treatment could have played a role in the thrombotic event.

Recently, Reinhart & Berchtold studied the effect of high-dose IVIG on blood rheology both *in vitro* and *in vivo* [28]. Their data show that the rise in viscosity occurring after IVIG therapy can significantly impair blood flow; for this reason IVIG infusions might be sufficient to generate myocardial infarction or stroke in predisposed patients, especially elderly patients at risk of cardiovascular and thromboembolic events. However, few severe thrombotic episodes have been observed with IVIG therapy and when mentioned in case reports, the aetiological link between the treatment and frequent events in old and severely ill patients is not obvious.

Contamination of IVIG batches

Immunologically active proteins. The levels of soluble class II molecules (sHLA-DR, -DQ and -DP) in IVIG preparations appear to exceed those found in the plasma of healthy individuals, suggesting a concentration process [29]; in contrast, HLA class I molecules (A,B,C) are not detectable. Based on the total dosage of IVIG per infusion, the contaminating sHLA class II molecules may become immunogenic.

Significant levels of soluble CD4 and CD8 molecules have been found in some commercial preparations [30]. Seventeen of these were tested by enzyme-linked immunosorbent assays for the presence of proteins and cytokines such as interferon- γ (IFN- γ), tumour necrosis factor, interleukin-1 (IL-1), sIL-2 and sIL-4. Of the substances studied, only IFN- γ was present at measurable concentrations [31]. The clinical relevance of these observations remains unclear.

Anticytoplasmic antigens (ANCA). One case of uveitis has been reported in a 9-year-old hypogammaglobulinaemic patient, which was attributed to a localized vasculitis [32]. Cytoplasmic ANCA activity was detected in IVIG batches and was proposed as the cause of the vasculitis. However, the causative role for ANCA in vasculitis remains unproven [33]. Attempts to transfer the disease to animals by the same mechanism have failed. Moreover, a transient peak in serum ANCA activity has been noted after IVIG infusion, attributed to displacement of ANCA from tissue sites [34]. The young patient in the case report might have had an underlying localized vasculitis.

Miscellaneous side-effects

Many side-effects of IVIG are in the literature as sporadic case reports. Generally, the assessment of a real cause-effect

relationship is sustained by a temporal association to the infusion and the absence of other obvious aetiological agents. Most of the time, no clear physiopathogenic explanation can be given.

Alopecia. Three cases of alopecia developing after infusion of IVIG have been reported [35]. The three women (aged 19, 42 and 61) were being treated for ITP and complained of diffuse alopecia up to 4 weeks after treatment. Their hair regrew within the 4 weeks following the withdrawal of IVIG. Two more cases have been reported by the IVIG manufacturers. An immunological basis for alopecia is possible, despite the negativity of immunofluorescence studies performed on the scalp biopsies of two of these patients.

Hypothermia. We saw one case of transitory hypothermia (to 35°C) in a 59-year-old CLL patient after each IVIG infusion. The pathogenesis of this observation remains obscure.

MANAGEMENT AND PREVENTION OF IVIG SIDE-EFFECTS

The management of the side-effects of IVIG is symptomatic and, in view of their mildness, they do not necessitate any aggressive treatment in most cases. Depending on the particular manifestation, drugs palliating the symptoms are analgesic, anti-pyretic, or anti-histaminic drugs; non-steroidal, anti-inflammatory agents; and/or low-dose corticosteroids.

Most adverse reactions to IVIG treatment could be reduced in three main ways: assuring the maximal purification of the product, screening the patient for factors predisposing to complications and respecting some rules of administration.

Purification of IVIG

One batch of IVIG results from processing the plasma of 3000–15 000 donors, all of whom are currently screened for hepatitis B and C, undergo HIV serology and measurement of transaminase levels. Commercial IVIG products are prepared from pooled plasma by the cold-ethanol fractionation technique based on Cohn's procedure and now in world-wide use. Once the plasma fraction II has been obtained, the immunoglobulins are stabilized by substances such as β -propiolactone. This procedure of cold-ethanol fractionation contributes to inactivation of viruses which might be present in the plasma pool, despite meticulous donor selection and the use of sensitive screening procedures. Moreover, β -propiolactone also has virucidal properties.

In addition, some manufacturers currently include a step of inactivation of lipid-enveloped viruses by a solvent detergent technique in the processing. This, concurrent with such measures as lowering the pH, raising the temperature, and increasing the incubation time during the production of IVIG, renders these products free of any major viral transmission.

The composition of each IVIG speciality is not exactly the same: they may differ in IgG subclass levels and IgA contaminants. Preparations containing very low levels of IgA should be selected for patients who present with serum anti-IgA antibodies or in emergency situations where this information cannot be obtained before IVIG treatment.

Screening of the patient

Most of the severe reactions to IVIG have been observed in patients with anti-IgA antibodies. This eventuality should be

assessed by systematic screening before any instauration of treatment, particularly in patients with hypogammaglobulinemia or autoimmune diseases [36].

As noted earlier, the presence of rheumatoid factor activity (especially in patients with B lymphoma) or renal impairment should be investigated in any candidate for IVIG treatment.

Drug administration

Rate of infusion. The rate of IVIG infusions should be low at the beginning and increased every 15–30 min, based on the patient's tolerance. Infusion of a standard dose (e.g. 400 mg/kg) may take up to 8 h in some patients. In most cases, symptoms such as chills, fever and headache during infusion may be alleviated by lowering the rate of infusion or briefly stopping it. A phase I rate-escalation study was conducted recently in patients undergoing bone marrow transplantation and receiving 500 mg/kg of IVIG per week prophylactically, to determine the minimal period of infusion of concentrated IVIG that was well tolerated [37]. After a first infusion over a 6-h period, the 40 patients were randomized to receive the same treatment over a period of 2, 3, 4 or 5 h. The conclusion was that IVIG could be infused over a 3-h period with good tolerance, but a faster rate of infusion was poorly tolerated. This rule should be respected, particularly in patients at risk of complications (those with multi-organ failure, previous severe reactions, etc.).

Premedication. For patients with repeated reactions unresponsive to reducing the infusion rate, premedication with hydrocortisone (100 mg intravenously) or an antihistaminic drug can be considered and is generally efficacious.

CONCLUSIONS

IVIG preparations are some of the safest biological products available. Although severe adverse experiences have been reported, they are all largely anecdotal. Besides, the aetiological role of IVIG in their pathogenesis is rarely unequivocal.

The benefits of IVIG have been described for a growing number of conditions where immunoregulatory disorders are suspected and for which satisfactory alternative treatment is lacking. This harmless drug has been 'tried' and isolated therapeutic responses that are occasionally dramatic and plausible have been reported, while failures are forgotten. In contrast to the preventive indications study, few randomized placebo-controlled trials have been conducted to assess the real therapeutic impact of IVIG in conditions such as rare vasculitis, demyelinating neuropathies or severe epilepsy, which require multicentre studies. Simultaneously, the specific side-effects attributed to IVIG in those special indications could be appreciated.

To date, and because patients can be screened for anti-IgA antibodies, IVIG can be administered very safely with minimal reactions. However, this currently very expensive form of therapy should still be restricted to adequately established indications.

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*Side-effects of IVIG***12:14 pm**

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3i. UnitedHealth IVIG Policy Document



DRUG POLICY

IMMUNE GLOBULIN (IVIG and SCIG)

Policy Number: 2016D0035S	Related Medical or Drug Policies: None
Effective Date: 2/1/2016	
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INSTRUCTIONS FOR USE

This Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Drug Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Drug Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

This policy refers to the following intravenous (IV) and subcutaneous (SC) immune globulin (IG) products (List not all inclusive):

- | | |
|----------------------------|---------------------|
| Bivigam™ (IV) | Gammaplex® (IV) |
| Carimune® NF (IV) | Octagam® (IV) |
| Flebogamma® DIF (IV) | Privigen® (IV) |
| Gammagard® Liquid (IV, SC) | Gamunex®-C (IV, SC) |
| Gammagard® S/D (IV) | Hizentra® (SC) |
| Gammaked™ (IV, SC) | HyQvia® (SC) |

In absence of a product listed, and in addition to applicable criteria outlined within the drug policy, prescribing and dosing information from the package insert is the clinical information used to determine benefit coverage.

The term "IVIG" will be used in this policy where prescribing and dosing information is specific to the intravenous formulation. At all other times, the term "immune globulin" will be used.

Diagnoses addressed in this policy

<u>Asthma (severe, persistent, high-dose steroid-dependent)</u>	<u>Autoimmune bullous diseases</u>	<u>Autoimmune uveitis</u>
<u>Bone marrow transplantation (BMT)</u>	<u>Chronic inflammatory demyelinating polyneuropathy</u>	<u>Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL</u>
<u>Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants</u>	<u>Dermatomyositis or polymyositis</u>	<u>Diabetes mellitus</u>
<u>Enteroviral meningoencephalitis</u>	<u>Fetomaternal alloimmune thrombocytopenia</u>	<u>Graves' ophthalmopathy</u>
<u>Guillain-Barré syndrome (GBS)</u>	<u>HIV-infection, prevention of bacterial infection in pediatric HIV</u>	<u>Idiopathic thrombocytopenic purpura (ITP)</u>
<u>IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy</u>	<u>Kawasaki disease</u>	<u>Lambert-Eaton myasthenic syndrome (LEMS)</u>
<u>Lennox Gastaut syndrome</u>	<u>Lymphoproliferative disease, treatment of bacterial infections</u>	<u>Monoclonal gammopathy</u>
<u>Multifocal motor neuropathy (MMN)</u>	<u>Multiple sclerosis, relapsing remitting (RRMS)</u>	<u>Myasthenic exacerbation</u>
<u>Neuromyelitis optica</u>	<u>Paraproteinemic neuropathy</u>	<u>Posttransfusion purpura</u>
<u>Primary immunodeficiency syndromes</u>	<u>Rasmussen syndrome</u>	<u>Renal transplantation, prevention of acute humoral rejection</u>
<u>Rheumatoid arthritis, severe</u>	<u>Rotaviral enterocolitis</u>	<u>Staphylococcal toxic shock</u>
<u>Stiff-person syndrome</u>	<u>Thrombocytopenia, secondary to HCV, HIV, and</u>	<u>Toxic epidermal necrolysis or Stevens-Johnson syndrome</u>
<u>Urticaria, delayed pressure</u>	<u>Unproven Uses</u>	

The following information pertains to medical necessity review:

A. General Requirements (applicable to **all** medical necessity requests):

1. For **initial therapy**, **both** of the following:
 - a. Diagnosis
AND
 - b. Medical records documenting **both** of the following:
 - (1) History and physical examination documenting the severity of the condition, including frequency and severity of infections where applicable
AND
 - (2) Laboratory results or diagnostic evidence supporting the indication for which immune globulin is requested
2. For **continuation of therapy**, **all** of the following:
 - a. Documentation of positive clinical response to immune globulin therapy
AND
 - b. Statement of expected frequency and duration of proposed immune globulin treatment
AND
 - c. For long term treatment, documentation of titration to the minimum effective dose and frequency needed to maintain a sustained clinical response.

B. Diagnosis-Specific Requirements

The information below indicates additional requirements for those indications having specific medical necessity criteria in the list of proven indications.

Immune globulin is **proven** for:

1. **Asthma (severe, persistent, high-dose steroid-dependent)**^{71,98,122}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **severe, persistent, high-dose steroid-dependent asthma** when **all** of the following criteria are met:

- a. Patient is receiving optimal conventional asthma therapy (e.g., high-dose inhaled glucocorticoids, short- and long-acting inhaled β agonists).

AND

- b. Patient has required continuous oral glucocorticoid therapy for a minimum of 2 months prior to the decision to initiate immune globulin therapy.

AND

- c. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

2. **Autoimmune bullous diseases** [pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, mucous membrane (cicatricial) pemphigoid, epidermolysis bullosa acquisita, pemphigoid gestationis, linear IgA bullous dermatosis]^{3,6,94,116,122,169}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of autoimmune bullous diseases when **all** of the following criteria are met:

- a. Diagnosis of an autoimmune bullous disease

AND

- b. Extensive and debilitating disease

AND

- c. History of failure, contraindication, or intolerance to systemic corticosteroids **with concurrent** immunosuppressive treatment (e.g., azathioprine, cyclophosphamide, mycophenolate mofetil).

AND

- d. IVIG dose does not exceed 1,000 to 2,000 mg/kg per month divided into 3 equal doses each given over 3 consecutive days or 400 mg/kg per day given over 5 consecutive days per month. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities.

AND

- e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

3. **Autoimmune uveitis**^{121,122}

4. **Bone marrow transplantation (BMT),**^{47,57,122,152,158,177}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** after allogeneic **BMT** when **all** of the following criteria are met:

- a. **One** of the following uses:

- (1) Prevention of acute graft vs. host disease (GVHD)

OR

- (2) Prevention of infection

AND

- b. Confirmed allogeneic bone marrow transplant within the last 100 days
AND
- c. Documented severe hypogammaglobulinemia (IgG < 400 mg/dL)
AND
- d. IVIG dose does not exceed 500 mg/kg once weekly for the first 90 days of therapy, then monthly up to 360 days after transplantation

5. **Chronic inflammatory demyelinating polyneuropathy**^{41,60,62,63,99,122,125,141,144,146,158,161}

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the treatment of **chronic inflammatory demyelinating polyneuropathy** when **all** of the following criteria are met:

a. **Initial treatment:**

- (1) Diagnosis of chronic inflammatory demyelinating polyneuropathy as confirmed by **all** of the following:
 - (a) Progressive symptoms present for at least 2 months
AND
 - (b) Symptomatic polyradiculoneuropathy as indicated by progressive or relapsing motor or sensory impairment of more than one limb
AND
 - (c) Electrophysiologic findings when at least **three** of the following four criteria are present
 - i. Partial conduction block of ≥ 1 motor nerve
 - ii. Reduced conduction velocity of ≥ 2 motor nerves
 - iii. Prolonged distal latency of ≥ 2 motor nerves
 - iv. Prolonged F-wave latencies of ≥ 2 motor nerves or the absence of F waves

AND

- (d) **Both** of the following findings following lumbar puncture:
 - i. White blood cell count $<10/\text{mm}^3$
 - ii. Elevated CSF protein

AND

- (2) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

b. **Continuation of treatment:**

- (1) Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]
AND
- (2) For long-term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect
AND
- (3) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.

6. **Chronic lymphocytic leukemia (CLL), prevention of infection in B-cell CLL**^{8,58,59,115,123,158}

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the prevention of infection in **B-cell chronic lymphocytic leukemia** when **all** of the following criteria are met:

- a. Diagnosis of B-cell chronic lymphocytic leukemia (CLL)
AND

- b. **One** of the following:
 - (1) Documented hypogammaglobulinemia (IgG < 500 mg/dL)
 - (2) History of bacterial infection(s) associated with B-cell CLL**AND**
- c. IVIG dose does not exceed 400 mg/kg every 3 to 4 weeks

7. Cytomegalovirus (CMV) induced pneumonitis in solid organ transplants

8. Dermatomyositis or polymyositis^{41,42,47,50,122,125,141}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **dermatomyositis or polymyositis** when **all** of the following criteria are met:

- a. Diagnosis of dermatomyositis or polymyositis
AND
- b. History of failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate)
AND
- c. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days administered as monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.
AND
- d. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

9. Diabetes mellitus^{73,122}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **autoimmune diabetes mellitus** when **both** of the following criteria are met:

- a. Patient is newly diagnosed with insulin dependent (type 1) diabetes mellitus
AND
- b. Patient is not a candidate for or is refractory to insulin therapy.

10. Enteroviral meningoencephalitis^{45,122,135}

11. Fetomaternal alloimmune thrombocytopenia^{1,8,134}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **fetomaternal alloimmune thrombocytopenia** when **all** of the following criteria are met:

- a. For pregnant women:
 - (1) Diagnosis of fetomaternal alloimmune thrombocytopenia
AND
 - (2) **One** or more of the following:
 - (a) Previously affected pregnancy
 - (b) Family history of the disease
 - (c) Platelet alloantibodies found on screening**AND**
 - (3) IVIG dose does not exceed 1,000 mg/kg once weekly until delivery**OR**
- b. For newborns:
 - (1) Diagnosis of fetomaternal alloimmune thrombocytopenia
AND
 - (2) Thrombocytopenia that persists after transfusion of antigen-negative compatible platelets

12. Graves' ophthalmopathy^{14,122}**13. Guillain-Barré syndrome (GBS)**^{41,50,79,80,122,125,141,161}

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the treatment of **Guillain-Barré syndrome** when **all** of the following criteria are met:

- a. Diagnosis of Guillain-Barré Syndrome
AND
- b. Severe disease requiring aid to walk
AND
- c. Onset of neuropathic symptoms within the last four weeks
AND
- d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.
AND
- e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

14. HIV-infection, prevention of bacterial infection in pediatric HIV^{57,89,111,158,178}

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the prevention of **bacterial infection in pediatric HIV** when **all** of the following criteria are met:

- a. Diagnosis of HIV disease^{57,89,111,158,178}
AND
- b. Patient age \leq 13 years
AND
- c. **One** of the following criteria:
 - (1) Documented hypogammaglobulinemia (IgG < 400 mg/dL)
OR
 - (2) Functional antibody deficiency as demonstrated by either poor specific antibody titers or recurrent bacterial infections**AND**
- d. IVIG dose does not exceed 400 mg/kg every 28 days

15. Idiopathic thrombocytopenic purpura (ITP)^{8,28,57,59,60,62,63,122,133,151,158}

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the treatment of **idiopathic thrombocytopenic purpura** when at least **one** of the following criteria is met:

- a. **All** of the following:
 - (1) Diagnosis of **acute** thrombocytopenic purpura (ITP)
AND
 - (2) Documented platelet count < $50 \times 10^9 / L$ (obtained within the past 30 days)¹⁵¹
AND
 - (3) IVIG dose does not exceed 1,000 mg/kg/day for 1 to 2 days.
OR
- b. **All** of the following:
 - (1) Diagnosis of **chronic** thrombocytopenic purpura (ITP)
AND
 - (2) ****History of failure, contraindication, or intolerance to at least one of the following:**
 - (a) Corticosteroids

(b) Splenectomy

AND

- (3) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

16. IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy^{41,122}

17. Kawasaki disease^{59,122,158,172}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **Kawasaki disease** when **both** of the following criteria are met:

- a. Diagnosis of Kawasaki disease
- AND**
- b. IVIG dose does not exceed 400 mg/kg for five consecutive days or a single dose of 2,000 mg/kg

18. Lambert-Eaton myasthenic syndrome (LEMS)^{41,47,50,122,125,141,181-2}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **Lambert-Eaton myasthenic syndrome** when **all** of the following criteria are met:

- a. Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)
- AND**
- b. History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids)
- AND**
- c. Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS
- AND**
- d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days.⁵⁰ IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.
- AND**
- e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

19. Lennox Gastaut syndrome^{47,50}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **Lennox Gastaut syndrome** when **all** of the following criteria are met:

- a. History of failure, contraindication or intolerance to initial treatment with traditional anti-epileptic pharmacotherapy (e.g., lamotrigine, phenytoin, valproic acid).
- AND**
- b. IVIG dose does not exceed 400 mg/kg/day given for 4 to 5 consecutive days. IVIG administration may be repeated monthly as needed in patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities.
- AND**

- c. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

20. Lymphoproliferative disease, treatment of bacterial infections¹²²

21. Monoclonal gammopathy^{66,122}

22. Multifocal motor neuropathy (MMN)^{41,47,50,58,122,125,183}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **multifocal motor neuropathy** when **both** of the following criteria are met:

- a. Initial treatment:
 - (1) Diagnosis of multifocal motor neuropathy as confirmed by **all** of the following:¹⁸³
 - (a) Weakness with slowly progressive or stepwise progressive course over at least one month
AND
 - (b) Asymmetric involvement of two or more nerves
AND
 - (c) Absence of motor neuron signs and bulbar signs
AND
 - (2) IVIG dose does not exceed 2,400 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval may need to be adjusted in patients with severe comorbidities.^{41,47,50,183}
- b. Continuation of treatment:
 - (1) Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale]
AND
 - (2) IVIG dose does not exceed 2,400 mg/kg per month given over 2 to 5 consecutive days. Dosing interval may need to be adjusted in patients with severe comorbidities.^{41,47,50,183}
AND
 - (3) For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

23. Multiple sclerosis, relapsing remitting (RRMS)^{47,49,50,67,77,122,149}

NOTE: Treatment of any other type of multiple sclerosis with immune globulin is not supported by clinical evidence.

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **relapsing remitting multiple sclerosis** when **all** of the following criteria are met:

- a. Initial treatment:
 - (1) Diagnosis of relapsing-remitting multiple sclerosis (RRMS)
AND
 - (2) Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy.
AND
 - (3) History of failure, contraindication, or intolerance to at least **two** of the following agents:
 - (a) Aubagio (teriflunomide)
 - (b) Avonex (interferon beta-1a)

- (c) Betaseron (interferon beta-1b)
- (d) Extavia (interferon beta-1b)
- (e) Copaxone (glatiramer acetate)
- (f) Gilenya (fingolimod)
- (g) Rebif (interferon beta-1a)
- (h) Tecfidera (dimethyl fumarate)
- (i) Tysabri (natalizumab)

AND

- (4) Induction, when indicated, does not exceed a dose of 400 mg/kg daily for up to five days

b. Continuation of treatment:

- (1) Medical records, including findings of interval examination including neurological deficits incurred and assessment of disability [e.g., Expanded Disability Status Scale (EDSS), Functional Systems Score (FSS), Multiple Sclerosis Functional Composite (MSFC), Disease Steps (DS)]

AND

- (2) Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS)

AND

- (3) Documentation of decreased number of relapses since starting immune globulin therapy

AND

- (4) Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

AND

- (5) IVIG dose does not exceed 1,000 mg/kg monthly

AND

- (6) For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

24. Myasthenic exacerbation^{41,47,50,56,72,122,125}

NOTE: Evidence does not support the use of immune globulin maintenance therapy for generalized myasthenia gravis or for ocular myasthenia.

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **myasthenic exacerbation** when **all** of the following criteria are met:

- a. Diagnosis of generalized myasthenia gravis

AND

- b. Evidence of myasthenic exacerbation, defined by at least **one** of the following symptoms in the last month:

- (1) Difficulty swallowing
- (2) Acute respiratory failure
- (3) Major functional disability responsible for the discontinuation of physical activity

AND

- c. **One** of the following:

- (1) History of failure, contraindication, or intolerance to immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis.
- (2) Currently receiving immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine) for long-term management of myasthenia gravis.

AND

- d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days administered in up to three monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

25. **Neuromyelitis optica**^{81,190-191}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **neuromyelitis optica** when **all** of the following criteria are met:

- a. Diagnosis of neuromyelitis optica
AND
- b. History of failure, contraindication, or intolerance to at least **two** of the following:
 - (1) Azathioprine
 - (2) Corticosteroids
 - (3) Mycophenolate mofetil
 - (4) Rituximab**AND**
- c. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days administered in up to six monthly infusions. Dosing interval may need to be adjusted in patients with severe comorbidities.

26. **Paraproteinemic neuropathy**^{86,122}

27. **Posttransfusion purpura**^{8,122}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **posttransfusion purpura** when **both** of the following criteria are met:

- a. Diagnosis of posttransfusion purpura
AND
- b. IVIG dose does not exceed 1,000 mg/kg for 2 days

28. **Primary immunodeficiency syndromes**^{8,28,51,52,57-63,76,118,122,133,158,164,173,183-9} (See disease list linked to below)

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **primary immunodeficiency syndromes** when **all** of the following criteria are met:

- a. Diagnosis of primary immunodeficiency
AND
- b. Clinically significant functional deficiency of humoral immunity as evidenced by **one** of the following:
 - (1) Documented failure to produce antibodies to specific antigens
OR
 - (2) History of significant recurrent infections
AND
- c. Initial IVIG dose is 300 to 600 mg/kg every 3 to 4 weeks and titrated based upon patient response.^{28,51-2,57-61,63,76,118,133} (For SCIG products, FDA-labeled dosing and conversion guidelines will used to determine benefit coverage.)

29. **Rasmussen syndrome**^{50,122}

Additional information to support medical necessity review where applicable:

Immune globulin is **medically necessary** for the treatment of **Rasmussen syndrome** when **both** of the following criteria are met:

- a. Documentation that short term amelioration of encephalitis is needed prior to definitive surgical therapy
AND

- b. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days. IVIG is not recommended for long-term therapy for Rasmussen's encephalitis as surgical treatment is the current standard of care.⁵⁰

- 30. **Renal transplantation, prevention or treatment of acute humoral rejection**^{30,87,104,112,122}
- 31. **Rheumatoid arthritis, severe**^{114,122,155}
- 32. **Rotaviral enterocolitis**^{68,122}
- 33. **Staphylococcal toxic shock**¹²²
- 34. **Stiff-person syndrome**^{41,47,50,122,179-80}

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the treatment of **stiff-person syndrome** when **all** of the following criteria are met:

- a. Diagnosis of stiff-person syndrome
AND
- b. History of failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines)^{47,50,179-80}
AND
- c. History of failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids)¹⁷⁹⁻⁸⁰
AND
- d. IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 days. IVIG administration may be repeated monthly as needed for patients requiring maintenance therapy. Dosing interval may need to be adjusted in patients with severe comorbidities.⁵⁰
AND
- e. For long term treatment, documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

- 35. **Thrombocytopenia, Secondary to Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), or pregnancy**¹⁹²

Additional information to support medical necessity review where applicable:
Immune globulin is **medically necessary** for the treatment of **thrombocytopenia** when **one** of the following criteria is met:

- a. For initial therapy, **all** of the following:
 - (1) **One** of the following:
 - (a) **Both** of the following:
 - i. Diagnosis of thrombocytopenia secondary to HCV infection
 - ii. **Patient is receiving concurrent antiviral therapy, unless contraindicated.
 - OR**
 - (b) **Both** of the following:
 - i. Diagnosis of thrombocytopenia secondary HIV infection
 - ii. **Patient is receiving concurrent antiviral therapy, unless contraindicated.
 - OR**
 - (c) Diagnosis of thrombocytopenia secondary to pregnancy
 - AND**

- (2) Documented platelet count $< 50 \times 10^9 / L$ (obtained within the past 30 days)¹⁵¹
AND
(3) IVIG dose does not exceed 1,000 mg/kg/day for 1 to 2 days
OR
- b. For continuation of therapy, **both** of the following:
- (1) **One** of the following:
- (a) **Both** of the following:
- Diagnosis of thrombocytopenia secondary to HCV infection
 - **Patient is receiving concurrent antiviral therapy, unless contraindicated.
- OR**
- (b) **Both** of the following:
- Diagnosis of thrombocytopenia secondary to HIV infection
 - **Patient is receiving concurrent antiviral therapy, unless contraindicated.
- OR**
- (c) Diagnosis of thrombocytopenia secondary to pregnancy
AND
- (2) IVIG dose does not exceed 2,000 mg/kg per month given over 2 to 5 consecutive days. IVIG administration may be repeated monthly as needed to prevent exacerbation. Dosing interval should be adjusted depending upon response and titrated to the minimum effective dose that can be given at maximum intervals to maintain safe platelet levels.

36. Toxic epidermal necrolysis or Stevens-Johnson syndrome^{55,122}

37. Urticaria, delayed pressure^{37,122}

Immune globulin is **unproven and not medically necessary** for:

- Acquired hemophilia
- Acute disseminated encephalomyelitis (ADEM)
- Adrenoleukodystrophy
- Alzheimer's disease
- Amyotrophic lateral sclerosis (ALS)
- Antiphospholipid antibody syndrome (APS) in pregnancy
- Asthma, non-steroid dependent
- Atopic dermatitis
- Autism spectrum disorders
- Autoimmune hemolytic anemia
- Autoimmune liver disease
- Autoimmune neutropenia
- Bone marrow transplantation (BMT), prevention of acute graft vs. host disease (GVHD) after autologous BMT
- Bone marrow transplantation (BMT), prevention of chronic graft vs. host disease (GVHD) after either allogeneic or autologous BMT
- Bone marrow transplantation (BMT), prevention of infection after autologous BMT
- Campylobacter* species-induced enteritis
- Cerebral infarctions with antiphospholipid antibodies
- Chronic fatigue syndrome
- Demyelinative brain stem encephalitis
- Demyelinating neuropathy associated with monoclonal IgM
- Dilated cardiomyopathy
- HIV infection, to reduce viral load
- HTLV-1-associated myelopathy
- Idiopathic dysautonomia, acute

25. Inclusion body myositis
26. Isolated IgA deficiency
27. Isolated IgG4 deficiency
28. Lumbosacral or brachial plexitis
29. Myocarditis, acute
30. Neonatal isoimmune hemolytic jaundice
31. Neonatal sepsis, prevention
32. Neonatal sepsis, treatment
33. Ocular myasthenia
34. Opsoclonus myoclonus
35. Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy
36. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
37. POEMS syndrome
38. Postinfectious cerebellar ataxia
39. Postoperative sepsis
40. Pseudomembranous colitis
41. Respiratory syncytial virus (RSV) lower respiratory tract infection
42. Rheumatic fever, acute
43. Sjogren's syndrome
44. Spontaneous recurrent abortions, prevention
45. Systemic lupus erythematosus
46. Urticaria, chronic
47. Vasculitides and antineutrophil antibody syndromes

Efficacy for these conditions has not been described in adequately designed studies. The available evidence is limited to case reports or case series, anecdotal reports, and open-label trials, or the available studies have failed to demonstrate a positive treatment effect. Further well-designed studies are needed to establish the role of immune globulin in these conditions.

Centers for Medicare and Medicaid Services (CMS):

Medicare covers Intravenous Immune Globulin when criteria are met. Refer to the National Coverage Determinations (NCDs) for Intravenous Immune Globulin for the Treatment of Autoimmune Mucocutaneous Blistering Diseases (250.3) and Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine) (260.7).

Local Coverage Determinations (LCDs) do exist. See the LCDs for Drugs and Biologicals: Immune Globulin Intravenous (IVIg), External Infusion Pumps, Immune Globulin Intravenous (IVIg), Immune Globulins, Intravenous Immune globulin and Intravenous Immune Globulin (IVIg).

Medicare does not have an NCD that specifically addresses the subcutaneous administration of immunoglobulins (Ig). Local Coverage Determinations (LCDs) do exist; refer to the LCDs for External Infusion Pumps.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>.

(Accessed September 23, 2015)

BENEFIT CONSIDERATIONS

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The enrollee-specific benefit document must be consulted to make coverage decisions for this service. Some states

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mandate benefit coverage for off-label use of medications when certain conditions are met. Regulations governing off-label use in the individual state must be consulted when deciding coverage. Benefit coverage for otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

BACKGROUND

Immune globulin, whether intravenous (IV) or subcutaneous (SC), is a sterile, purified preparation of human immunoglobulin derived from pooled human plasma from thousands of donors. Consisting primarily of immunoglobulin G, one of 5 classes of immunoglobulin (Ig), each batch of immune globulin (typically referred to as IVIG) provides immunomodulating peptides and antibodies against most exogenous antigens, many normal human proteins, and Fab, the antigen-binding region of autoantibodies.⁷² All currently available products contain high concentrations of IgG with subclass distribution corresponding to that of normal serum.^{28,51,52,57-63,76,118,133,164}

IVIG is considered a mainstay of treatment for immunodeficiency conditions and bullous skin disorders. It has been prescribed off-label to treat a wide variety of autoimmune and inflammatory neurologic conditions.⁷²

CLINICAL EVIDENCE

Proven

Autoimmune Diseases

IVIG is beneficial for treatment of a number of autoimmune diseases based upon US Food and Drug Administration (FDA) approval, published practice guidelines, professional society evidence reviews, and/or randomized, controlled clinical trials. These include immune thrombocytopenic purpura,^{8,28,57,59,60,62,63,122,133,151,158} Graves' ophthalmopathy,^{14,122} autoimmune uveitis,^{121,122} dermatomyositis and polymyositis,^{41,42,47,50,122,125,141} severe rheumatoid arthritis,^{114,122,155} and autoimmune diabetes mellitus.^{73,122}

IVIG is a first-line therapy for fetomaternal alloimmune thrombocytopenia.^{1,8,134}

An article by Anderson et al. summarized the National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for hematologic conditions. Response rates in available reports of post-transfusion purpura, a rare and life-threatening condition were high.⁸

Infectious and Infection-related Diseases

IVIG is beneficial for a number of infectious and infection-related diseases based upon FDA approval, published practice guidelines, professional society evidence reviews, and/or randomized, controlled clinical trials. These include prevention of coronary artery aneurysms associated with Kawasaki syndrome,^{59,122,158,172} treatment of CMV-induced pneumonitis in solid organ transplants,^{93,122} treatment of rotaviral enterocolitis,^{68,122} treatment of staphylococcal toxic

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shock,¹²² treatment of enteroviral meningoencephalitis,^{45,122,135} treatment of bacterial infections in lymphoproliferative diseases,¹²² prevention of bacterial infections in patients with hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell chronic lymphocytic leukemia (CLL).^{8,59,115,123,158}

Neuroimmunologic Disorders

IVIg is beneficial for treatment of a number of neuroimmunologic diseases based upon FDA approval, published practice guidelines, professional society evidence reviews, and/or randomized, controlled clinical trials. These include chronic inflammatory demyelinating polyneuropathy,^{41,60,62,63,99,122,125,141,144,146,158,161} Guillain-Barré syndrome,^{41,50,79,80,122,125,141,162} multifocal motor neuropathy,^{41,47,50,58,122,125} Lambert-Eaton myasthenic syndrome,^{41,47,50,122,125,141} IgM antimyelin-associated glycoprotein paraprotein-associated peripheral neuropathy,¹²² paraproteinemic neuropathy,^{66,122} stiff-person syndrome,^{41,47,50,122} myasthenia gravis,^{41,47,50,56,72,122,125} Lennox-Gastaut,^{47,50} Rasmussen syndrome,^{50,122} and monoclonal gammopathy.^{66,122}

The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions states that IVIG should be reserved as an option for patients with relapsing-remitting MS who fail, decline, or are not able to take standard immunomodulatory therapies. Based on consensus by the expert panel, IVIG is not recommended for treatment of primary or secondary progressive MS or for acute exacerbations of MS.⁵⁰

In their Guidelines for the Use of Intravenous Immunoglobulin in the Treatment of Neurological Diseases, the European Federation of Neurological Societies (EFNS) states that IVIG could be considered as a second or third-line therapy in RRMS if conventional immunomodulatory therapies are not tolerated because of side effects or concomitant diseases, and in particular in pregnancy where other therapies may not be used. IVIG cannot be recommended for treatment in secondary progressive MS. IVIG does not seem to have any valuable effect as add-on therapy to methylprednisolone for acute exacerbations and cannot be recommended as treatment for chronic symptoms in MS. In clinically isolated syndromes and in primary progressive MS, the EFNS Task Force concluded that there is not sufficient evidence to make any recommendations.⁴⁷

Similar findings were reported in a review of evidence by members of the Primary Immunodeficiency Committee of the AAAAI. The Committee concluded that IVIG might provide benefit for relapsing-remitting multiple sclerosis.¹²² A meta-analysis and a review of multiple sclerosis clinical trials also found that evidence supports the use of IVIG for reduction of relapses in relapsing-remitting MS.^{67,149} The use of IVIG in relapsing-remitting MS should only be considered when other established therapies have failed or cannot be utilized.

In their review of relapse therapy and intermittent long-term therapy, the Neuromyelitis Optica Study Group (NEMOS) suggests IVIG therapy as an alternative for patients with contraindication to one of the other treatments (azathioprine and rituximab) or, particularly, in children.⁸¹ The use of intravenous immunoglobulin (IVIg) as treatment for acute relapses in NMO was reported in a retrospective review of 10 patients.¹⁹⁰ In the majority of cases, IVIG was used due to lack of response to steroids with/without plasma exchange. Improvement was noted in five of 11 (45.5%) events; the remaining had no further worsening. In a case series of eight Spanish patients with neuromyelitis optica (NMO), positive results were observed from bimonthly IVIG treatment (0.7 g/kg body weight/day for 3 days).¹⁹¹ The primary outcome measure in the study was the occurrence of serious adverse effects. Secondary outcome measures were changes in the yearly rate of attacks and in the degree of neurological disability measured with the Expanded Disability Status Scale (EDSS). All 8 patients were treated with IVIG; 5 had relapsing optic neuritis with or without myelitis and 3 had recurrent longitudinally extensive transverse myelitis (LETM). The mean age of onset was 20.5 years (range, 7-31 years) and 87.5% were female. The mean duration of the disease before beginning treatment was 9.0

years (range, 3-17 years). Following 83 infusions (range, 4-21 per patient) and a mean follow-up time of 19.3 months (range, 6-39 months), minor adverse events had occurred (headache in 3 patients and a mild cutaneous eruption in a single patient). The relapse rate decreased from 1.8 in the previous year to 0.006 during follow-up ($z = -2.5$, $p=0.01$). The EDSS score fell from 3.3 [SD 1.3] to 2.6 [SD 1.5] ($z = -2.0$, $p=0.04$). The investigators concluded that treatment with IVIG is safe and well-tolerated, and it may be used as a treatment alternative for NMO spectrum disorders.

Primary and Secondary Immune Deficiencies

IVIG is indicated as replacement therapy in primary immune deficiencies.^{8,28,51,52,57-63,76,118,122,133,158,164,173}

IVIG is also beneficial in chronic lymphocytic leukemia with reduced IgG and history of infections^{8,58,59,115,123,158} and prevention of bacterial infection in HIV-infected children.^{57,89,111,158}

Miscellaneous Categories

Evidence supports IVIG for autoimmune bullous diseases;^{3,6,94,116,122,172} toxic epidermal necrolysis and Stevens-Johnson syndrome;^{55,122} severe, persistent, high-dose, steroid-dependent asthma;^{71,98,122} delayed-pressure urticaria;^{37,122} prevention of infection and acute GVHD after allogeneic bone marrow transplantation;^{46,57,122,152,158,177} and prevention and treatment of acute humoral rejection in renal transplantation.^{30,87,104,112,122}

Unproven

Acquired hemophilia: An article by Anderson et al. summarized the National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for hematologic conditions. In the opinion of the expert panel, there is no convincing evidence of clinical benefit of IVIG in this disorder, and routine use is not recommended.⁸

Acute disseminated encephalomyelitis (ADEM): This is a nonvasculitic inflammatory demyelinating condition of brain that usually occurs following a viral infection but may appear following vaccination, bacterial or parasitic infection, or even appear spontaneously. The widely accepted first-line treatment is high doses of intravenous corticosteroids. Several case reports, but no controlled trials, have provided evidence of IVIG's successful use in ADEM. The largest by Ravaglia et al. reported that in 10 of 19 ADEM patients who had failed steroids, IVIG was effective in improving motor dysfunction. Among an additional 5 patients who received IVIG first-line due to steroid contraindications, 3 were responsive to IVIG.¹³⁶

Adrenoleukodystrophy (ALD): This is one of a group of genetic disorders called the leukodystrophies that cause damage to the myelin sheath surrounding nerve cells in the brain and progressive dysfunction of the adrenal gland. In one very small randomized trial 6 patients received IVIG in addition to the dietary therapy while 6 received dietary therapy alone. No treatment effect of IVIG was demonstrated in this study. MRI findings and clinical status deteriorated in both groups.²⁷ The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that IVIG should not be used for ALD.⁵⁰

Alzheimer's disease: An open label dose-ranging study was conducted in 8 mild Alzheimer's disease (AD) patients. IVIG was added to approved AD therapies for 6 months, discontinued, and then resumed for another 9 months. Anti-A β antibodies in the serum from AD patients increased in proportion to IVIG dose and had a shorter half-life than anti-hepatitis antibodies and total IgG. Plasma A β levels increased transiently after each infusion. Cerebrospinal fluid A β decreased significantly at 6 months, returned to baseline after washout and decreased again after IVIG was re-administered for an additional 9 months. Mini-mental state scores increased an average of 2.5 points after 6 months, returned to baseline during washout and remained stable during

subsequent IVIG treatment. This study did not include an adequate number of AD patients to establish whether IVIG altered cognitive status.¹³⁷

Devi et al. reported on a retrospective investigation of patients (n=10) with Alzheimer's disease treated with IVIG. Eight of the patients completed 6 months of treatment; two completed 3.5 months of treatment. Two patients developed a pruritic, maculopapular, generalized rash, resolving with appropriate treatment, but both continued with IVIG. Patients showed stability on neurocognitive scores overall, with trends toward decline on their WAIS verbal scale and full-scale intelligence scores ($p < 0.1$), as well as on the WAIS information ($p < 0.1$) subtest and the BNT ($p = 0.1$). Patients showed trends toward improvement on the WMS logical memory II recall ($p < 0.1$), WMS verbal paired associates ($p = 0.15$), and the WMS auditory delayed memory test ($p = 0.1$). It was found that IVIG was well tolerated and effective in this sample, with patients showing stability on neurocognitive test scores and trends toward improvement in some areas.⁴⁰

Further studies are needed to establish efficacy, to determine the optimal dosing regimen and to confirm the safety of IVIG in the general population of AD patients.

Amyotrophic lateral sclerosis (ALS): This is a disease characterized by progressive motor neuron degeneration, which manifests as weakness, spasticity, and muscle atrophy, usually beginning with the upper limbs. Two small-scale, uncontrolled studies (n=7,9) examined the use of IVIG for treatment of ALS; neither of these studies found a positive treatment effect. During and after treatment, all patients showed progressive deterioration at a pace similar to that observed before treatment or faster.^{35,109} The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that there is no role for IVIG in the treatment of ALS.⁵⁰

Antiphospholipid antibody syndrome (APS) in pregnancy: In their guideline for the treatment of recurrent first-trimester and second-trimester miscarriage, the Royal College of Obstetricians and Gynaecologists (RCOG) recommends against the use of IVIG.¹⁴² There are several reports supporting a role for IVIG in the treatment of antiphospholipid antibody syndrome (APS), including in patients with APS undergoing in vitro fertilization. However, a meta-analysis of several modes of therapy (heparin, aspirin, glucocorticosteroids, and IVIG) in this clinical setting did not support any improved outcome with IVIG and a possible association with pregnancy loss or premature birth.⁴⁸ A small randomized controlled study (n=16) demonstrated no greater benefit from IVIG (plus heparin and aspirin) than from heparin and aspirin alone.²⁰ Because the efficacy of IVIG has not been proved in appropriately designed studies, its use is not recommended for APS in pregnancy.²

Asthma, non-steroid dependent: While there have been studies done on the effect of IVIG on steroid-dependent asthma patients with efficacy shown in a trial with a subgroup that required relatively high doses of daily oral steroids, there are no clinical trials or studies to support the effect on non-steroid dependent patients.¹²²

Atopic dermatitis: IVIG treatment has shown success in small, open, uncontrolled trials of patients not responding to standard therapies.¹²² A small, randomized, evaluator-blinded trial (n = 10) did not support the routine use of IVIG in patients with atopic dermatitis.¹²⁶

Autism spectrum disorders: According to the review of evidence by members of the Primary Immunodeficiency Committee of the AAAAI, there are no formal randomized studies to evaluate the use of IVIG in autism.¹²² They found that two small, open-trial reports of autistic children placed on IVIG for 6 months showed no benefit.^{39,131} The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that the available evidence does not support the use of IVIG in the treatment of autism.⁵⁰

Autoimmune hemolytic anemia: Multiple anecdotal reports demonstrate benefit from the use of IVIG in the treatment of autoimmune hemolytic anemia (AIHA), but the use of IVIG should be considered only when other therapeutic modalities fail.^{16,53,75,97,100} An article by Anderson et al. summarized the National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for hematologic conditions. They found "sparse evidence" on the use of IVIG in AIHA and despite a literal definition of response rates, those with IVIG were substantially less than accepted published response rates with other treatment alternatives. Therefore, they agreed the overall role of IVIG in AIHA is very limited.⁸

Autoimmune liver disease: In one case report of a patient with immuno-mediated chronic active hepatitis not eligible for steroids, IVIG treatment successfully normalized liver enzymes, led to undetectable circulating immune complexes, and disappearance of periportal mononuclear cell infiltrates.²⁹ Further studies evaluating the use of IVIG in autoimmune liver disease are needed, however, to determine the safety and efficacy of use.

Autoimmune neutropenia: Improvement in neutrophil counts has been described in several small series of patients with autoimmune neutropenia treated with IVIG,^{23-25,97} and anecdotal reports also suggest utility for IVIG in post- bone marrow transplantation neutropenia, which might be autoimmune in nature.^{91,95,108} It is unclear whether IVIG offers any advantage over corticosteroid therapy for the treatment of autoimmune neutropenia. The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts evidence-based practice guideline on the use of IVIG for hematologic conditions found that "the evidence to support treatment with IVIG is sparse and of poor quality. However, there was some discussion regarding its use in rare circumstances when other options (e.g. intravenous antibiotics and G-CSF) have failed."⁸

Bone marrow transplantation (BMT), prevention of acute graft-versus-host disease (GVHD) after autologous BMT: According to the Centers for Disease Control and Prevention, routine use of IVIG among autologous recipients is not recommended.¹⁷⁷

Bone marrow transplantation (BMT), prevention of chronic graft-versus-host disease (GVHD) after either allogeneic or autologous BMT: The use of IVIG was studied in a randomized, double-blind, dose-effect, placebo-controlled, multicenter trial in related allogeneic marrow transplantation.³² The trial included 200 patients receiving HLA-identical sibling marrow. IVIG-treated patients experienced no benefit versus placebo in reduction of incidence of infection, interstitial pneumonia, GVHD, transplantation-related mortality, or overall survival. There was a statistically higher incidence of grade 3 (severe) veno-occlusive disease associated with high-dose IVIG. The patients given higher doses of IVIG also had more side effects, such as fever and chills. The data does not support a recommendation for IVIG in HLA-identical sibling bone marrow transplants.⁸

Bone marrow transplantation (BMT), prevention of infection after autologous BMT: According to the Centers for Disease Control and Prevention, routine use of IVIG among autologous recipients is not recommended.¹⁷⁷

Campylobacter species-induced enteritis: The value of immunoglobulin therapy has been anecdotally described in *Campylobacter jejuni* infection when administered orally.⁷⁰ This uncontrolled report is insufficient to support the use for the treatment of this condition.

Cerebral infarctions with antiphospholipid antibodies: Only single case reports were found that reported successful treatment of patients with stroke associated with antiphospholipid syndrome. Horn et al. reported that a 32-year old woman with antiphospholipid antibody syndrome who developed progressive cerebral thrombosis rapid resolution of her neurological impairment after administration of IVIG.⁷⁸ Arabshahi et al. treated a child with trisomy 21, hypothyroidism, and insulin-dependent diabetes who developed acute hemiplegia due to the

antiphospholipid antibody syndrome at age four. Antiphospholipid antibodies were no longer detectable within 6 months and have continued to be negative. There was no clinical deterioration or further changes on magnetic resonance arteriography over 7 years.⁹

Chronic fatigue syndrome: Numerous anecdotal reports have shown subjective benefits of IVIG for chronic fatigue syndrome. However, a double-blind, placebo-controlled trial demonstrated IVIG was not effective in the treatment of typical chronic fatigue syndrome.^{122,165}

Demyelinative brain stem encephalitis: The disease is characterized by the acute onset of neurologic deficit days to weeks after a variety of viral and bacterial infections or vaccinations. The literature search identified one case series of 2 patients with acute demyelinating brainstem encephalitis who were treated with IVIG and improved rapidly, concomitant with the course of therapy.¹³

Demyelinating neuropathy associated with monoclonal IgM: Mariette et al. conducted a 12 month multicenter, prospective, randomized, open clinical trial to compare IVIG (n=10) and interferon alpha (n=10) in the treatment of 20 patients with polyneuropathy associated with monoclonal IgM. After six months of treatment 1 out of 10 patients treated with IVIG had an improvement of neurological symptoms versus eight out of 10 patients treated with interferon alpha. The mean functional score worsened in the IVIG group whereas it improved in the interferon group.¹⁰⁶

Dilated cardiomyopathy: According to a review of evidence by the members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, "Case reports suggest that patients with acute myocarditis benefit from high-dose IVIG. Placebo-controlled trials evaluating the benefit of IVIG use in recent-onset cardiomyopathy showed no benefit over placebo. High-dose IVIG might provide help to patients with acute myocarditis but has no therapeutic role in recent-onset dilated cardiomyopathy."¹²²

HIV infection, to reduce viral load: Although IVIG is FDA-approved for reducing the incidence of secondary infection in HIV-infected children, its use in treating HIV infection per se has not been as widely evaluated. A study examining the effect of a 2 g/kg IVIG dose on viral load found that p24 antigen levels and numbers of HIV RNA copies were significantly increased after treatment.³¹ Thus IVIG might be useful for preventing bacterial infections but should not be considered an antiviral therapy in the HIV-infected patient.¹²²

Human T-Lymphotropic Virus Type 1 (HTLV-1)-associated myelopathy: HTLV-1-associated myelopathy, also known as tropical spastic paresis, is a chronic inflammatory disease of the central nervous system (CNS). The one report of IVIG usage for HTLV-1-associated myelopathy was a very small case series study (n=14) that reported a positive response to IVIG therapy in 10 (71%) patients and included an increase of 30% to 280% in muscle strength. Effects were evident beginning from day 3 to day 7 after initial IVIG treatment and were sustained for over 3 weeks in 6 patients.⁹⁶

Idiopathic dysautonomia, acute: This is a disorder characterized by severe sympathetic and parasympathetic failure with relative preservation of motor and sensory function. There is some anecdotal evidence that IVIG is effective in this disorder. Yoshimaru et al. described a case of a 32-year old man with acute idiopathic autonomic neuropathy (AIAN) in which IVIG proved effective.¹⁷⁰ Smit et al. reported that a 33-year-old woman with acute idiopathic postganglionic parautonomic neuropathy experienced prompt recovery of all dysautonomic symptoms after receiving high-dose intravenous immunoglobulin therapy.¹⁴⁸

Inclusion body myositis: The treatment of inclusion body myositis (IBM) with IVIG has been studied in two randomized, double-blind, placebo controlled trials. In the first study (n=19), no statistically significant treatment differences were noted between IVIG and placebo.³⁴ In the second study (n=22), outcome measures showed a trend towards improvement with IVIG.¹⁶⁷

Based on these studies, IVIG is not recommended as routine therapy for IBM due to the variability of response and expense of therapy.⁴¹

In an additional placebo-controlled trial (n=36), no significant changes in primary outcomes were noted from baseline at each month after treatment.³⁶

IVIG for inclusion body myositis was also assessed in open-label trials, but generalized conclusions or recommendations are not presently possible.^{7,122,150}

The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated that IVIG should not be used for the treatment of IBM.⁵⁰

In their Guidelines for the Use of Intravenous Immunoglobulin in the Treatment of Neurological Diseases, the European Federation of Neurological Societies (EFNS) states that IVIG cannot be recommended for the treatment of sporadic IBM.⁴⁷

In their evidence-based guideline on IVIG in the treatment of neuromuscular disorders, the American Academy of Neurology states that there is insufficient evidence to support the use of IVIG in IBM.¹²⁵

Isolated IgA deficiency: This is the most common immunodeficiency disorder characterized by a deficiency of IgA with normal levels of other immunoglobulin classes. Isolated IgA deficiency is marked by recurrent sinusitis, bronchitis, and pneumonia, and recurrent diarrhea, although many patients have no symptoms. Management of selective IgA deficiency is limited to treating associated infections. Some advocate prophylactic daily doses of antibiotics for patients with multiple, recurrent infections. No intervention is available to either replace IgA via infusion or increase production of native IgA.¹⁴⁰ Selective IgA deficiency is not an indication for IVIG replacement therapy, although in some cases poor specific IgG antibody production, with or without IgG2 subclass deficiency, might coexist; in these patients IVIG might be required. Intravenous administration of IVIG can pose a risk of anaphylaxis for IgA-deficient patients who have IgE anti-IgA antibodies or reactions caused by complement activation if IgG anti-IgA antibodies are present.¹²²

Isolated IgG4 deficiency: IgG4 deficiency may be found in 10-15% of the general population. The significance of isolated, or selective, IgG4 deficiency is unclear.^{22,160}

Lumbosacral or brachial plexitis: Only anecdotal experience is available for assessing the treatment with IVIG for lumbar and brachial plexitis. The literature search revealed single case reports with mixed outcomes.^{10,124,171}

Myocarditis, acute: According to a review of evidence by the members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, "Case reports suggest that patients with acute myocarditis benefit from high-dose IVIG. Placebo-controlled trials evaluating the benefit of IVIG use in recent-onset cardiomyopathy showed no benefit over placebo. High-dose IVIG might provide help to patients with acute myocarditis but has no therapeutic role in recent-onset dilated cardiomyopathy."¹²²

Neonatal isoimmune hemolytic jaundice: In a 2004 Cochrane review, seven studies were identified. Three of these fulfilled the inclusion criteria and included a total of 189 infants. Term and preterm infants and infants with rhesus and ABO incompatibility were included. The use of exchange transfusion decreased significantly in the IVIG treated group (typical RR 0.28, 95% CI 0.17, 0.47; typical RD -0.37, 95% CI -0.49, -0.26; NNT 2.7). The mean number of exchange transfusions per infant was also significantly lower in the IVIG treated group (WMD -0.52, 95% CI -0.70, -0.35). None of the studies assessed long term outcomes.

Although the results show a significant reduction in the need for exchange transfusion in those treated with intravenous immunoglobulin, the applicability of the results is limited. The number of studies and infants included is small and none of the three included studies was of high quality. The protocols of two of the studies mandated the use of early exchange transfusion, limiting the generalizability of the results. Further well designed studies are needed before routine use of intravenous immunoglobulin can be recommended for the treatment of isoimmune haemolytic jaundice.⁴

Neonatal sepsis, prevention: A recent meta-analysis found that there is insufficient evidence to support the routine administration of IVIG to prevent mortality in infants with suspected or subsequently proved neonatal infection.¹²⁰ Despite encouraging trials of IVIG as an adjunct to enhance the antibacterial defenses of premature newborn infants, there are substantial contradictory data and insufficient overall evidence to support the routine administration of IVIG in infants at risk for neonatal infection.¹²²

Neonatal sepsis, treatment: In a multi-center, international, double-blind controlled trial of 3,493 infants receiving antibiotics for suspected or proven infection, subjects were randomly assigned to receive two infusions of either polyvalent IgG immune globulin (500 mg/kg) or placebo 48 hours apart. The investigators found that there was no significant between-group difference in the rates of primary outcome which was death or major disability at the age of 2 years. The primary outcome was observed in 686 of 1,759 infants (39.0%) in the intravenous immune globulin group and in 677 of 1,734 infants (39.0%) in the placebo group (relative risk, 1.00; 95% confidence interval, 0.92 to 1.08). No significant differences in the rates of seven pre-specified secondary outcomes were observed, including the incidence of subsequent sepsis episodes and causative organisms. In follow-up of survivors at 2 years, there were no significant differences in the rates of major or non-major disability or of adverse events. The authors concluded that the use of immune globulin was not associated with significant differences in the risk of major complications or other adverse outcomes in neonates with suspected or proven sepsis.²¹

A recent meta-analysis also found that there is insufficient evidence to support the routine administration of IVIG to prevent mortality in infants with suspected or subsequently proved neonatal infection.¹²⁰

Ocular myasthenia: Myasthenia gravis is an autoimmune disorder in which the body's own antibodies block the transmission of nerve impulses to muscles, causing fluctuating weakness and muscles that tire easily. Approximately half of patients present with purely ocular symptoms (ptosis, diplopia), so-called ocular myasthenia. Between 50% and 60% of people who have ocular myasthenia will progress to develop generalized myasthenia gravis (GMG) and weakness affecting other muscles. The aims of treatment for ocular myasthenia are to return the person to a state of clear vision and to prevent the development, or limit the severity of GMG. Treatments proposed for ocular myasthenia include drugs that suppress the immune system including corticosteroids and azathioprine, thymectomy, and acetylcholinesterase inhibitors. There are retrospective, but no prospective, data, which indicate that immunosuppressive treatment of ocular myasthenia may decrease the likelihood of developing GMG. It is not clear from these studies whether treatment actually reduces the incidence of GMG, delays its onset, or just masks its symptoms. Plasmapheresis and intravenous immune globulin are used for the short-term management of severe GMG, but available evidence does not indicate that either therapy has a role in patients with ocular myasthenia.¹⁷⁴⁻⁵

Opsoclonus myoclonus is a rare neurological disorder that may occur in association with tumors (paraneoplastic) or viral infections and is characterized by an unsteady, trembling gait, myoclonus and opsoclonus (irregular, rapid eye movements). It is more common in children. Published evidence consists of single case reports and case series that included patients with different etiology of opsoclonus-myoclonus and different treatment approaches. Bataller et al. analyzed neurological outcomes in adult patients with idiopathic (n=10) and paraneoplastic (n=14) opsoclonus-myoclonus following IVIG treatment. The authors found that most patients with

idiopathic opsoclonus-myoclonus make a good recovery that seems to be accelerated by steroids or IVIG. Among the 14 patients with paraneoplastic opsoclonus-myoclonus, eight patients whose tumors were treated showed complete or partial neurological recovery. In contrast, five of the six patients whose tumors were not treated died of the neurological syndrome despite steroids, IVIG or plasma exchange.¹⁵

Russo et al. conducted a retrospective case series involving 29 children diagnosed with neuroblastoma and opsoclonus-myoclonus. Patients were treated with different treatment options including ACTH (n=14), prednisone (n=12), IVIG (n=6), Imuran (n=2), and other drugs (n=2). Eighteen of 29 children (62%) had resolution of opsoclonus-myoclonus symptoms. Twenty of 29 children (69%) had persistent neurologic deficits including speech delay, cognitive deficits, motor delay, and behavioral problems. Interestingly, 6/9 children with complete recovery received chemotherapy as part of their treatment.¹⁴³ Based on this case series it is difficult to assess the effectiveness of IVIG compared to other treatment options.

Improvement following the administration of IVIG has been described in abundant single cases.^{65,129,130,163}

Paraneoplastic cerebellar degeneration, sensory neuropathy, or encephalopathy:

Paraneoplastic neurological syndromes are remote effects of cancer that are not caused by invasion of the tumor or its metastases. Immunologic factors appear important in their pathogenesis because antineuronal autoantibodies against nervous system antigens have been defined for many of these disorders.³⁸

Uchuya et al. evaluated 22 patients with neurological paraneoplastic syndromes (paraneoplastic encephalomyelitis and sensory neuronopathy syndrome =18; paraneoplastic cerebellar degeneration =4) and found treatment with IVIG was not effective in paraneoplastic CNS syndromes associated with antineuronal antibodies. Of the 21 patients who were evaluable one patient with subacute sensory neuronopathy improved for at least 15 months, 10 remained stable, and 10 deteriorated.¹⁵⁷

Keime-Guibert et al. evaluated 17 patients with paraneoplastic encephalomyelitis/sensory neuropathy (PEM/SN=10) or cerebellar degeneration (PCD=7) who received one to nine cycles of a combination of IVIG, cyclophosphamide and methylprednisolone. Of the seven patients with severe symptoms (bedridden), none improved. Of the nine patients who were still ambulatory, none improved but three stabilized.⁹⁰

Blaes et al. reported that IVIG treatment was effective in two patients, one suffering from paraneoplastic cerebellar degeneration and the other from paraneoplastic brain stem encephalitis and polyneuropathy who started infusions within 3 weeks of the onset of neurological symptoms. However, two other patients, who had suffered from paraneoplastic neuropathy for 3 and 6 months showed no improvement with the intravenous immunoglobulin therapy.¹⁷

Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS): Streptococcal infections induce exacerbation of symptoms in some children with obsessive-compulsive and tic disorders, possibly on an autoimmune basis. The syndrome of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection is referred to as pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS). According to a review of evidence by the members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology, IVIG might provide benefit for PANDAS. However, it should be noted that those children who do not have the autoimmune feature do not benefit from IVIG.¹²² The review cited only one case-¹²⁸

controlled, single-dose study which showed benefit from plasmapheresis and IVIG therapy. Additional double-blind, placebo-controlled studies are needed before this becomes a standard of therapy.

POEMS syndrome: Polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes (POEMS) syndrome also known as Crow-Fukase syndrome or osteosclerotic myeloma is a unique multisystem disorder strongly associated with plasma cell dyscrasia. Only anecdotal experience is available for assessing IVIG as treatment for POEMS syndrome. The National Advisory Committee on Blood and Blood Products of Canada (NAC) and Canadian Blood Services panel of national experts' evidence-based practice guideline on the use of IVIG for neurologic conditions stated there is no role for IVIG in the treatment of POEMS syndrome.⁵⁰

Postinfectious cerebellar ataxia: Acute cerebellar ataxia in childhood is a usually a self-limited disease which occurs after viral infections.¹¹⁷ Treatment with IVIG has not yet been established. Published evidence consists of isolated case reports. Daaboul et al. treated a 19 year-old man presented with acute cerebellar ataxia after a recent Epstein-Barr virus infection with IVIG. Progressive neurologic improvement occurred over two weeks.³³

Postoperative sepsis: A meta-analysis identified six trials which enrolled surgical patients. The largest trial included 104 participants (50 received IVIG). In general, results favored IVIG versus control, although one trial did not favor IVIG for reduction in number of deaths. Use in this setting should be evaluated in large trials in patients receiving current standard-of-care therapies.¹⁵⁶

Pseudomembranous colitis: The value of IVIG therapy has been anecdotally described in pseudomembranous colitis caused by *Clostridium difficile* (*C. difficile*).^{101,145} A retrospective analysis of 79 hospital-admitted patients who had a positive *C. difficile* toxin titer and severe disease included 18 patients given IVIG treatment (200-300 mg/kg) along with standard therapy. These patients were pair matched by propensity scoring with 18 patients not receiving IVIG who had the most similar characteristics and severity. There were no statistical differences in clinical outcomes as measured by all-cause mortality, colectomies, and length of stay. The investigators concluded that the use of IVIG in severe *C. difficile*-associated diarrhea remains unsubstantiated.⁸⁸

Rheumatic fever, acute: In a prospective, double-blind trial, 59 patients with first episode of rheumatic fever, stratified by presence and severity of carditis (39 with carditis and/or migratory polyarthritis), were randomized to receive IVIG (1 g/kg on days 1 and 2 and 0.4 g/kg on days 14 and 28) or placebo. No difference in erythrocyte sedimentation rate or acute-phase proteins was found between the groups at 6 weeks. After 1 year, no difference in cardiac outcomes was found between the groups.¹⁶⁶

RSV lower respiratory tract infection: The use of IVIG combined with ribavirin in the treatment of RSV-induced pneumonitis was reported in small series of immunodeficient patients.^{64,168} Survival rates were encouraging and suggested that IVIG might be of benefit as an adjunct therapy to ribavirin. In a double-blind, controlled study involving 35 RSV-infected, hospitalized infants and children, IVIG 2 grams/kilogram was given over 12 to 24 hours. Therapy resulted in significant reductions in nasal RSV shedding and in improvements in transcutaneous oximetry readings. However, the mean duration of hospitalization was not reduced by IVIG treatment.⁷⁴

Sjogren's syndrome: IVIG has shown some efficacy in Sjogren's syndrome. Most of the reports have focused on associated dysautonomia or neuropathy although they have been very small case studies.^{43,69,92,110,113,153,154} One case study was of a 41 year old man with severe sympathetic and parasympathetic autonomic dysfunction as a consequence of acetylcholine receptor antibodies and Sjogren's syndrome who failed to respond to IVIG.¹⁹ Other published literature has described IVIG use for vasculitis of the skin and central nervous system.^{26,44} Larger, blinded and controlled studies of IVIG are required regarding its efficacy for Sjogren's syndrome.

Spontaneous recurrent abortions, prevention: Results of treatment with IVIG have been conflicting. While prospective studies have suggested that the use of IVIG in pregnant women with a history of recurrent abortions imparted a protective benefit, other studies suggested no benefit. The members of the Primary Immunodeficiency Committee of the American Academy of

Allergy, Asthma and Immunology assessed a review from a number of high-quality randomized, placebo-controlled, multicenter studies and found that, "Given the review of randomized trials, cumulative current evidence does not presently support the use of IVIG for the prevention of recurrent spontaneous abortions."⁸

In a Cochrane review by Porter et al., randomized trials of immunotherapies used to treat women with three or more prior miscarriages and no more than one live birth after were considered. Twenty trials of high quality were included. The various forms of immunotherapy investigated (paternal cell immunization, third party donor leukocytes, trophoblast membranes, and intravenous immune globulin) were found to provide no significant beneficial effect over placebo in improving the live birth rate.¹³²

Systemic lupus erythematosus: The use of IVIG in the treatment of systemic lupus erythematosus (SLE) has been studied in a few open label trials. In the first trial, 20 patients with severe thrombocytopenia associated with SLE received IVIG 2 g/kg for 5 consecutive days each month and patients received between 1-8 treatment courses.¹⁰² A beneficial response was noted in 17 out of 20 patients based on either the disappearance or marked clinical improvement of the main clinical manifestation. In 9 patients who had Systemic Lupus Activity Measure (SLAM) scores before and after IVIG, there was a significant reduction in SLAM scores (19.3 ± 4.7 to 4 ± 2.9 ; $p < 0.0001$). The average daily dose of prednisolone was decreased (29.7 ± 18.2 mg/day to 13.8 ± 16.7 mg/day; $p = 0.02$) and laboratory abnormalities improved after IVIG. Two other open label studies, with 12 patients each, showed similar results.^{54,147} In another trial, 14 patients with progressive lupus nephritis who had received cyclophosphamide 1 g/m² monthly for 6 months with 0.5 mg/kg/d of prednisone were randomized to cyclophosphamide 1 g/m² every 2 months for 6 months and then every 3 months for 1 year or to IVIG 400 mg/kg monthly for 18 months. The two groups were similar after randomization and at the end of follow-up.¹⁸ In a retrospective study of 59 SLE patients, 65% of the thirty-one subjects given IVIG had clinical improvement. However, responses were transient.¹¹ In other case reports high-dose IVIG led to disease resolution in patients with lupus affecting specific organs. However, there is limited anecdotal experience and concerns about potential prothrombotic effects and possible IVIG-associated azotemia in SLE.¹²²

Urticaria, chronic: A report of 5 patients with common variable immunodeficiency and chronic urticaria showed improvement of urticaria in response to IVIG therapy.⁵ The efficacy of IVIG (0.15 g/kg, for a minimum of 6 months and a maximum of 51 months) was also assessed in 29 outpatients (F=20, M=9) with the diagnosis of autoimmune chronic urticaria.¹²⁷ All the patients had unsatisfactory response to conventional therapy and a positive intradermal autologous serum test (AST). A clinical improvement was observed in 26 patients, with reduction of urticaria or angioedema complaints ($p < 0.0001$) and decreasing need for oral antihistamine medication ($p = 0.002$). The number of infusions needed to achieve clinical control showed great range between patients. In a report of delayed-pressure urticaria, a difficult-to-treat variant, 9 of 10 patients with chronic urticaria were reported to benefit from IVIG therapy, whereas, in another delayed-pressure urticaria report, no benefit was observed.^{12,119} The use of IVIG in patients with delayed-pressure urticaria was reported in another open trial.³⁷ One third of the enrolled patients underwent a remission, another third experienced some benefit, and the rest did not respond. Due to the conflicting evidence for IVIG in patients with chronic urticaria, additional studies are needed.

Vasculitides and antineutrophil antibody syndromes: The efficacy of IVIG in the treatment of anti-neutrophil cytoplasm antibody (ANCA)-associated systemic vasculitis (AASV) was assessed in a randomized, placebo-controlled trial.⁶⁶ Thirty four patients (24 diagnosed with Wegener's granulomatosis, 10 diagnosed with microscopic polyangiitis) were randomized to a single course of either 400 mg/kg/day IVIG or placebo for 5 days. A therapeutic response was defined as a 50% decrease in the Birmingham Vasculitis Activity Score (BVAS) at 3 months. A therapeutic response was found in 14/17 patients who received IVIG and 6/17 patients who received placebo (OR = 8.56, 95% CI = 1.74 - 42.2, $p = 0.015$). The C-reactive protein (CRP) level decrease was

significantly greater at 2 weeks and one month in the IVIG group compared to the placebo group. After 3 months, there was no difference in disease activity or CRP level between the IVIG and placebo groups. In addition, small open label trials of IVIG found some clinical benefit as an alternative therapeutic agent.^{82-85,103,107,138,139} Results were reported as transient in several of these. Additional randomized controlled trials will need to be conducted to determine its place in therapy.

Professional Societies

Immune Deficiency Foundation (IDF)

There are more than 250 primary immunodeficiency diseases (PIDs) recognized by the World Health Organization. The following diseases are PIDs and thus are proven indications for immune globulin (list not all inclusive). Additional PID information can be found at the IDF website: primaryimmune.org. [Back to criteria](#)

1. Autosomal recessive agammaglobulinemia
2. Autosomal recessive hyperimmunoglobulin M syndrome (HIM)
3. Bruton's disease
4. Chronic mucocutaneous moniliasis (CMC or APCED),
5. Combined immunodeficiency disorders
 - a. Ataxia-telangiectasia
 - b. DiGeorge syndrome
 - c. Nijmegen breakage syndrome
 - d. WHIM (warts, hypogammaglobulinemia, immunodeficiency, and myelokathexis) syndrome
 - e. Wiskott Aldrich syndrome
6. Common variable immunodeficiency (CVID)
7. Congenital hypogammaglobulinemia late onset, ICOS impaired
8. Congenital / X-linked agammaglobulinemia
9. Good syndrome (immunodeficiency with thymoma)
10. Hyperimmunoglobulinemia E syndrome
11. Hypogammaglobulinemia
12. ICF syndrome
13. Polyendocrinopathy and enteropathy (IPEX)
14. Selective IgG subclass deficiencies (persistent absence of IgG1, IgG2, and/or IgG3)
15. Selective IgM deficiency
16. Severe combined immunodeficiency
17. Specific antibody deficiency
18. Transient hypogammaglobulinemia of infancy, short-term treatment of recurrent severe bacterial infections
19. X-linked immunodeficiency with hyperimmunoglobulin M

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

There are currently eight clinical indications for which IVIG has been licensed by the United States Food and Drug Administration (FDA).¹⁵⁸ The indications can be summarized as follows:

- 1) treatment of primary immunodeficiencies such as common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies^{28,51,52,57-63,76,118,133,164,173}
- 2) prevention of bacterial infections in patients with hypogammaglobulinemia and recurrent bacterial infection caused by B-cell chronic lymphocytic leukemia⁵⁹
- 3) prevention of coronary artery aneurysms in Kawasaki disease (KD)⁵⁹
- 4) prevention of infections, pneumonitis, and acute graft-versus-host disease (GVHD) after bone marrow transplantation⁵⁷
- 5) reduction of serious bacterial infection in children with human immunodeficiency virus (HIV)⁵⁷

- 6) increase of platelet counts in idiopathic thrombocytopenic purpura to prevent or control bleeding^{28,57,58,60,62,63,133}
- 7) to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse in chronic inflammatory demyelinating polyneuropathy (CIDP)^{60,62,63}
- 8) as a maintenance therapy to improve muscle strength and disability in adult patients with multifocal motor neuropathy⁵⁸

Subcutaneous human immune globulin products are FDA approved for the treatment of patients with primary immune deficiency.^{60,63,76,164,193}

The FDA issued a Safety Communication dated November 13, 2012 to provide an update to their August 2002 interim statement regarding thrombotic events as a potential risk following the administration of human immunoglobulin.¹⁵⁹ The updated safety communication also addressed hemolysis, another risk potentially associated with the administration of human immune globulin.

In their update, the FDA issued the following recommendations regarding thrombosis:

- Care should be used when immune globulin products are given to individuals determined to be at increased risk of thrombosis.
- Patients at increased risk of thrombosis include those with acquired or hereditary hypercoagulable states, prolonged immobilization, in-dwelling vascular catheters, advanced age, estrogen use, a history of venous or arterial thrombosis, cardiovascular risk factors (including history of atherosclerosis and/or impaired cardiac output), and hyperviscosity (including cryoglobulins, fasting chylomicronemia and/or high triglyceride levels, and monoclonal gammopathies).
- Patients at risk for thrombosis should receive immune globulin products at the slowest infusion rate practicable, and should be monitored for thrombotic complications.
- Consideration should also be given to measurement of baseline blood viscosity in individuals at risk for hyperviscosity.

The FDA also issued the following recommendations regarding hemolysis:

- Patients at increased risk for hemolysis following treatment with immune globulins include those with non-O blood group types, those who have underlying associated inflammatory conditions, and those receiving high cumulative doses of immune globulins over the course of several days.
- Clinical symptoms and signs of hemolysis include fever, chills and dark urine. If these occur, appropriate laboratory testing should be obtained.

The FDA issued a Safety Communication dated June 10, 2013 to report that a recent data analysis that has strengthened the association between the use of intravenous, subcutaneous and intramuscular human immune globulin products and the risk of thrombosis.¹⁷⁶ Because additional caution regarding the use of these products is warranted, the FDA is requiring manufacturers to add information on thrombosis to the current boxed warning in the labels of all intravenous human immune globulin products and to add a boxed warning to the labels of all subcutaneous and intramuscular human immune globulin products to highlight the risk of thrombosis and to add information on its mitigation.

APPLICABLE CODES

The Current Procedural Terminology (CPT[®]) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT Code	Description
90283	Immune globulin (IgIV), human, for intravenous use
90284	Immune globulin (SCIG), human, for use in subcutaneous infusions, 100 mg, each

HCPCS Code	Description
J1459	Injection, immune globulin (Privigen), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1556	Injection, immune globulin (Bivigam), 500 mg
J1557	Injection, immune globulin, (Gammalex), intravenous, non-lyophilized (e.g. liquid), 500 mg
J1559	Injection, immune globulin (Hizentra), 100 mg
J1561	Injection, immune globulin, (Gamunex-C/Gammaked), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1566	Injection, immune globulin, intravenous, lyophilized (e.g., powder), not otherwise specified, 500 mg
J1568	Injection, immune globulin, (Octagam), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1569	Injection, immune globulin, (Gammagard liquid), intravenous, nonlyophilized, (e.g., liquid), 500 mg
J1572	Injection, immune globulin, (Flebogamma/Flebogamma DIF), intravenous, nonlyophilized (e.g., liquid), 500 mg
J1575	Injection, immune globulin/hyaluronidase, (Hyqvia), 100 mg immunoglobulin
J1599	Injection, immune globulin, intravenous, nonlyophilized (e.g., liquid), not otherwise specified, 500 mg

ICD-9 Codes (Discontinued 10/1/15)

The following list of codes is provided for reference purposes only. Effective October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) implemented ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures), replacing the ICD-9-CM diagnosis and procedure code sets.

ICD-9 codes will not be accepted for services provided on or after October 1, 2015.

ICD-9 Code (Discontinued 10/1/2015)	Description
008.61	Intestinal infection, enteritis due to rotavirus
040.82	Toxic shock syndrome
042	Human immunodeficiency virus [HIV]
047.0	Meningitis due to enterovirus; Coxsackie virus
047.1	Meningitis due to enterovirus; ECHO virus
047.8	Meningitis due to enterovirus; other specific viral meningitis
047.9	Meningitis due to enterovirus; unspecified viral meningitis
048	Other enterovirus diseases of central nervous system
204.10	Chronic lymphoid leukemia, without mention of having achieved remission
204.11	Chronic lymphoid leukemia in remission
204.12	Chronic lymphoid leukemia, in relapse
238.79	Neoplasm of uncertain behavior of other and unspecified sites and tissues; other lymphatic and hematopoietic tissues
242.00	Toxic diffuse goiter without mention of thyrotoxic crisis or storm
242.01	Toxic diffuse goiter with mention of thyrotoxic crisis or storm
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled

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250.33	Diabetes with other coma, type I [juvenile type], uncontrolled
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled
258.1	Other combinations of endocrine dysfunction
273.1	Monoclonal paraproteinemia
279.00	Unspecified hypogammaglobulinemia
279.02	Selective IgM immunodeficiency
279.03	Other selective immunoglobulin deficiencies
279.04	Congenital hypogammaglobulinemia
279.05	Immunodeficiency with increased IgM
279.06	Common variable immunodeficiency
279.09	Other deficiency of humoral immunity
279.10	Immunodeficiency with predominant T-cell defect, unspecified
279.11	DiGeorge's syndrome
279.12	Wiskott-Aldrich syndrome
279.2	Combined immunity deficiency
279.3	Unspecified immunity deficiency
279.41	Autoimmune lymphoproliferative syndrome
279.51	Acute graft-versus-host disease
279.53	Acute on chronic graft-versus-host disease
279.8	Other specified disorders involving the immune mechanism
279.9	Unspecified disorder of immune mechanism
287.31	Immune thrombocytopenic purpura
287.41	Posttransfusion purpura
287.49	Other secondary thrombocytopenia
323.01	Encephalitis and encephalomyelitis in viral diseases classified elsewhere
323.02	Myelitis in viral diseases classified elsewhere
323.81	Other causes of encephalitis and encephalomyelitis
323.9	Unspecified cause of encephalitis, myelitis, and encephalomyelitis
333.91	Stiff-man syndrome
334.8	Other spinocerebellar diseases
340	Multiple sclerosis
341.0	Neuromyelitis optica
345.80	Other forms of epilepsy and recurrent seizures, without mention of intractable epilepsy
345.81	Other forms of epilepsy and recurrent seizures, with intractable epilepsy
357.0	Acute infective polyneuritis
357.4	Polyneuropathy in other diseases classified elsewhere
357.81	Chronic inflammatory demyelinating polyneuritis
357.89	Other inflammatory and toxic neuropathy
357.9	Inflammatory and toxic neuropathy; Unspecified
358.01	Myasthenia gravis with (acute) exacerbation
358.30	Lambert-Eaton syndrome, unspecified

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358.31	Lambert-Eaton syndrome in neoplastic disease
358.39	Lambert-Eaton syndrome in other diseases classified elsewhere
364.00	Unspecified acute and subacute iridocyclitis
364.01	Primary iridocyclitis
364.02	Recurrent iridocyclitis
364.04	Secondary iridocyclitis, noninfectious
446.1	Acute febrile mucocutaneous lymph node syndrome (MCLS)
484.1	Pneumonia in cytomegalic inclusion disease
493.01	Extrinsic asthma with status asthmaticus
493.02	Extrinsic asthma, with (acute) exacerbation
493.11	Intrinsic asthma with status asthmaticus
493.12	Intrinsic asthma, with (acute) exacerbation
646.80	Other specified complication of pregnancy, unspecified as to episode of care
646.81	Other specified complication of pregnancy, with delivery
646.83	Other specified complication, antepartum
694.4	Pemphigus
694.5	Pemphigoid
694.60	Benign mucous membrane pemphigoid without mention of ocular involvement
694.61	Benign mucous membrane pemphigoid with ocular involvement
694.8	Other specified bullous dermatosis
695.13	Stevens-Johnson syndrome
695.14	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
695.15	Toxic epidermal necrolysis
708.8	Other specified urticaria
710.3	Dermatomyositis
710.4	Polymyositis
714.0	Rheumatoid arthritis
714.1	Felty's syndrome
714.2	Other rheumatoid arthritis with visceral or systemic involvement
714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified
714.31	Polyarticular juvenile rheumatoid arthritis, acute
714.32	Pauciarticular juvenile rheumatoid arthritis
714.33	Monoarticular juvenile rheumatoid arthritis
776.1	Transient neonatal thrombocytopenia
996.81	Complications of transplanted organ; kidney
996.85	Complications of transplanted organ; bone marrow
V42.81	Bone marrow replaced by transplant
V42.82	Peripheral stem cells replaced by transplant

ICD-10 Codes (Effective 10/1/15)

ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures) must be used to report diagnoses for services provided on or after October 1, 2015.

ICD-10 codes will not be accepted for services provided prior to October 1, 2015.

ICD-10 Diagnosis Code (Effective 10/1/15)	Description
A08.0	Rotaviral enteritis
A48.3	Toxic shock syndrome
A87.0	Enteroviral meningitis
A87.8	Other viral meningitis
A87.9	Viral meningitis, unspecified

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A88.0	Enteroviral exanthematous fever [Boston □xanthema]
A88.8	Other specified viral infections of central nervous system
B20	Human immunodeficiency virus [HIV] disease
B25.0	Cytomegaloviral pneumonitis
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D47.2	Monoclonal gammopathy
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D69.3	Immune thrombocytopenic purpura
D69.51	Posttransfusion purpura
D69.59	Other secondary thrombocytopenia
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.8	Other specified immunodeficiencies
D89.2	Hypergammaglobulinemia, unspecified
D89.810	Acute graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
E05.01	Thyrotoxicosis with diffuse goiter with thyrotoxic crisis or storm
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma
E10.21	Type 1 diabetes mellitus with diabetic nephropathy
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema

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E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.59	Type 1 diabetes mellitus with other circulatory complications
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy
E10.620	Type 1 diabetes mellitus with diabetic dermatitis
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E10.628	Type 1 diabetes mellitus with other skin complications
E10.630	Type 1 diabetes mellitus with periodontal disease
E10.638	Type 1 diabetes mellitus with other oral complications
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications
E31.0	Autoimmune polyglandular failure
G04.81	Other encephalitis and encephalomyelitis
G04.90	Encephalitis and encephalomyelitis, unspecified
G05.3	Encephalitis and encephalomyelitis in diseases classified elsewhere
G05.4	Myelitis in diseases classified elsewhere
G11.3	Cerebellar ataxia with defective DNA repair
G25.82	Stiff-man syndrome
G35	Multiple sclerosis
G36.0	Neuromyelitis optica [Devic]
G40.811	Lennox-Gastaut syndrome, not intractable, with status epilepticus
G40.812	Lennox-Gastaut syndrome, not intractable, without status epilepticus
G40.813	Lennox-Gastaut syndrome, intractable, with status epilepticus
G40.814	Lennox-Gastaut syndrome, intractable, without status epilepticus
G61.0	Guillain-Barré syndrome
G61.81	Chronic inflammatory demyelinating polyneuritis
G61.89	Other inflammatory polyneuropathies
G61.9	Inflammatory polyneuropathy, unspecified
G62.89	Other specified polyneuropathies
G62.9	Polyneuropathy, unspecified
G65.0	Sequelae of Guillain-Barré syndrome
G70.01	Myasthenia gravis with (acute) exacerbation

G70.80	Lambert-Eaton syndrome, unspecified
G70.81	Lambert-Eaton syndrome in disease classified elsewhere
G73.1	Lambert-Eaton syndrome in neoplastic disease
H20.00	Unspecified acute and subacute iridocyclitis
H20.011	Primary iridocyclitis, right eye
H20.012	Primary iridocyclitis, left eye
H20.013	Primary iridocyclitis, bilateral
H20.019	Primary iridocyclitis, unspecified eye
H20.021	Recurrent acute iridocyclitis, right eye
H20.022	Recurrent acute iridocyclitis, left eye
H20.023	Recurrent acute iridocyclitis, bilateral
H20.029	Recurrent acute iridocyclitis, unspecified eye
H20.041	Secondary noninfectious iridocyclitis, right eye
H20.042	Secondary noninfectious iridocyclitis, left eye
H20.043	Secondary noninfectious iridocyclitis, bilateral
H20.049	Secondary noninfectious iridocyclitis, unspecified eye
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
L10.0	Pemphigus vulgaris
L10.2	Pemphigus foliaceus
L12.0	Bullous pemphigoid
L12.1	Cicatricial pemphigoid
L12.30	Acquired epidermolysis bullosa, unspecified
L12.35	Other acquired epidermolysis bullosa
L13.8	Other specified bullous disorders
L50.8	Other urticaria
L51.1	Stevens-Johnson syndrome
L51.2	Toxic epidermal necrolysis [Lyell]
L51.3	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
M05.00	Felty's syndrome, unspecified site
M05.011	Felty's syndrome, right shoulder
M05.012	Felty's syndrome, left shoulder
M05.019	Felty's syndrome, unspecified shoulder
M05.021	Felty's syndrome, right elbow
M05.022	Felty's syndrome, left elbow
M05.029	Felty's syndrome, unspecified elbow
M05.031	Felty's syndrome, right wrist
M05.032	Felty's syndrome, left wrist
M05.039	Felty's syndrome, unspecified wrist
M05.041	Felty's syndrome, right hand
M05.042	Felty's syndrome, left hand
M05.049	Felty's syndrome, unspecified hand
M05.051	Felty's syndrome, right hip
M05.052	Felty's syndrome, left hip
M05.059	Felty's syndrome, unspecified hip
M05.061	Felty's syndrome, right knee
M05.062	Felty's syndrome, left knee
M05.069	Felty's syndrome, unspecified knee
M05.071	Felty's syndrome, right ankle and foot
M05.072	Felty's syndrome, left ankle and foot
M05.079	Felty's syndrome, unspecified ankle and foot
M05.09	Felty's syndrome, multiple sites
M05.20	Rheumatoid vasculitis with rheumatoid arthritis of unspecified site

M05.211	Rheumatoid vasculitis with rheumatoid arthritis of right shoulder
M05.212	Rheumatoid vasculitis with rheumatoid arthritis of left shoulder
M05.219	Rheumatoid vasculitis with rheumatoid arthritis of unspecified shoulder
M05.221	Rheumatoid vasculitis with rheumatoid arthritis of right elbow
M05.222	Rheumatoid vasculitis with rheumatoid arthritis of left elbow
M05.229	Rheumatoid vasculitis with rheumatoid arthritis of unspecified elbow
M05.231	Rheumatoid vasculitis with rheumatoid arthritis of right wrist
M05.232	Rheumatoid vasculitis with rheumatoid arthritis of left wrist
M05.239	Rheumatoid vasculitis with rheumatoid arthritis of unspecified wrist
M05.241	Rheumatoid vasculitis with rheumatoid arthritis of right hand
M05.242	Rheumatoid vasculitis with rheumatoid arthritis of left hand
M05.249	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hand
M05.251	Rheumatoid vasculitis with rheumatoid arthritis of right hip
M05.252	Rheumatoid vasculitis with rheumatoid arthritis of left hip
M05.259	Rheumatoid vasculitis with rheumatoid arthritis of unspecified hip
M05.261	Rheumatoid vasculitis with rheumatoid arthritis of right knee
M05.262	Rheumatoid vasculitis with rheumatoid arthritis of left knee
M05.269	Rheumatoid vasculitis with rheumatoid arthritis of unspecified knee
M05.271	Rheumatoid vasculitis with rheumatoid arthritis of right ankle and foot
M05.272	Rheumatoid vasculitis with rheumatoid arthritis of left ankle and foot
M05.279	Rheumatoid vasculitis with rheumatoid arthritis of unspecified ankle and foot
M05.29	Rheumatoid vasculitis with rheumatoid arthritis of multiple sites
M05.30	Rheumatoid heart disease with rheumatoid arthritis of unspecified site
M05.311	Rheumatoid heart disease with rheumatoid arthritis of right shoulder
M05.312	Rheumatoid heart disease with rheumatoid arthritis of left shoulder
M05.319	Rheumatoid heart disease with rheumatoid arthritis of unspecified shoulder
M05.321	Rheumatoid heart disease with rheumatoid arthritis of right elbow
M05.322	Rheumatoid heart disease with rheumatoid arthritis of left elbow
M05.329	Rheumatoid heart disease with rheumatoid arthritis of unspecified elbow
M05.331	Rheumatoid heart disease with rheumatoid arthritis of right wrist
M05.332	Rheumatoid heart disease with rheumatoid arthritis of left wrist
M05.339	Rheumatoid heart disease with rheumatoid arthritis of unspecified wrist
M05.341	Rheumatoid heart disease with rheumatoid arthritis of right hand
M05.342	Rheumatoid heart disease with rheumatoid arthritis of left hand
M05.349	Rheumatoid heart disease with rheumatoid arthritis of unspecified hand
M05.351	Rheumatoid heart disease with rheumatoid arthritis of right hip
M05.352	Rheumatoid heart disease with rheumatoid arthritis of left hip
M05.359	Rheumatoid heart disease with rheumatoid arthritis of unspecified hip
M05.361	Rheumatoid heart disease with rheumatoid arthritis of right knee
M05.362	Rheumatoid heart disease with rheumatoid arthritis of left knee
M05.369	Rheumatoid heart disease with rheumatoid arthritis of unspecified knee
M05.371	Rheumatoid heart disease with rheumatoid arthritis of right ankle and foot
M05.372	Rheumatoid heart disease with rheumatoid arthritis of left ankle and foot
M05.379	Rheumatoid heart disease with rheumatoid arthritis of unspecified ankle and foot
M05.39	Rheumatoid heart disease with rheumatoid arthritis of multiple sites
M05.40	Rheumatoid myopathy with rheumatoid arthritis of unspecified site
M05.411	Rheumatoid myopathy with rheumatoid arthritis of right shoulder
M05.412	Rheumatoid myopathy with rheumatoid arthritis of left shoulder
M05.419	Rheumatoid myopathy with rheumatoid arthritis of unspecified shoulder
M05.421	Rheumatoid myopathy with rheumatoid arthritis of right elbow
M05.422	Rheumatoid myopathy with rheumatoid arthritis of left elbow
M05.429	Rheumatoid myopathy with rheumatoid arthritis of unspecified elbow
M05.431	Rheumatoid myopathy with rheumatoid arthritis of right wrist

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M05.432	Rheumatoid myopathy with rheumatoid arthritis of left wrist
M05.439	Rheumatoid myopathy with rheumatoid arthritis of unspecified wrist
M05.441	Rheumatoid myopathy with rheumatoid arthritis of right hand
M05.442	Rheumatoid myopathy with rheumatoid arthritis of left hand
M05.449	Rheumatoid myopathy with rheumatoid arthritis of unspecified hand
M05.451	Rheumatoid myopathy with rheumatoid arthritis of right hip
M05.452	Rheumatoid myopathy with rheumatoid arthritis of left hip
M05.459	Rheumatoid myopathy with rheumatoid arthritis of unspecified hip
M05.461	Rheumatoid myopathy with rheumatoid arthritis of right knee
M05.462	Rheumatoid myopathy with rheumatoid arthritis of left knee
M05.469	Rheumatoid myopathy with rheumatoid arthritis of unspecified knee
M05.471	Rheumatoid myopathy with rheumatoid arthritis of right ankle and foot
M05.472	Rheumatoid myopathy with rheumatoid arthritis of left ankle and foot
M05.479	Rheumatoid myopathy with rheumatoid arthritis of unspecified ankle and foot
M05.49	Rheumatoid myopathy with rheumatoid arthritis of multiple sites
M05.50	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified site
M05.511	Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder
M05.512	Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder
M05.519	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified shoulder
M05.521	Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow
M05.522	Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow
M05.529	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified elbow
M05.531	Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist
M05.532	Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist
M05.539	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified wrist
M05.541	Rheumatoid polyneuropathy with rheumatoid arthritis of right hand
M05.542	Rheumatoid polyneuropathy with rheumatoid arthritis of left hand
M05.549	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hand
M05.551	Rheumatoid polyneuropathy with rheumatoid arthritis of right hip
M05.552	Rheumatoid polyneuropathy with rheumatoid arthritis of left hip
M05.559	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified hip
M05.561	Rheumatoid polyneuropathy with rheumatoid arthritis of right knee
M05.562	Rheumatoid polyneuropathy with rheumatoid arthritis of left knee
M05.569	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified knee
M05.571	Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot
M05.572	Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot
M05.579	Rheumatoid polyneuropathy with rheumatoid arthritis of unspecified ankle and foot
M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.611	Rheumatoid arthritis of right shoulder with involvement of other organs and systems
M05.612	Rheumatoid arthritis of left shoulder with involvement of other organs and systems
M05.619	Rheumatoid arthritis of unspecified shoulder with involvement of other organs and systems
M05.621	Rheumatoid arthritis of right elbow with involvement of other organs and systems
M05.622	Rheumatoid arthritis of left elbow with involvement of other organs and systems
M05.629	Rheumatoid arthritis of unspecified elbow with involvement of other organs and systems
M05.631	Rheumatoid arthritis of right wrist with involvement of other organs and systems
M05.632	Rheumatoid arthritis of left wrist with involvement of other organs and systems
M05.639	Rheumatoid arthritis of unspecified wrist with involvement of other organs and systems
M05.641	Rheumatoid arthritis of right hand with involvement of other organs and systems
M05.642	Rheumatoid arthritis of left hand with involvement of other organs and systems
M05.649	Rheumatoid arthritis of unspecified hand with involvement of other organs and systems
M05.651	Rheumatoid arthritis of right hip with involvement of other organs and systems
M05.652	Rheumatoid arthritis of left hip with involvement of other organs and systems

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M05.659	Rheumatoid arthritis of unspecified hip with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.671	Rheumatoid arthritis of right ankle and foot with involvement of other organs and systems
M05.672	Rheumatoid arthritis of left ankle and foot with involvement of other organs and systems
M05.679	Rheumatoid arthritis of unspecified ankle and foot with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M05.711	Rheumatoid arthritis with rheumatoid factor of right shoulder without organ or systems involvement
M05.712	Rheumatoid arthritis with rheumatoid factor of left shoulder without organ or systems involvement
M05.719	Rheumatoid arthritis with rheumatoid factor of unspecified shoulder without organ or systems involvement
M06.1	Adult-onset Still's disease
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.019	Unspecified juvenile rheumatoid arthritis, unspecified shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.029	Unspecified juvenile rheumatoid arthritis, unspecified elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.039	Unspecified juvenile rheumatoid arthritis, unspecified wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.049	Unspecified juvenile rheumatoid arthritis, unspecified hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.059	Unspecified juvenile rheumatoid arthritis, unspecified hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.069	Unspecified juvenile rheumatoid arthritis, unspecified knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.079	Unspecified juvenile rheumatoid arthritis, unspecified ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.20	Juvenile rheumatoid arthritis with systemic onset, unspecified site
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.219	Juvenile rheumatoid arthritis with systemic onset, unspecified shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.229	Juvenile rheumatoid arthritis with systemic onset, unspecified elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.239	Juvenile rheumatoid arthritis with systemic onset, unspecified wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand

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M08.249	Juvenile rheumatoid arthritis with systemic onset, unspecified hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.259	Juvenile rheumatoid arthritis with systemic onset, unspecified hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.269	Juvenile rheumatoid arthritis with systemic onset, unspecified knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.279	Juvenile rheumatoid arthritis with systemic onset, unspecified ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.40	Pauciarticular juvenile rheumatoid arthritis, unspecified site
M08.411	Pauciarticular juvenile rheumatoid arthritis, right shoulder
M08.412	Pauciarticular juvenile rheumatoid arthritis, left shoulder
M08.419	Pauciarticular juvenile rheumatoid arthritis, unspecified shoulder
M08.421	Pauciarticular juvenile rheumatoid arthritis, right elbow
M08.422	Pauciarticular juvenile rheumatoid arthritis, left elbow
M08.429	Pauciarticular juvenile rheumatoid arthritis, unspecified elbow
M08.431	Pauciarticular juvenile rheumatoid arthritis, right wrist
M08.432	Pauciarticular juvenile rheumatoid arthritis, left wrist
M08.439	Pauciarticular juvenile rheumatoid arthritis, unspecified wrist
M08.441	Pauciarticular juvenile rheumatoid arthritis, right hand
M08.442	Pauciarticular juvenile rheumatoid arthritis, left hand
M08.449	Pauciarticular juvenile rheumatoid arthritis, unspecified hand
M08.451	Pauciarticular juvenile rheumatoid arthritis, right hip
M08.452	Pauciarticular juvenile rheumatoid arthritis, left hip
M08.459	Pauciarticular juvenile rheumatoid arthritis, unspecified hip
M08.461	Pauciarticular juvenile rheumatoid arthritis, right knee
M08.462	Pauciarticular juvenile rheumatoid arthritis, left knee
M08.469	Pauciarticular juvenile rheumatoid arthritis, unspecified knee
M08.471	Pauciarticular juvenile rheumatoid arthritis, right ankle and foot
M08.472	Pauciarticular juvenile rheumatoid arthritis, left ankle and foot
M08.479	Pauciarticular juvenile rheumatoid arthritis, unspecified ankle and foot
M08.48	Pauciarticular juvenile rheumatoid arthritis, vertebrae
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee

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M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, vertebrae
M08.89	Other juvenile arthritis, multiple sites
M08.90	Juvenile arthritis, unspecified, unspecified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
M30.3	Mucocutaneous lymph node syndrome [Kawasaki]
M33.00	Juvenile dermatopolymyositis, organ involvement unspecified
M33.01	Juvenile dermatopolymyositis with respiratory involvement
M33.02	Juvenile dermatopolymyositis with myopathy
M33.09	Juvenile dermatopolymyositis with other organ involvement
M33.10	Other dermatopolymyositis, organ involvement unspecified
M33.11	Other dermatopolymyositis with respiratory involvement
M33.12	Other dermatopolymyositis with myopathy
M33.19	Other dermatopolymyositis with other organ involvement
M33.20	Polymyositis, organ involvement unspecified
M33.21	Polymyositis with respiratory involvement
M33.22	Polymyositis with myopathy
M33.29	Polymyositis with other organ involvement
M33.90	Dermatopolymyositis, unspecified, organ involvement unspecified
M33.91	Dermatopolymyositis, unspecified with respiratory involvement
M33.92	Dermatopolymyositis, unspecified with myopathy
M33.99	Dermatopolymyositis, unspecified with other organ involvement
M36.0	Dermato(poly)myositis in neoplastic disease
O26.40	Herpes gestationis, unspecified trimester
O26.41	Herpes gestationis, first trimester
O26.42	Herpes gestationis, second trimester
O26.43	Herpes gestationis, third trimester

P61.0	Transient neonatal thrombocytopenia
T86.00	Unspecified complication of bone marrow transplant
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.10	Unspecified complication of kidney transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant
Z48.290	Encounter for aftercare following bone marrow transplant
Z94.81	Bone marrow transplant status
Z94.84	Stem cells transplant status

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
2/1/2016	Annual Review. Added titration to minimum effective dose to general requirements. Consolidated clinical criteria for bone marrow transplantation, renal transplantation, and secondary thrombocytopenia, Added J1575. Updated ICD9 & ICD10 codes. Approved by the National Pharmacy & Therapeutics Committee on 11/18/2015. Policy 2015D0035R archived.
10/1/2015	Updated Applicable Codes for ICD-10 transition. Policy 2015D0035Q archived.
3/1/2015	Policy updated to include trial/failure language to myasthenia gravis. Updated Benefits Consideration. Removed J1562. Added codes 279.02 and D80.4. Approved by the National Pharmacy & Therapeutics Committee on 2/18/2015. Policy 2015D0035P archived.
1/1/2015	Policy updated to include HyQvia and additional language supporting new products and SCIG dosing. Removed NJ language. Approved by the National Pharmacy & Therapeutics Committee on 11/19/2014. Policy 2014D0035O archived.
9/1/2014	Added NMO and secondary thrombocytopenia as proven uses. Updated medical necessity criteria for ITP. Clarified examples of PID subtypes. Updated clinical evidence and references. Updated list of ICD-9 codes (added 204.11, 287.49, 341.0, 647.60, 647.61, 647.63, and 647.64) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 7/8/2014. Policy 2014D0035N archived.
4/1/2014	Clarified General Criteria for Medical Necessity Review. Revised dosing criteria for ITP and PID. Added dose titration criterion to asthma, autoimmune bullous diseases, CIDP, dermatomyositis, polymyositis, Guillain-Barré syndrome, LEMS, Lennox Gastaut syndrome, MMN, MS, and stiff person syndrome. Removed concomitant immunomodulator requirement from continuation of therapy criteria for CIDP and MMN. Updated clinical evidence and references. Updated list of ICD-9 codes (added 334.8 and 448.0) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 2/18/2014. Policy 2013D0035M archived.
1/1/2014	Policy updated with code J1556, effective on 1/1/2014.
N/A	Added product selection criteria. Approved by the National Pharmacy & Therapeutics Committee on 11/12/2013.
12/1/2013	Full policy review. Removed Gamunex from list of products. Changed "myasthenia gravis, acute exacerbation" to "myasthenic exacerbation," and revised medical necessity criteria for this indication. Revised medical necessity criteria for CIDP, dermatomyositis and polymyositis, GBS, LEMS, MMN, MS, and stiff-person syndrome. Specified that IVIG is proven in allogeneic BMT. Added treatment of acute GVHD after autologous BMT, prevention of infection after autologous BMT, and ocular myasthenia to the list of unproven uses. Added FDA Safety Communication. Updated clinical evidence and references. Updated list of ICD-9 codes (added 355.9) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 10/8/2013. Policy 2013D0035L archived.
6/1/2013	Revised dosing for prevention of infection and prevention of GVHD after BMT and for fetomaternal alloimmune thrombocytopenia. Approved by the National Pharmacy & Therapeutics Committee on 4/9/2013. Policy 2013D0035K archived.
4/1/2013	Policy updated. Added Bivigam to list of products. Updated list of ICD-9 codes (added 242.00 and 242.01, and removed 242.0, 287.33, 337.00, 337.09, 356.9, 358.00, 714.4, and 776.7) and associated ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 2/19/2013.
4/1/2013	Annual policy review. Removed Vivaglobin from list of products. Added Alzheimer's

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	disease to the list of unproven uses. Revised paraproteinemic neuropathy from unproven to proven use. Reformatted list of proven and unproven uses to appear in alphabetical order. Added medical necessity criteria. Updated clinical evidence and references. Added FDA Safety Communication. Added CPT codes 90283 and 90284 to the policy. Updated list of ICD-9 codes (added 204.12, 279.11, 279.8, 279.9, 288.09, 288.1, 323.01, 323.02, 323.9, 357.9, 484.1, 646.80, 646.81, 646.82, 646.83, 646.84, 678.00, 678.03, 757.39, 776.8, and 776.9, and removed 038.10, 041.01, 279.02, 337.01, 694.0, 772.10, 772.11, 772.12, 772.13, 772.14, 995.91, and 995.92) and applicable ICD-10 codes. Approved by the National Pharmacy & Therapeutics Committee on 11/13/2012. Modifications to policy based upon societal input approved by the National Pharmacy & Therapeutics Committee on 12/14/2012. Policy 2012D0035J archived.
11/1/2012	Policy updated. Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infection (PANDAS) revised to unproven use. Updated FDA section to list multifocal motor neuropathy as a new indication for Gammagard. Updated clinical evidence and references. Updated list of ICD-9 codes (added 337.00, 337.01, 337.09, 772.10, 772.11, 772.12, 772.13, 772.14, and 773.2, and removed 337.0, 493, 772.1, and 996.8). Added list of applicable ICD-10 codes (preview draft) in preparation for the transition from ICD-9 to ICD-10 medical coding on 10/01/14. Approved by the National Pharmacy & Therapeutics Committee on 7/10/2012. Policy 2012D0035I archived.
3/1/2012	Policy updated. Added Gammaked to list of products. Approved by the National Pharmacy & Therapeutics Committee on 1/10/2012. Policy 2012D0035H archived.
2/1/2012	Policy updated. Gammagard Liquid added to list of subcutaneous products. Prevention and treatment of neonatal sepsis revised to unproven status. Addition of Clinical Evidence related to treatment and prevention of neonatal sepsis. Updated list of proven ICD-9 codes (removed 771.81). Added code J1557, which became effective on 1/1/2012. Approved by the National Pharmacy & Therapeutics Committee on 11/8/2011. Policy 2012D0035G archived.
1/1/2012	Policy updated with code J1557, effective on 1/1/2012. Policy 2011D0035F archived.
10/1/2011	Policy updated with addition of ICD-9 codes 358.30, 358.31, and 358.39, which became effective on 10/1/2011. Incomplete ICD-9 code 041.0 updated to 041.01. Policy 2011D0035E archived.
9/1/2011	Annual policy review. Added Flebogamma DIF and Gamunex-C to list of products. Autoimmune blistering skin diseases revised to proven use. Revised proven status and evidence for intractable childhood epilepsy to be specific to Lennox Gastaut syndrome. Updated list of proven ICD-9 codes (added 041.0, 238.79, 242.0, 273.1, 279.51, 279.53, 323.81, 337.0, 345.00, 345.01, 345.10, 345.11, 493, 493.01, 493.11, 493.21, 694.0, 694.4, 694.5, 694.60, 694.61, 694.8, 695.13, 695.14, 695.15, 708.5, 708.8, 772.1, 776.7, 995.91, 995.92, 996.8, 996.81, and 996.85, and removed 204.00 and 446.6). Removed all unproven ICD-9 codes from the policy because standard policy format is to list only proven ICD-9 codes. Approved by the National Pharmacy & Therapeutics Committee on 7/12/2011. Policy 2010D0035D archived.
1/5/2011	Policy updated with addition of codes J1559 and J1599, which became effective on 1/1/2011.
11/14/2010	Removed 287.4 from and added 287.41 to list of proven ICD-9 codes.
8/16/2010	Policy revised per annual review. Posttransfusion purpura revised to proven use. Clinical evidence and references revised. Switched ICD-9 287.4 to proven. Approved by the National Pharmacy & Therapeutics Committee on 5/11/2010. Added Gammaplex to list of products and information to Background section regarding product IgG content. Approved by the National Pharmacy & Therapeutics Committee on 8/11/2010. Policy 2009D0035C archived.
11/16/2009	Updated list of proven indications for immune globulin (IVIG) to add fetomaternal alloimmune thrombocytopenia; enteroviral meningoencephalitis; staphylococcal toxic shock; treatment of acute humoral rejection in renal transplantation; and primary immune defects with normogammaglobulinemia and impaired specific antibody production. Revised coverage rationale to indicate the use of IVIG for the treatment of diabetes

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	mellitus is proven for autoimmune, type 1 diabetes mellitus only and the use of IVIG for the treatment of multiple sclerosis (MS) is proven for relapsing-remitting multiple sclerosis only. Updated the list of unproven indications to include Sjogren's syndrome. Updated list of proven ICD-9 codes (added 038.10, 040.82, 048, 279.12, and 776.1 and removed 249.00-249.91, 250.00, 250.02, 250.10, 250.12, 250.20, 250.22, 250.30, 250.32, 250.40, 250.42, 250.50, 250.52, 250.60, 250.62, 250.70, 250.72, 250.80, 250.82, 250.90, 250.92, 279.01 and 694.60). Approved by National Pharmacy & Therapeutics Committee on 6/9/2009. Policy 2008D0035B archived.
7/7/2009	Policy updated with separation of monoclonal gammopathy and multiple sclerosis (MS) diagnoses in neuroimmunologic disorders section.
1/2/2009	Policy updated with deletion of codes G0332 and Q4097 and addition of code J1459. Policy 2008D0035A archived.
11/7/2008	New ICD9 code added 90283.
9/17/2008	New ICD9 Codes for Diabetes added as Proven.
9/16/2008	Diagnosis codes 279.01 and 279.02 added as Proven.
8/18/2008	Diagnosis codes 279.00 and 279.03 added to Proven Diagnosis Code list per National Pharmacy & Therapeutics Committee.
6/30/2008	Proven diagnosis code list updated per Manager, Coding and Integrity.
6/30/2008	Diagnosis code 279.00 removed and 358.1 added to Proven Diagnosis Code list per Manger, Coding and Integrity.
4/22/2008	Diagnosis codes 279.05 and 279.06 removed from Unproven Diagnosis Codes per Manager, Coding and Integrity.
4/10/2008	Immune Globulin (IVIG)2008D0035A replaces the previous policies, Intravenous Immune Serum Globulin (IVIG) for Recurrent Spontaneous Abortion 2006D0009B; Intravenous Immune Globulin (IVig) Use in Rheumatological Disorders 2005D0015C; Intravenous Immune Globulin (IVig) Use in Neurological and Neuromuscular Disorders 2005D0014C; Intravenous Immune Globulin (IVig) Use in Infectious Disease 2005D2019C; Intravenous Immune Globulin (IVig) Use in Miscellaneous Disorders 2007D0020D; Intravenous Immune Globulin (IVig) Use in Hematological Disorders 2005D0018C. Previous policies were archived.

**7. Response to State Health Plan's Current CON
Criteria for Home Health Agencies**

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AxelaCare Health Resources--CN 1606-022
Supplemental Response to Application Section C.Need, Item 1
(Specific Criteria: Home Health)

Standards and Criteria--State Health Plan

- 1. Determination of Need: In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. This 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed Service Area.**
- 2. The need for home health services should be projected three years from the latest available year of final JAR data.**
- 3. The use rate of existing home health agencies in each county of the Service Area will be determined by examining the latest utilization rate as calculated from the JARs of existing home health agencies in the Service Area. Based on the number of patients served by home health agencies in the Service Area, an estimation will be made as to how many patients could be served in the future.**

In the table on page 29 of the CON application, TDOH projected the service area need/surplus in conformity to criteria 1 and 3 above, but used its customary 4-year (2020) projection horizon for calculating need as specified in an earlier version of these Guidelines.

At the end of this response, the applicant is submitting a Supplemental Table One, a revised Need projection that uses the 2018 population projections of the TDOH to comply with the 3-year planning horizon now specified in the current State Plan. The table indicates a surplus capacity of 15,122 patients, based on the 1.5% criterion and the most recent (2015) JAR home health data. This surplus varies insignificantly from the 15,237 surplus the TDOH projected on a four-year horizon (CY2020) in the original application.

This projected surplus is neither accurate nor relevant to this specialty project. First, the projection methodology is stated as a "general guideline" and it uses a simple 1.5% "need" planning factor for each county's population. A one-size-fits-all methodology is not helpful to identify the needs of such a specialized group as immune-compromised patients who require IVIG therapy. Second, the State-Plan projection methodology is seriously inaccurate. There were 39,117 actual home health agency patients served in the area in 2015, which is an evidence-based indicator of need. That utilization was 59% higher than the 24,625 patients that the 1.5% formula projects to be needed in CY2018. This alone calls into question the reliability of this projection methodology.

- 4. County Need Standard: The applicant should demonstrate that there is a need for home health services in each county in the proposed Service Area by providing documentation (e.g., letters) where: a) health care providers had difficulty or were unable successfully to refer a patient to a home care organization and/or were dissatisfied with the quality of services provided by existing home care organizations based on Medicare's system Home Health Compare and/or similar data; b) potential patients or providers in the proposed Service Area attempted to find appropriate home health services but were not able to secure**

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such services; c) providers supply an estimate of the potential number of patients that they might refer to the applicant.

The applicant has submitted several such letters of support from area physicians who cite the need for the project, due to difficulty of finding home health providers in this service area who are able and willing to respond timely to their patients' needs with the level of service that AxelaCare proposes to provide. Physicians are not willing to provide estimates of future referrals to a prospective provider.

5. Current Service Area Utilization: The applicant should document by county: a) all existing providers of home health services within the proposed Service Area; and b) the number of patients served during the most recent 12-month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use final data provided by the JARs maintained by the Tennessee Department of Health. In each county of the proposed Service Area, the applicant should identify home health agencies that have reported serving 5 or fewer patients for each of the last three years based on final and available JAR data. If an agency in the proposed Service Area who serves few or no patients is opposing the application, that opponent agency should provide evidence as to why it does not serve a larger number of patients.

The applicant submitted three years of JAR-reported patient data for every home health agency with authorization to provide care to any of the 21 counties in the project service area. The applicant also provided the patients each agency served in CY2015 within this project's service area. That data was in Tables Six-A through Nine-C on pages 44a-44g of the application.

The applicant has identified several existing agencies that have served five or fewer patients in this service area during each of the past three years. They are shown on Supplemental Table Two, attached at the end of this response.

6. Adequate Staffing: Using TDH Licensure data, the applicant should document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and document that such personnel are available to work in the proposed Service Area. The applicant should state the percentage of qualified personnel directly employed or employed through a third party staffing agency.

AxelaCare has extensive experience in recruiting, employing, training, assessing the competencies of, and supervising and retaining skilled nursing staff to specifically manage IVIG care in the patients' homes.

AxelaCare is America's fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission, and holds the Joint Commission's Gold Seal of Approval for the quality of its programs. AxelaCare's National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction which it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

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AxelaCare is both a licensed pharmaceutical provider and a home health services provider. As a provider of medications, AxelaCare pharmacies prepare and ship home infusion pharmaceuticals to patients in 48 States. As a services provider in 17 States (through 33 branch offices) AxelaCare operates a full-scope program that integrates (a) the AxelaCare Pharmacy with (b) AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of those medications in patients' homes, as directed by their physicians. AxelaCare nurses and pharmacists in all 17 states are available 24/7 for patient assistance and for consultation with referring physicians -- before, during and after the patient's infusion.

Based on the above company experience and demonstrated quality, AxelaCare anticipates no problems in attracting superior staff for this project, in urban areas and healthcare centers the size of Memphis and Jackson. Implementation of this project will require development of only a small clinical staff -- between 3 and 4 skilled care nurses with documented competencies in infusion care. These will all be employed; none will be employed through a third-party staffing agency.

7. Community Linkage Plan: The applicant should provide a community linkage plan that demonstrates factors such as, but not limited to, referral arrangements with appropriate health care system providers/services (that comply with CMS patient choice protections) and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems. A new provider may submit a proposed community linkage plan.

The applicant will be a new provider of nursing services for home infusion of Immune Globulin (IG) pharmaceuticals. For this type of patient, the primary community linkages will be referring specialty physicians, because they will make referral and treatment decisions for these special-needs patients. AxelaCare will regularly call on all area specialty physician groups who serve patients with potential needs for IVIG, to keep them currently advised of AxelaCare's resources to optimize their patients' care. AxelaCare will meet monthly with all physicians who refer patients to them, to review and discuss their patient outcome data and to confer on future treatment options.

Secondary community linkages will be to area hospitals' discharge planners and medical staff. AxelaCare representatives will be in regular communication with those groups at most service area hospitals, to ensure their awareness of AxelaCare treatment options.

8. TennCare Managed Care Organizations (MCOs) and Financial Viability: Given the time frame required to obtain Medicare certification, an applicant proposing to contract with the Bureau of TennCare's MCOs should provide evidence of financial viability during the time period necessary to receive such certification. Applicants should be aware that MCOs are under no obligation to contract with home care organizations, even if Medicare certification is obtained, and that Private Duty Services are not Medicare certifiable services. Applicants who believe there is a need to serve TennCare patients should contact the TennCare MCOs in the region of the proposed Service Area and inquire whether their panels are open for home health services, as advised in the notice posted on the HSDA website, to determine whether at any given point there is a need for a provider in a particular area of the state;

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letters from the TennCare MCOs should be provided to document such need. See Note 2 for additional information.

Not applicable. The applicant will not be able to serve TennCare patients because the applicant will not have a Medicare provider number, which is a condition of contracting with the MCO's.

Applicants should also provide information on projected revenue sources, including non-TennCare revenue sources.

As stated in the application, the applicant's gross revenues will be 98% from multiple commercial insurers, because the applicant will not be serving Medicare and TennCare patients. It does not seem helpful to the review process to identify the large number of commercial insurance companies who reimburse providers for IVIG care--any one of which could have a covered patient in Tennessee.

9. Proposed Charges: The applicant's proposed charges should be reasonable in comparison with those of other similar agencies in the Service Area or in adjoining service areas. The applicant should list:

a. The average charge per visit and/or episode of care by service category, if available in the JAR data.

b. The average charge per patient based upon the projected number of visits and/or episodes of care and/or hours per patient, if available in the JAR data.

Table Four on page 34 of the application provided 2015 JAR data on charges per visit and charges per hour for all area agencies who reported those. Reporting is very sketchy in the HHA Joint Annual Reports. The data is for skilled nursing only, which is the only home health service proposed in this application. However, this JAR data does not allow a meaningful comparison to AxelaCare's very different pricing structure.

AxelaCare pays its infusion nurses between \$37 and \$45 per hour; an average is approximately \$40 per hour. However, AxelaCare projects Year One (2017) average expected nursing revenues of \$240 per visit, much higher than general home health agencies who are not providing infusion care.

The only comparable specialty infusion-specific charge data identified by the applicant in publicly available sources was CN1406-018, approved in 2014 for Coram/CVS Specialty Infusion Services to do specialty home infusion care. In that document, Coram projected average charges for its "specialty infusion patient" at \$290-\$348 (see page 87 of Coram's CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is \$240 for the nursing component. This is consistent with the Coram projections. The Coram 2015 Joint Annual Report provides no data on average charges. It is Coram's first such report since becoming operational in late 2015.

10. Access: In concert with the factors set forth in HSDA Rule 0720-11-.01(1) (which lists those factors concerning need on which an application may be evaluated), the HSDA may

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choose to give special consideration to an applicant that is able to show that there is limited access in the proposed Service Area for groups with special medical needs such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. Pediatrics is a special medical needs population, and therefore any provider applying to provide these services should demonstrate documentation of adequately trained staff specific to this population's needs with a plan to provide ongoing best practice education. For purposes of this Standard, an applicant should document need using population, service, special needs, and/or disease incidence rates. If granted, the Certificate of Need should be restricted on condition, and thus in its licensure, to serving the special group or groups identified in the application. The restricting language should be as follows: **CONDITION: Home health agency services are limited to (*identified specialty service group*); the expansion of service beyond (*identified specialty service group*) will require the filing of a new Certificate of Need application. Please see Note 3 regarding federal law prohibitions on discrimination in the provision of health care services.**

The applicant will serve a relatively small specialty patient population -- those whose physicians prescribe immune globulin infusions (IVIG). It is not clear that this criterion of the State Health Plan encompasses an IVIG patient. Regardless, the applicant requests that its CON be limited to home infusion of immune globulin pharmaceuticals, consistent with the wording in this criterion.

11. Quality Control and Monitoring: The applicant should identify and document its existing or proposed plan for data reporting (including data on patient re-admission to hospitals), quality improvement, and an outcome and process monitoring system (including continuum of care and transitions of care from acute care facilities). If applicable, the applicant should provide documentation that it is, or that it intends to be, fully accredited by the Joint Commission, the Community Health Accreditation Program, Inc., the Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS.

The applicant has submitted documentation of its accreditation by the Joint Commission, including its Gold Seal award. Examples of AxelaCare's highly articulated Quality Improvement program were submitted as Attachments to the application.

12. Data Requirements: Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant so agrees, as stated on page 66 of this CON application.

Attachments:

1. Supplemental Table One: Revised Need Projection Table
2. Supplemental Table Two: Area Agencies Who Served 5 or Fewer Patients in the Service Area

SUPPLEMENTAL #1**June 23, 2016****12:14 pm****Supplemental Table One: AxelaCare West Tennessee Service Area--Three-Year Projection of Service Area Need Under State Health Plan Guidelines**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2015 Population	Use Rate	Projected 2018 Population	Projected Capacity	Projected Need	Need or (Surplus) for 2018
Tennessee	1,635	1,473	170,384	6,735,706	0.0252956409	6,962,031	176,109	104,430	(71,679)
Benton	12	11	684	16,655	0.0410687481	16,711	686	251	(436)
Carroll	13	13	1,465	28,430	0.0515300739	28,298	1,458	424	(1,034)
Chester	13	13	545	18,076	0.0301504758	18,633	562	279	(282)
Crockett	12	11	567	14,845	0.0381946783	14,982	572	225	(348)
Decatur	15	15	648	11,939	0.0542759025	12,029	653	180	(472)
Dyer	9	9	1,902	39,155	0.0485761716	39,607	1,924	594	(1,330)
Fayette	21	20	707	43,631	0.0162040751	46,608	755	699	(56)
Gibson	14	14	1,870	51,119	0.0365813103	51,934	1,900	779	(1,121)
Hardeman	15	14	920	27,285	0.0337181602	27,284	920	409	(511)
Hardin	16	15	1,101	26,479	0.0415801201	26,680	1,109	400	(709)
Haywood	15	13	649	18,477	0.0351247497	18,274	642	274	(368)
Henderson	12	12	1,209	29,101	0.0415449641	29,836	1,240	448	(792)
Henry	11	10	1,270	33,267	0.0381759702	33,771	1,289	507	(783)
Lake	7	6	357	8,230	0.0433778858	8,441	366	127	(240)
Lauderdale	14	12	907	28,529	0.0317922114	28,930	920	434	(486)
McNairy	14	14	1,138	27,019	0.0421185092	27,486	1,158	412	(745)
Madison	18	17	3,220	102,429	0.0314364096	104,799	3,295	1,572	(1,723)
Obion	10	10	1,314	31,722	0.0414223567	31,625	1,310	474	(836)
Shelby	26	26	16,269	953,899	0.0170552648	970,212	16,547	14,553	(1,994)
Tipton	21	19	1,172	66,234	0.0176948395	69,239	1,225	1,039	(187)
Weakley	15	15	1,203	35,894	0.0335153508	36,300	1,217	545	(672)
PSA TOTAL	303	289	39,117	1,612,415		1,641,679	39,747	24,625	(15,122)

*Most recent year of Joint Annual Report data for Home Health Agencies

Data is projected three years from the year the Home Health data was **finalized, not the actual year of Home Health data.

Population Data Source: The University of Tennessee Center for Business and Economic Research (UTCBER) Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.

Note: Population data will not match the UTCBER data exactly due to rounding.

SUPPLEMENTAL #1**June 23, 2016****12:14 pm**

Supplemental Table 2: Agencies Serving Fewer than Five Area Residents Per Year (State Health Plan Home Health Review Criterion #5)					
State ID	Agency Name	Home County	2013 Patients	2014 Patients	2015 Patients
33103	Amedysis Home Health	Hamilton	0	0	0
79446	Baptist Trinity Home Care--Private Pay	Shelby	1	1	1
79556	Coram/CVS Specialty Infusion	Shelby	na	na	4
19544	Home Care Solutions	Davidson	0	0	0
60024	NHC HomeCare	Maury	0	2	0
41034	Saint Thomas Home Health	Hickman	0	0	1

Note: Coram/CVS was not operational until late 2015

12. UnitedHealth Group Earnings Report, Q1 2016

June 23, 2016**12:14 pm****NEWS RELEASE****UNITEDHEALTH GROUP®**

Investors:	Brett Manderfeld	John S. Penshorn	Media:	Don Nathan	Tyler Mason
	Vice President	Senior Vice President		Senior Vice President	Vice President
	952-936-7216	952-936-7214		952-936-1885	424-333-6122

(For Immediate Release)

UNITEDHEALTH GROUP REPORTS FIRST QUARTER RESULTS

- *First Quarter Revenues of \$44.5 Billion Grew 25% Year-Over-Year*
- *UnitedHealthcare Added 2 Million More People Domestically in the Past 12 Months, Including 1.3 Million More People in the First Quarter*
- *Optum Revenues of \$19.7 Billion Grew 54% Year-Over-Year*
- *Cash Flows from Operations were \$2.3 Billion in the Quarter*
- *First Quarter Adjusted Net Earnings of \$1.81 Per Share Grew 17% Year-Over-Year*

NEW YORK, NY (April 19, 2016) – UnitedHealth Group (NYSE: UNH) today reported first quarter results, highlighted by strong execution, consistent operating performance and compelling product and service offerings driving broad-based growth across the Company.

“Our commitment and determination to constantly improve how we serve customers and consumers in health benefits and services is reflected in consistent, market-leading organic growth and strong levels of customer retention in the first quarter,” said Stephen J. Hemsley, chief executive officer of UnitedHealth Group.

Based on the first quarter results and business trends, the Company now expects 2016 revenues of approximately \$182 billion and adjusted net earnings in a range of \$7.75 to \$7.95 per share. The increase in the outlook for adjusted net earnings of \$0.15 per share is due to changes in the expected income tax rate and intangible amortization. Management affirmed its outlook for strong cash flows from operations of up to \$10 billion.

UNITEDHEALTH GROUP*

	Quarterly Financial Performance		
	<u>Three Months Ended</u>		
	March 31,	March 31,	December 31,
	<u>2016</u>	<u>2015</u>	<u>2015</u>
Revenues	\$44.5 billion	\$35.8 billion	\$43.6 billion
Earnings From Operations	\$3.0 billion	\$2.6 billion	\$2.5 billion
Net Margin	3.6%	4.0%	2.8%

- UnitedHealth Group first quarter 2016 revenues of \$44.5 billion grew 25 percent or \$8.8 billion year-over-year. Growth was broad-based and reflected growing market demand for the Company's product and service offerings. UnitedHealthcare revenues grew 10 percent and Optum revenues grew 54 percent, with revenue growth of 20 percent or more at each Optum business.
- First quarter earnings from operations were \$3 billion and adjusted net earnings grew 17 percent year-over-year to \$1.81 per share. As expected, the first quarter net margin of 3.6 percent decreased 40 basis points year-over-year, due principally to an increased level of pharmacy care services business.
- First quarter 2016 cash flows from operations of \$2.3 billion were 1.4 times net earnings.
- The consolidated medical care ratio increased 30 basis points year-over-year to 81.7 percent in the first quarter of 2016, reflecting the extra calendar day of service in the quarter. Prior year medical reserve development was \$360 million, compared to \$140 million in the first quarter of 2015, and first quarter 2016 medical cost trends were well-controlled and consistent with management expectations.
- The first quarter 2016 operating cost ratio of 15.2 percent decreased 110 basis points year-over-year primarily due to changes in business mix.
- The first quarter 2016 tax rate of 39.8 percent decreased 350 basis points year-over-year from 43.3 percent in first quarter 2015, due to the adoption of a new accounting standard. Under the new standard, certain corporate tax benefits related to stock-based compensation programs are recorded through the tax provision. This new standard, which added roughly \$0.06 per share to net earnings due to the concentration of activity in the first quarter, is expected to have considerably less earnings impact in the remaining quarters of 2016.
- First quarter 2016 days claims payable of 51 days increased 4 days year-over-year and 1 day sequentially; days sales outstanding of 16 days increased 3 days, due to increased government receivables and business mix.
- The Company's financial position is strong, with a debt to total capital ratio of 49 percent at March 31, 2016. The Company expects this ratio to decrease during the second half of 2016 as debt levels are reduced. First quarter 2016 annualized return on equity was 19 percent, an increase of 1 percentage point year-over-year.
- UnitedHealth Group repurchased 4.2 million shares for \$0.5 billion in first quarter 2016, at a weighted average price of \$119 per share.



UnitedHealthcare provides health care benefits, serving individuals and employers ranging from sole proprietorships to large, multi-site and national and international organizations; delivers health and well-being benefits to Medicare beneficiaries and retirees; manages health care benefit programs on behalf of state Medicaid and community programs; and serves the nation's military service members, retirees and their families through the TRICARE program.

Quarterly Financial Performance

	<u>Three Months Ended</u>		
	<u>March 31,</u> <u>2016</u>	<u>March 31,</u> <u>2015</u>	<u>December 31,</u> <u>2015</u>
Revenues	\$35.9 billion	\$32.6 billion	\$32.8 billion
Earnings From Operations	\$1.9 billion	\$1.9 billion	\$949 million
Operating Margin	5.2%	5.8%	2.9%

UnitedHealthcare continues to consistently grow as more customers choose its products and services, due to the combination of distinctive service, product innovation and integrated clinical and network value they offer.

UnitedHealthcare has developed a balanced mix of business across the commercial, government and international markets, reflecting its deliberate strategy of diversifying and serving the breadth of needs in those markets.

- UnitedHealthcare grew organically over the past year to serve 2 million more people in the U.S. medical benefits markets, with well-diversified growth across commercial, Medicare and Medicaid offerings. First quarter growth contributed 1.3 million people to this total, helping UnitedHealthcare's first quarter revenues grow \$3.3 billion or 10 percent year-over-year to nearly \$36 billion.
- First quarter 2016 earnings from operations for UnitedHealthcare of \$1.9 billion were roughly even with first quarter 2015, as strong growth largely offset a 60 basis point reduction in operating margins to 5.2 percent. The year-over-year margin decrease was driven by increased quarterly costs from an extra calendar day of service and public exchange performance, partially offset by reserve development.

UnitedHealthcare Employer & Individual

- UnitedHealthcare Employer & Individual grew to serve approximately 700,000 more people in the first quarter and 1 million more people year-over-year. First quarter growth was well-balanced, with growth of more than 300,000 people in risk-based and nearly 400,000 people in fee-based offerings, including increases in people served through the fee-based national account, public sector, mid-sized employer, small employer and individual segments of the market.
- First quarter revenues of \$12.8 billion grew \$1.4 billion or 12 percent year-over-year, driven by growth in the number of people served and price increases matching medical cost trends for risk-based products.

UnitedHealthcare Medicare & Retirement

- First quarter 2016 UnitedHealthcare Medicare & Retirement revenues of \$14.1 billion grew \$1.3 billion or 10 percent year-over-year, due to consistent growth in services to seniors:
 - In Medicare Advantage, UnitedHealthcare grew to serve 325,000 more seniors year-over-year, a 10 percent increase, including nearly 300,000 seniors in the first quarter.
 - Medicare Supplement products grew 7 percent to serve 270,000 more people year-over-year, including 165,000 in the first quarter.
 - UnitedHealthcare's stand-alone Medicare Part D program served 5 million people at March 31, 2016. UnitedHealthcare partially offset its planned 2016 pull-back in subsidized Part D products with an acquisition that broadened its Part D product portfolio, resulting in a net decrease of 70,000 people served in the first quarter.

UnitedHealthcare Community & State

- First quarter 2016 UnitedHealthcare Community & State revenues of \$7.7 billion grew \$823 million or 12 percent year-over-year due to strong overall growth and an increasing mix of higher need members.
- In the past year, UnitedHealthcare grew to serve 410,000 more people in Medicaid, an increase of 8 percent, including 145,000 more people in first quarter 2016. UnitedHealthcare continues to receive and implement new state-based awards, including serving 55,000 people as of January 1, 2016 under the New York Essential Plan and more than 200,000 people as of April 1, 2016 through the new Iowa Health Link program. UnitedHealthcare received a superior score on the re-procurement and program expansion serving Nebraska's Medicaid program in 2017.



Optum is a health services business serving the broad health care marketplace, including payers, care providers, employers, governments, life sciences companies and consumers. Using advanced data analytics and technology, Optum's people help improve overall health system performance: optimizing care quality, reducing costs and improving the consumer experience and care provider performance.

	Quarterly Financial Performance		
	<u>Three Months Ended</u>		
	March 31, <u>2016</u>	March 31, <u>2015</u>	December 31, <u>2015</u>
Revenues	\$19.7 billion	\$12.8 billion	\$21.9 billion
Earnings From Operations	\$1.1 billion	\$742 million	\$1.5 billion
Operating Margin	5.6%	5.8%	6.9%

Optum's growth continues to reflect its differentiated capabilities and comprehensive solutions for stakeholders broadly across the health care system, both domestically and abroad.

- First quarter 2016 Optum revenues of \$19.7 billion grew \$6.9 billion or 54 percent year-over-year. Optum earnings from operations grew 49 percent or \$364 million year-over-year to \$1.1 billion, with solid operating margins from all business segments. Strong growth in pharmacy care services increased operating earnings and reduced Optum's overall operating margin, which decreased by 20 basis points year-over-year to 5.6 percent.
 - OptumHealth revenues of \$4 billion grew \$709 million or 22 percent year-over-year due to growth in its health care delivery businesses, including expansion in neighborhood care centers. OptumHealth served 79 million consumers at March 31, 2016, for growth of 8 million people or 11 percent year-over-year.
 - OptumInsight revenues grew 20 percent to \$1.7 billion in the first quarter of 2016, driven by growth in technology services, care provider revenue management services and payer services. OptumInsight's revenue backlog grew to \$11 billion at March 31, 2016, an increase of 21 percent year-over-year. Revenue backlog growth rates will fluctuate quarter to quarter, based on the timing of contract awards.
 - OptumRx revenues of \$14.3 billion grew 72 percent year-over-year, driven by both acquisitions and organic growth. In total, OptumRx grew script fulfillment by 71 percent to 252 million adjusted scripts in the first quarter of 2016.

June 23, 2016**12:14 pm****About UnitedHealth Group**

UnitedHealth Group (NYSE: UNH) is a diversified health and well-being company dedicated to helping people live healthier lives and helping make the health system work better for everyone. UnitedHealth Group offers a broad spectrum of products and services through two distinct platforms: UnitedHealthcare, which provides health care coverage and benefits services; and Optum, which provides information and technology-enabled health services. For more information, visit UnitedHealth Group at www.unitedhealthgroup.com or follow @UnitedHealthGrp on Twitter.

Earnings Conference Call

As previously announced, UnitedHealth Group will discuss the Company's results, strategy and future outlook on a conference call with investors at 8:45 a.m. Eastern Time today. UnitedHealth Group will host a live webcast of this conference call from the Investors page of the Company's website (www.unitedhealthgroup.com). Following the call, a webcast replay will be available on the same site through May 3, 2016. The conference call replay can also be accessed by dialing 1-800-283-9429. This earnings release and the Form 8-K dated April 19, 2016 can also be accessed from the Investors page of the Company's website.

Non-GAAP Financial Measures

This news release presents information about the Company's adjusted net earnings per share, which is a non-GAAP financial measure provided as a complement to the results provided in accordance with accounting principles generally accepted in the United States of America ("GAAP"). A reconciliation of the foregoing non-GAAP financial measure to the most directly comparable GAAP financial measure is provided in the accompanying tables found at the end of this release.

Forward-Looking Statements

The statements, estimates, projections, guidance or outlook contained in this document include "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These statements are intended to take advantage of the "safe harbor" provisions of the PSLRA. Generally the words "believe," "expect," "intend," "estimate," "anticipate," "forecast," "outlook," "plan," "project," "should" and similar expressions identify forward-looking statements, which generally are not historical in nature. These statements may contain information about financial prospects, economic conditions and trends and involve risks and uncertainties. We caution that actual results could differ materially from those that management expects, depending on the outcome of certain factors.

Some factors that could cause actual results to differ materially from results discussed or implied in the forward-looking statements include: our ability to effectively estimate, price for and manage our medical costs, including the impact of any new coverage requirements; new laws or regulations, or changes in existing laws or regulations, or their enforcement or application, including increases in medical, administrative, technology or other costs or decreases in enrollment resulting from U.S., Brazilian and other jurisdictions' regulations affecting the health care industry;

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assessments for insolvent payers under state guaranty fund laws; our ability to achieve improvement in CMS Star ratings and other quality scores that impact revenue; reductions in revenue or delays to cash flows received under Medicare, Medicaid and TRICARE programs, including sequestration and the effects of a prolonged U.S. government shutdown or debt ceiling constraints; changes in Medicare, including changes in payment methodology, the CMS Star ratings program or the application of risk adjustment data validation audits; our participation in federal and state health insurance exchanges which entail uncertainties associated with mix and volume of business; cyber-attacks or other privacy or data security incidents; failure to comply with privacy and data security regulations; regulatory and other risks and uncertainties of the pharmacy benefits management industry; competitive pressures, which could affect our ability to maintain or increase our market share; challenges to our public sector contract awards; our ability to execute contracts on competitive terms with physicians, hospitals and other service providers; failure to achieve targeted operating cost productivity improvements, including savings resulting from technology enhancement and administrative modernization; increases in costs and other liabilities associated with increased litigation, government investigations, audits or reviews; failure to manage successfully our strategic alliances or complete or receive anticipated benefits of acquisitions and other strategic transactions, including our acquisition of Catamaran; fluctuations in foreign currency exchange rates on our reported shareholders' equity and results of operations; downgrades in our credit ratings; adverse economic conditions, including decreases in enrollment resulting from increases in the unemployment rate and commercial attrition; the performance of our investment portfolio; impairment of the value of our goodwill and intangible assets in connection with dispositions or if estimated future results do not adequately support goodwill and intangible assets recorded for our existing businesses or the businesses that we acquire; increases in health care costs resulting from large-scale medical emergencies; failure to maintain effective and efficient information systems or if our technology products do not operate as intended; and our ability to obtain sufficient funds from our regulated subsidiaries or the debt or capital markets to fund our obligations, to maintain our debt to total capital ratio at targeted levels, to maintain our quarterly dividend payment cycle or to continue repurchasing shares of our common stock.

This list of important factors is not intended to be exhaustive. We discuss certain of these matters more fully, as well as certain risk factors that may affect our business operations, financial condition and results of operations, in our filings with the Securities and Exchange Commission, including our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. Any or all forward-looking statements we make may turn out to be wrong, and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. By their nature, forward-looking statements are not guarantees of future performance or results and are subject to risks, uncertainties and assumptions that are difficult to predict or quantify. Actual future results may vary materially from expectations expressed or implied in this document or any of our prior communications. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. We do not undertake to update or revise any forward-looking statements, except as required by applicable securities laws.

UNITEDHEALTH GROUP
Earnings Release Schedules and Supplementary Information
Quarter Ended March 31, 2016

- Condensed Consolidated Statements of Operations
- Condensed Consolidated Balance Sheets
- Condensed Consolidated Statements of Cash Flows
- Supplemental Financial Information - Businesses
- Supplemental Financial Information - Business Metrics
- Reconciliation of Non-GAAP Financial Measure

SUPPLEMENTAL #1

June 23, 2016

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UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues		
Premiums	\$ 34,811	\$ 31,674
Products	6,393	1,230
Services	3,140	2,706
Investment and other income	183	146
Total revenues	<u>44,527</u>	<u>35,756</u>
Operating costs		
Medical costs	28,430	25,790
Operating costs	6,758	5,834
Cost of products sold	5,877	1,114
Depreciation and amortization	502	378
Total operating costs	<u>41,567</u>	<u>33,116</u>
Earnings from operations	2,960	2,640
Interest expense	(259)	(150)
Earnings before income taxes	2,701	2,490
Provision for income taxes	(1,074)	(1,077)
Net earnings	1,627	1,413
Earnings attributable to noncontrolling interests	(16)	—
Net earnings attributable to UnitedHealth Group common shareholders	1,611	1,413
Diluted earnings per share attributable to UnitedHealth Group common shareholders	1.67	1.46
Adjusted earnings per share attributable to UnitedHealth Group common shareholders (a)	1.81	1.55
Diluted weighted-average common shares outstanding	967	969

(a) See page 6 for a reconciliation of non-GAAP measure

UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions)
(unaudited)

	March 31, 2016	December 31, 2015 (a)
Assets		
Cash and short-term investments	\$ 13,014	\$ 12,911
Accounts receivable, net	7,777	6,523
Other current assets	12,954	12,205
Total current assets	33,745	31,639
Long-term investments	20,895	18,792
Other long-term assets	63,215	60,823
Total assets	\$ 117,855	\$ 111,254
Liabilities, redeemable noncontrolling interests and equity		
Medical costs payable	\$ 15,823	\$ 14,330
Commercial paper and current maturities of long-term debt	6,504	6,634
Other current liabilities	23,958	21,934
Total current liabilities	46,285	42,898
Long-term debt, less current maturities	27,218	25,331
Other long-term liabilities	7,461	7,564
Redeemable noncontrolling interests	1,824	1,736
Equity	35,067	33,725
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(a) The Company reclassified \$129 of debt issuance costs related to the adoption of a new accounting standard.

June 23, 2016

12:14 PM

UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating Activities		
Net earnings	\$ 1,627	\$ 1,413
Noncash items:		
Depreciation and amortization	502	378
Deferred income taxes and other	151	78
Share-based compensation	157	125
Net changes in operating assets and liabilities	(119)	275
Cash flows from operating activities	2,318	2,269
Investing Activities		
Purchases of investments, net of sales and maturities	(2,073)	(545)
Purchases of property, equipment and capitalized software	(425)	(373)
Cash paid for acquisitions, net	(1,697)	(575)
Other, net	14	(32)
Cash flows used for investing activities	(4,181)	(1,525)
Financing Activities		
Common share repurchases	(500)	(896)
Dividends paid	(477)	(357)
Net change in commercial paper and long-term debt	1,599	778
Other, net	880	971
Cash flows from financing activities	1,502	496
Effect of exchange rate changes on cash and cash equivalents	34	(85)
(Decrease) increase in cash and cash equivalents	(327)	1,155
Cash and cash equivalents, beginning of period	10,923	7,495
Cash and cash equivalents, end of period	\$ 10,596	\$ 8,650

UNITEDHEALTH GROUP
SUPPLEMENTAL FINANCIAL INFORMATION - BUSINESSES

(in millions, except percentages)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues		
UnitedHealthcare	\$ 35,900	\$ 32,623
Optum	19,684	12,815
Eliminations	(11,057)	(9,682)
Total consolidated revenues	<u>\$ 44,527</u>	<u>\$ 35,756</u>
Earnings from Operations		
UnitedHealthcare	\$ 1,854	\$ 1,898
Optum (a)	1,106	742
Total consolidated earnings from operations	<u>\$ 2,960</u>	<u>\$ 2,640</u>
Operating Margin		
UnitedHealthcare	5.2%	5.8%
Optum	5.6%	5.8%
Consolidated operating margin	6.6%	7.4%
Revenues		
UnitedHealthcare Employer & Individual	\$ 12,820	\$ 11,423
UnitedHealthcare Medicare & Retirement	14,065	12,781
UnitedHealthcare Community & State	7,728	6,905
UnitedHealthcare Global	1,287	1,514
OptumHealth	3,998	3,289
OptumInsight	1,667	1,390
OptumRx	14,273	8,295
Optum eliminations	(254)	(159)

(a) Earnings from operations for Optum for the three months ended March 31, 2016 and 2015 included \$300 and \$234 for OptumHealth; \$246 and \$222 for OptumInsight; and \$560 and \$286 for OptumRx, respectively.

UNITEDHEALTH GROUP
SUPPLEMENTAL FINANCIAL INFORMATION - BUSINESS METRICS

UNITEDHEALTHCARE CUSTOMER PROFILE
(in thousands)

People Served	March 31, 2016	March 31, 2015	December 31, 2015
Commercial risk-based	8,600	8,115	8,285
Commercial fee-based, including TRICARE	21,825	21,315	21,445
Total Commercial	30,425	29,430	29,730
Medicare Advantage	3,530	3,205	3,235
Medicaid	5,450	5,040	5,305
Medicare Supplement (Standardized)	4,200	3,930	4,035
Total Public and Senior	13,180	12,175	12,575
Total UnitedHealthcare - Domestic Medical	43,605	41,605	42,305
International	4,065	4,160	4,090
Total UnitedHealthcare - Medical	47,670	45,765	46,395
Supplemental Data			
Medicare Part D stand-alone	4,990	5,105	5,060

OPTUM PERFORMANCE METRICS

	March 31, 2016	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
OptumHealth Consumers Served (in millions)	79	71	76	77	78
OptumInsight Contract Backlog (in billions)	\$ 11.0	\$ 9.1	\$ 9.8	\$ 10.2	\$ 10.4
OptumRx Quarterly Adjusted Scripts (in millions)	252	147	148	226	258

Note: UnitedHealth Group served 132 million unique individuals across all businesses at March 31, 2016, 129 million at December 31, 2015, and 101 million at March 31, 2015.

UNITEDHEALTH GROUP
RECONCILIATION OF NON-GAAP FINANCIAL MEASURE
ADJUSTED NET EARNINGS AND EARNINGS PER SHARE (a)

(in millions, except per share data)
(unaudited)

	Three Months Ended		Projected Year Ended
	March 31, 2016	March 31, 2015	
GAAP net earnings	\$ 1,611	\$ 1,413	\$6,950 to \$7,200
Intangible amortization, net of tax effects	140	86	~550
Adjusted net earnings	<u>\$ 1,751</u>	<u>\$ 1,499</u>	<u>\$7,500 to \$7,750</u>
GAAP diluted earnings per share	\$ 1.67	\$ 1.46	\$7.20 to \$7.40
Intangible amortization, net of tax effects per share	0.14	0.09	~\$0.55
Adjusted diluted earnings per share	<u>\$ 1.81</u>	<u>\$ 1.55</u>	<u>\$7.75 to \$7.95</u>

(a) GAAP and adjusted net earnings and earnings per share are attributable to UnitedHealth Group common shareholders.

Use of Non-GAAP Financial Measure

Adjusted earnings per share is a non-GAAP financial measure and should not be considered a substitute for or superior to a financial measure calculated in accordance with GAAP. Management believes that the use of adjusted earnings per share provides investors and management useful information about the earnings impact of acquisition-related intangible asset amortization. This non-GAAP measure does not reflect all of the expenses associated with the operations of our business as determined in accordance with GAAP. As a result, one should not consider this measure in isolation.

12. UnitedHealth Group Earnings Report, Q1 2016

June 23, 2016**12:14 pm****NEWS RELEASE****UNITEDHEALTH GROUP***

Investors:	Brett Manderfeld	John S. Peshorn	Media:	Don Nathan	Tyler Mason
	Vice President	Senior Vice President		Senior Vice President	Vice President
	952-936-7216	952-936-7214		952-936-1885	424-333-6122

*(For Immediate Release)***UNITEDHEALTH GROUP REPORTS FIRST QUARTER RESULTS**

- *First Quarter Revenues of \$44.5 Billion Grew 25% Year-Over-Year*
- *UnitedHealthcare Added 2 Million More People Domestically in the Past 12 Months, Including 1.3 Million More People in the First Quarter*
- *Optum Revenues of \$19.7 Billion Grew 54% Year-Over-Year*
- *Cash Flows from Operations were \$2.3 Billion in the Quarter*
- *First Quarter Adjusted Net Earnings of \$1.81 Per Share Grew 17% Year-Over-Year*

NEW YORK, NY (April 19, 2016) – UnitedHealth Group (NYSE: UNH) today reported first quarter results, highlighted by strong execution, consistent operating performance and compelling product and service offerings driving broad-based growth across the Company.

“Our commitment and determination to constantly improve how we serve customers and consumers in health benefits and services is reflected in consistent, market-leading organic growth and strong levels of customer retention in the first quarter,” said Stephen J. Hemsley, chief executive officer of UnitedHealth Group.

Based on the first quarter results and business trends, the Company now expects 2016 revenues of approximately \$182 billion and adjusted net earnings in a range of \$7.75 to \$7.95 per share. The increase in the outlook for adjusted net earnings of \$0.15 per share is due to changes in the expected income tax rate and intangible amortization. Management affirmed its outlook for strong cash flows from operations of up to \$10 billion.

UNITEDHEALTH GROUP®

	Quarterly Financial Performance		
	<u>Three Months Ended</u>		
	March 31,	March 31,	December 31,
	<u>2016</u>	<u>2015</u>	<u>2015</u>
Revenues	\$44.5 billion	\$35.8 billion	\$43.6 billion
Earnings From Operations	\$3.0 billion	\$2.6 billion	\$2.5 billion
Net Margin	3.6%	4.0%	2.8%

- UnitedHealth Group first quarter 2016 revenues of \$44.5 billion grew 25 percent or \$8.8 billion year-over-year. Growth was broad-based and reflected growing market demand for the Company's product and service offerings. UnitedHealthcare revenues grew 10 percent and Optum revenues grew 54 percent, with revenue growth of 20 percent or more at each Optum business.
- First quarter earnings from operations were \$3 billion and adjusted net earnings grew 17 percent year-over-year to \$1.81 per share. As expected, the first quarter net margin of 3.6 percent decreased 40 basis points year-over-year, due principally to an increased level of pharmacy care services business.
- First quarter 2016 cash flows from operations of \$2.3 billion were 1.4 times net earnings.
- The consolidated medical care ratio increased 30 basis points year-over-year to 81.7 percent in the first quarter of 2016, reflecting the extra calendar day of service in the quarter. Prior year medical reserve development was \$360 million, compared to \$140 million in the first quarter of 2015, and first quarter 2016 medical cost trends were well-controlled and consistent with management expectations.
- The first quarter 2016 operating cost ratio of 15.2 percent decreased 110 basis points year-over-year primarily due to changes in business mix.
- The first quarter 2016 tax rate of 39.8 percent decreased 350 basis points year-over-year from 43.3 percent in first quarter 2015, due to the adoption of a new accounting standard. Under the new standard, certain corporate tax benefits related to stock-based compensation programs are recorded through the tax provision. This new standard, which added roughly \$0.06 per share to net earnings due to the concentration of activity in the first quarter, is expected to have considerably less earnings impact in the remaining quarters of 2016.
- First quarter 2016 days claims payable of 51 days increased 4 days year-over-year and 1 day sequentially; days sales outstanding of 16 days increased 3 days, due to increased government receivables and business mix.
- The Company's financial position is strong, with a debt to total capital ratio of 49 percent at March 31, 2016. The Company expects this ratio to decrease during the second half of 2016 as debt levels are reduced. First quarter 2016 annualized return on equity was 19 percent, an increase of 1 percentage point year-over-year.
- UnitedHealth Group repurchased 4.2 million shares for \$0.5 billion in first quarter 2016, at a weighted average price of \$119 per share.



UnitedHealthcare provides health care benefits, serving individuals and employers ranging from sole proprietorships to large, multi-site and national and international organizations; delivers health and well-being benefits to Medicare beneficiaries and retirees; manages health care benefit programs on behalf of state Medicaid and community programs; and serves the nation's military service members, retirees and their families through the TRICARE program.

Quarterly Financial Performance			
	<u>Three Months Ended</u>		
	March 31,	March 31,	December 31,
	<u>2016</u>	<u>2015</u>	<u>2015</u>
Revenues	\$35.9 billion	\$32.6 billion	\$32.8 billion
Earnings From Operations	\$1.9 billion	\$1.9 billion	\$949 million
Operating Margin	5.2%	5.8%	2.9%

UnitedHealthcare continues to consistently grow as more customers choose its products and services, due to the combination of distinctive service, product innovation and integrated clinical and network value they offer.

UnitedHealthcare has developed a balanced mix of business across the commercial, government and international markets, reflecting its deliberate strategy of diversifying and serving the breadth of needs in those markets.

- UnitedHealthcare grew organically over the past year to serve 2 million more people in the U.S. medical benefits markets, with well-diversified growth across commercial, Medicare and Medicaid offerings. First quarter growth contributed 1.3 million people to this total, helping UnitedHealthcare's first quarter revenues grow \$3.3 billion or 10 percent year-over-year to nearly \$36 billion.
- First quarter 2016 earnings from operations for UnitedHealthcare of \$1.9 billion were roughly even with first quarter 2015, as strong growth largely offset a 60 basis point reduction in operating margins to 5.2 percent. The year-over-year margin decrease was driven by increased quarterly costs from an extra calendar day of service and public exchange performance, partially offset by reserve development.

UnitedHealthcare Employer & Individual

- UnitedHealthcare Employer & Individual grew to serve approximately 700,000 more people in the first quarter and 1 million more people year-over-year. First quarter growth was well-balanced, with growth of more than 300,000 people in risk-based and nearly 400,000 people in fee-based offerings, including increases in people served through the fee-based national account, public sector, mid-sized employer, small employer and individual segments of the market.
- First quarter revenues of \$12.8 billion grew \$1.4 billion or 12 percent year-over-year, driven by growth in the number of people served and price increases matching medical cost trends for risk-based products.

UnitedHealthcare Medicare & Retirement

- First quarter 2016 UnitedHealthcare Medicare & Retirement revenues of \$14.1 billion grew \$1.3 billion or 10 percent year-over-year, due to consistent growth in services to seniors:
 - In Medicare Advantage, UnitedHealthcare grew to serve 325,000 more seniors year-over-year, a 10 percent increase, including nearly 300,000 seniors in the first quarter.
 - Medicare Supplement products grew 7 percent to serve 270,000 more people year-over-year, including 165,000 in the first quarter.
 - UnitedHealthcare's stand-alone Medicare Part D program served 5 million people at March 31, 2016. UnitedHealthcare partially offset its planned 2016 pull-back in subsidized Part D products with an acquisition that broadened its Part D product portfolio, resulting in a net decrease of 70,000 people served in the first quarter.

UnitedHealthcare Community & State

- First quarter 2016 UnitedHealthcare Community & State revenues of \$7.7 billion grew \$823 million or 12 percent year-over-year due to strong overall growth and an increasing mix of higher need members.
- In the past year, UnitedHealthcare grew to serve 410,000 more people in Medicaid, an increase of 8 percent, including 145,000 more people in first quarter 2016. UnitedHealthcare continues to receive and implement new state-based awards, including serving 55,000 people as of January 1, 2016 under the New York Essential Plan and more than 200,000 people as of April 1, 2016 through the new Iowa Health Link program. UnitedHealthcare received a superior score on the re-procurement and program expansion serving Nebraska's Medicaid program in 2017.



Optum is a health services business serving the broad health care marketplace, including payers, care providers, employers, governments, life sciences companies and consumers. Using advanced data analytics and technology, Optum's people help improve overall health system performance: optimizing care quality, reducing costs and improving the consumer experience and care provider performance.

	Quarterly Financial Performance		
	<u>Three Months Ended</u>		
	March 31, 2016	March 31, 2015	December 31, 2015
Revenues	\$19.7 billion	\$12.8 billion	\$21.9 billion
Earnings From Operations	\$1.1 billion	\$742 million	\$1.5 billion
Operating Margin	5.6%	5.8%	6.9%

Optum's growth continues to reflect its differentiated capabilities and comprehensive solutions for stakeholders broadly across the health care system, both domestically and abroad.

- First quarter 2016 Optum revenues of \$19.7 billion grew \$6.9 billion or 54 percent year-over-year. Optum earnings from operations grew 49 percent or \$364 million year-over-year to \$1.1 billion, with solid operating margins from all business segments. Strong growth in pharmacy care services increased operating earnings and reduced Optum's overall operating margin, which decreased by 20 basis points year-over-year to 5.6 percent.
 - OptumHealth revenues of \$4 billion grew \$709 million or 22 percent year-over-year due to growth in its health care delivery businesses, including expansion in neighborhood care centers. OptumHealth served 79 million consumers at March 31, 2016, for growth of 8 million people or 11 percent year-over-year.
 - OptumInsight revenues grew 20 percent to \$1.7 billion in the first quarter of 2016, driven by growth in technology services, care provider revenue management services and payer services. OptumInsight's revenue backlog grew to \$11 billion at March 31, 2016, an increase of 21 percent year-over-year. Revenue backlog growth rates will fluctuate quarter to quarter, based on the timing of contract awards.
 - OptumRx revenues of \$14.3 billion grew 72 percent year-over-year, driven by both acquisitions and organic growth. In total, OptumRx grew script fulfillment by 71 percent to 252 million adjusted scripts in the first quarter of 2016.

June 23, 2016**12:14 pm****About UnitedHealth Group**

UnitedHealth Group (NYSE: UNH) is a diversified health and well-being company dedicated to helping people live healthier lives and helping make the health system work better for everyone. UnitedHealth Group offers a broad spectrum of products and services through two distinct platforms: UnitedHealthcare, which provides health care coverage and benefits services; and Optum, which provides information and technology-enabled health services. For more information, visit UnitedHealth Group at www.unitedhealthgroup.com or follow @UnitedHealthGrp on Twitter.

Earnings Conference Call

As previously announced, UnitedHealth Group will discuss the Company's results, strategy and future outlook on a conference call with investors at 8:45 a.m. Eastern Time today. UnitedHealth Group will host a live webcast of this conference call from the Investors page of the Company's website (www.unitedhealthgroup.com). Following the call, a webcast replay will be available on the same site through May 3, 2016. The conference call replay can also be accessed by dialing 1-800-283-9429. This earnings release and the Form 8-K dated April 19, 2016 can also be accessed from the Investors page of the Company's website.

Non-GAAP Financial Measures

This news release presents information about the Company's adjusted net earnings per share, which is a non-GAAP financial measure provided as a complement to the results provided in accordance with accounting principles generally accepted in the United States of America ("GAAP"). A reconciliation of the foregoing non-GAAP financial measure to the most directly comparable GAAP financial measure is provided in the accompanying tables found at the end of this release.

Forward-Looking Statements

The statements, estimates, projections, guidance or outlook contained in this document include "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These statements are intended to take advantage of the "safe harbor" provisions of the PSLRA. Generally the words "believe," "expect," "intend," "estimate," "anticipate," "forecast," "outlook," "plan," "project," "should" and similar expressions identify forward-looking statements, which generally are not historical in nature. These statements may contain information about financial prospects, economic conditions and trends and involve risks and uncertainties. We caution that actual results could differ materially from those that management expects, depending on the outcome of certain factors.

Some factors that could cause actual results to differ materially from results discussed or implied in the forward-looking statements include: our ability to effectively estimate, price for and manage our medical costs, including the impact of any new coverage requirements; new laws or regulations, or changes in existing laws or regulations, or their enforcement or application, including increases in medical, administrative, technology or other costs or decreases in enrollment resulting from U.S., Brazilian and other jurisdictions' regulations affecting the health care industry;

June 23, 2016**12:14 pm**

assessments for insolvent payers under state guaranty fund laws; our ability to achieve improvement in CMS Star ratings and other quality scores that impact revenue; reductions in revenue or delays to cash flows received under Medicare, Medicaid and TRICARE programs, including sequestration and the effects of a prolonged U.S. government shutdown or debt ceiling constraints; changes in Medicare, including changes in payment methodology, the CMS Star ratings program or the application of risk adjustment data validation audits; our participation in federal and state health insurance exchanges which entail uncertainties associated with mix and volume of business; cyber-attacks or other privacy or data security incidents; failure to comply with privacy and data security regulations; regulatory and other risks and uncertainties of the pharmacy benefits management industry; competitive pressures, which could affect our ability to maintain or increase our market share; challenges to our public sector contract awards; our ability to execute contracts on competitive terms with physicians, hospitals and other service providers; failure to achieve targeted operating cost productivity improvements, including savings resulting from technology enhancement and administrative modernization; increases in costs and other liabilities associated with increased litigation, government investigations, audits or reviews; failure to manage successfully our strategic alliances or complete or receive anticipated benefits of acquisitions and other strategic transactions, including our acquisition of Catamaran; fluctuations in foreign currency exchange rates on our reported shareholders' equity and results of operations; downgrades in our credit ratings; adverse economic conditions, including decreases in enrollment resulting from increases in the unemployment rate and commercial attrition; the performance of our investment portfolio; impairment of the value of our goodwill and intangible assets in connection with dispositions or if estimated future results do not adequately support goodwill and intangible assets recorded for our existing businesses or the businesses that we acquire; increases in health care costs resulting from large-scale medical emergencies; failure to maintain effective and efficient information systems or if our technology products do not operate as intended; and our ability to obtain sufficient funds from our regulated subsidiaries or the debt or capital markets to fund our obligations, to maintain our debt to total capital ratio at targeted levels, to maintain our quarterly dividend payment cycle or to continue repurchasing shares of our common stock.

This list of important factors is not intended to be exhaustive. We discuss certain of these matters more fully, as well as certain risk factors that may affect our business operations, financial condition and results of operations, in our filings with the Securities and Exchange Commission, including our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. Any or all forward-looking statements we make may turn out to be wrong, and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. By their nature, forward-looking statements are not guarantees of future performance or results and are subject to risks, uncertainties and assumptions that are difficult to predict or quantify. Actual future results may vary materially from expectations expressed or implied in this document or any of our prior communications. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. We do not undertake to update or revise any forward-looking statements, except as required by applicable securities laws.

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June 23, 2016

12:14 pm

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Diluted weighted-average common shares outstanding	967	969

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(in millions)
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(a) The Company reclassified \$129 of debt issuance costs related to the adoption of a new accounting standard.

UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Operating Activities		
Net earnings	\$ 1,627	\$ 1,413
Noncash items:		
Depreciation and amortization	502	378
Deferred income taxes and other	151	78
Share-based compensation	157	125
Net changes in operating assets and liabilities	(119)	275
Cash flows from operating activities	2,318	2,269
Investing Activities		
Purchases of investments, net of sales and maturities	(2,073)	(545)
Purchases of property, equipment and capitalized software	(425)	(373)
Cash paid for acquisitions, net	(1,697)	(575)
Other, net	14	(32)
Cash flows used for investing activities	(4,181)	(1,525)
Financing Activities		
Common share repurchases	(500)	(896)
Dividends paid	(477)	(357)
Net change in commercial paper and long-term debt	1,599	778
Other, net	880	971
Cash flows from financing activities	1,502	496
Effect of exchange rate changes on cash and cash equivalents	34	(85)
(Decrease) increase in cash and cash equivalents	(327)	1,155
Cash and cash equivalents, beginning of period	10,923	7,495
Cash and cash equivalents, end of period	\$ 10,596	\$ 8,650

June 23, 2016

12:14 PM

UNITEDHEALTH GROUP
SUPPLEMENTAL FINANCIAL INFORMATION - BUSINESSES

(in millions, except percentages)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues		
UnitedHealthcare	\$ 35,900	\$ 32,623
Optum	19,684	12,815
Eliminations	(11,057)	(9,682)
Total consolidated revenues	<u>\$ 44,527</u>	<u>\$ 35,756</u>
Earnings from Operations		
UnitedHealthcare	\$ 1,854	\$ 1,898
Optum (a)	1,106	742
Total consolidated earnings from operations	<u>\$ 2,960</u>	<u>\$ 2,640</u>
Operating Margin		
UnitedHealthcare	5.2%	5.8%
Optum	5.6%	5.8%
Consolidated operating margin	6.6%	7.4%
Revenues		
UnitedHealthcare Employer & Individual	\$ 12,820	\$ 11,423
UnitedHealthcare Medicare & Retirement	14,065	12,781
UnitedHealthcare Community & State	7,728	6,905
UnitedHealthcare Global	1,287	1,514
OptumHealth	3,998	3,289
OptumInsight	1,667	1,390
OptumRx	14,273	8,295
Optum eliminations	(254)	(159)

(a) Earnings from operations for Optum for the three months ended March 31, 2016 and 2015 included \$300 and \$234 for OptumHealth; \$246 and \$222 for OptumInsight; and \$560 and \$286 for OptumRx, respectively.

**UNITEDHEALTH GROUP
SUPPLEMENTAL FINANCIAL INFORMATION - BUSINESS METRICS**

**UNITEDHEALTHCARE CUSTOMER PROFILE
(in thousands)**

	March 31, 2016	March 31, 2015	December 31, 2015
People Served			
Commercial risk-based	8,600	8,115	8,285
Commercial fee-based, including TRICARE	21,825	21,315	21,445
Total Commercial	30,425	29,430	29,730
Medicare Advantage	3,530	3,205	3,235
Medicaid	5,450	5,040	5,305
Medicare Supplement (Standardized)	4,200	3,930	4,035
Total Public and Senior	13,180	12,175	12,575
Total UnitedHealthcare - Domestic Medical	43,605	41,605	42,305
International	4,065	4,160	4,090
Total UnitedHealthcare - Medical	47,670	45,765	46,395
Supplemental Data			
Medicare Part D stand-alone	4,990	5,105	5,060

OPTUM PERFORMANCE METRICS

	March 31, 2016	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
OptumHealth Consumers Served (in millions).....	79	71	76	77	78
OptumInsight Contract Backlog (in billions).....	\$ 11.0	\$ 9.1	\$ 9.8	\$ 10.2	\$ 10.4
OptumRx Quarterly Adjusted Scripts (in millions)	252	147	148	226	258

Note: UnitedHealth Group served 132 million unique individuals across all businesses at March 31, 2016, 129 million at December 31, 2015, and 101 million at March 31, 2015.

UNITEDHEALTH GROUP
RECONCILIATION OF NON-GAAP FINANCIAL MEASURE
ADJUSTED NET EARNINGS AND EARNINGS PER SHARE (a)

(in millions, except per share data)
(unaudited)

	Three Months Ended		Projected
	March 31, 2016	March 31, 2015	Year Ended December 31, 2016
GAAP net earnings	\$ 1,611	\$ 1,413	\$6,950 to \$7,200
Intangible amortization, net of tax effects	140	86	~550
Adjusted net earnings	<u>\$ 1,751</u>	<u>\$ 1,499</u>	<u>\$7,500 to \$7,750</u>
GAAP diluted earnings per share	\$ 1.67	\$ 1.46	\$7.20 to \$7.40
Intangible amortization, net of tax effects per share	0.14	0.09	~\$0.55
Adjusted diluted earnings per share	<u>\$ 1.81</u>	<u>\$ 1.55</u>	<u>\$7.75 to \$7.95</u>

(a) GAAP and adjusted net earnings and earnings per share are attributable to UnitedHealth Group common shareholders.

Use of Non-GAAP Financial Measure

Adjusted earnings per share is a non-GAAP financial measure and should not be considered a substitute for or superior to a financial measure calculated in accordance with GAAP. Management believes that the use of adjusted earnings per share provides investors and management useful information about the earnings impact of acquisition-related intangible asset amortization. This non-GAAP measure does not reflect all of the expenses associated with the operations of our business as determined in accordance with GAAP. As a result, one should not consider this measure in isolation.

**17. AxelaCare Health Solutions
Tennessee and Kansas Licensure Information**

RECEIVED APR 13 2015

SUPPLEMENTAL #1
 STATE OF TENNESSEE
 DEPARTMENT OF
 12:14 PM
 ID NUMBER: 0000004637
 EXPIRATION DATE: 03/31/2017
 This is to certify that all requirements of the State of Tennessee have been met.
 PHARMACY BOARD
 PHARMACY
 AXELACARE HEALTH SOLUTIONS, LLC
Raemarie Otto
 DIRECTOR, HEALTH RELATED BOARDS

AXELACARE HEALTH SOLUTIONS, LLC
15529 COLLEGE BLVD.
LENEXA KS 66219-1351



9544722
41352

State of Tennessee
 TENNESSEE BOARD OF PHARMACY
 PHARMACY
 AXELACARE HEALTH SOLUTIONS, LLC
 15529 COLLEGE BLVD.
 LENEXA KS 66219

*This is to certify that all requirements of the State of Tennessee
 have been met.*

ID NUMBER: 0000004637
 EXPIRATION DATE: 03/31/2017

CONTROLLED SUBSTANCE REGISTRATION

Raemarie Otto
 DIRECTOR, HEALTH RELATED BOARDS

9527533

20692

State of Tennessee



TENNESSEE BOARD OF PHARMACY
MANUFACTURER/WHOLESALE/DISTRIBUTOR
AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD.
LENEXA KS 66215

*This is to certify that all requirements of the State of Tennessee
have been met.*

ID NUMBER: 0000003281
EXPIRATION DATE: 03/31/2017

Openaria OHO

DIRECTOR, HEALTH RELATED BOARDS



Kansas Board of Pharmacy
License Portal



Facility/Provider Information

Search Again

[Board of Pharmacy Home](#) | [License Verification](#) | [Exam Scores](#)



The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

General

Name or Business:	AXELACARE HEALTH SOLUTIONS LLC	Original Date:	2/11/2015
City/State/Zip:	LENEXA, KS 66219		
Classification:	Pharmacy/Facility	On Probation:	No
L/P/R No:	2-13075 / 1.2	Discipline on File:	No
Status:	Active		

Licenses

L/P/R #	Description	Effective	Expires	Issued	Status
2-13075	Pharmacy Permit	6/6/2016	6/30/2017	2/11/2015	Active

Notes

N/A

Kansas State Board of Pharmacy **June 23, 2016**
12:14 pm



Sam Brownback
Governor

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

RECEIVED
FEB 03 2016
BY:

Alexandra Blasi
Executive Secretary

AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Retail Pharmacy Inspection Form

Pharmacy: AXELACARE HEALTH SOLUTIONS LLC Reg No.: 2-13075 Renewal: 6-16
Address: 15529 COLLEGE BLVD City: LENEXA County: JO Phone: (877) 342-9352
Pharmacist-in-Charge: DEBORA WAGNER License#: 1-12933 DEA #: FA0905705 /
Other Pharmacist: _____
Type: PHARMACY Inspector: MELISSA MARTIN

Pharmacy Records

- Prescription Files: (21 CFR 1304.04)
- Prescription Content: (KSA 65-1637(b), KARs 68-20-18(c), 68-20-20(a))
- Daily Print-out Dispensing Log: (KAR 68-9-1,21 CFRs 1304.04, 1306.22)
- OTC Sales: (KAR 68-20-22)
- Invoice Record Files: (21 CFR 1304.04)
- Biennial Inventory: (21 CFRs 1304.11,1304.04)
- Incident Reports: (KAR 68-7-12)
- Duration of Record Keeping: (KAR 68-20-16(a))
- Library: (KARs 68-7-11(b), 68-7-11(i), 68-7-11(j)(2))
- Continuous Quality Improvement Documentation: (KSA 65-1695)

Pharmacy Practice

- Consumer Counseling: (KAR 68-2-20)
- Technician to Pharmacist Ratio: (KSA 68-5-16)
- Documentation of Technician Training: (KAR 68-5-15)

Other Miscellaneous

- Prescription Labeling: (KAR 68-7-14)
- Prepackaging / Repackaging Labels: (KARs 68-7-15, 68-7-16)
- Necessary Equipment: (KSA 65-1642(a), KAR 68-2-12a(b))
- Display of Certificates / Persons on Duty: (KSAs 65-1645(e), 65-1642(b), KAR 68-2-15)

Security

- Pharmacy: (KSA 65-1637, KARs 68-1-8, 68-2-11)
- Controlled Substances: (21 CFR 1301.75)

Comments: Spoke with Debora R.Ph please review CQI and Incident Report language to meet the requirements.

Date of Inspection: 1/22/2016

Kansas State Board of Pharmacy **June 23, 2016**

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

12:14 pm

FEB 03 2016



Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HOLDINGS INC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Inspection Form
Distributor

Company: AXELACARE HOLDINGS INC **Reg No.:** 5-31275 **Renewal:** 6-16
Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352
Person Responsible: DEBORA WAGNER **DEA #:** FA0905705 /
Type: DISTRIBUTOR **Inspector:** MELISSA MARTIN

Record Keeping

- Distribution Records: (KARs 68-14-7(f) if applicable...68-14-8)
- Bi-ennial Inventory: (21 CFRs 1304.04, 1304.11)
- Duration of Record Keeping: (KAR 68-14-7(f)(2))

Work Area

- Facilities: (KAR 68-14-7(a))
- Drug Storage / Quarantine Area: (KARs 68-14-7(a)(c)(e), 68-15-4)
- Security: (KAR 68-14-7(b))
- Examination of Materials: (KAR 68-14-7(d))

Comments:

Date of Inspection: 1/22/2016

Kansas State Board of Pharmacy June 23, 2016

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

12:14 pm

RECEIVED
FEB 03 2016



Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HOLDINGS INC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Inspection Form
Distributor

Company: AXELACARE HOLDINGS INC Reg No.: 5-31275 Renewal: 6-16
Address: 15529 COLLEGE BLVD City: LENEXA County: JO Phone: (877) 342-9352
Person Responsible: DEBORA WAGNER DEA #: FA0905705 /
Type: DISTRIBUTOR Inspector: MELISSA MARTIN

Record Keeping

Work Area

- Distribution Records: (KARs 68-14-7(f) if applicable...68-14-8)
- Bi-ennial Inventory: (21 CFRs 1304.04, 1304.11)
- Duration of Record Keeping: (KAR 68-14-7(f)(2))

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- Drug Storage / Quarantine Area: (KARs 68-14-7(a)(c)(e), 68-15-4)
- Security: (KAR 68-14-7(b))
- Examination of Materials: (KAR 68-14-7(d))

Comments:

Date of Inspection: 1/22/2016

**Pharmacy
Certificate of Renewal of Permit**

Original Permit # 2-13075
Pharmacy Name AXELACARE-HEALTH SOLUTIONS LLC
P.I.C. / Lic # DEBORA WAGNER 1-12933
Address 15529 COLLEGE BLVD
City/State/Zip LENEXA, KS 66219
Owner AXELACARE-HEALTH SOLUTIONS LLC

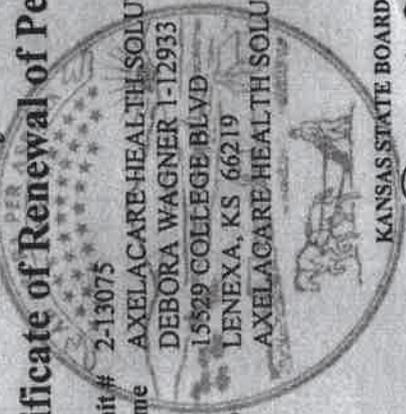
RECEIVED

MAY 20 2015

NOTICE: Display this renewal with original certificate in a prominent location site

APPLICANT MAILING ADDRESS

DEBORA WAGNER
AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD
LENEXA, KS 66219



2015 - 2016

Expires June 30, 2016

(This is a renewal, not an original registration)

Debra J. Billingsley

Executive Secretary
(785) 296-4056

June 23, 2016

12:14 pm
RECEIVED APR 07 2016



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive
Nashville, TN 37243
tennessee.gov/health

TENNESSEE BOARD OF PHARMACY
(615) 741-2718 or Fax (615) 741-2722

March 31, 2015

AxelaCare Health Solutions, LLC
15529 College Blvd.
Lenexa, KS 66219

RE: STERILE COMPOUNDING MODIFIER

To Whom It May Concern:

This letter certifies that AxelaCare Health Solutions, LLC is qualified to engage in the practices of sterile compounding under Tennessee rules and regulations. This qualification is specific to the following facility:

LICENSE TYPE: Pharmacy
ADDRESS: 15529 College Blvd.
Lenexa, KS 66219
LICENSE NUMBER: 4637

COMMENTS: Please keep a copy of this letter on file at your facility. Once the board has completed implementation of the sterile compounding modifier, an updated license will be mailed to the address on record.

Sincerely,
Ailene Lynn
Administrative Assistant II
Tennessee Board of Pharmacy



June 23, 2016

12:14 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

AxelaCare Health Solutions -- Shelby County

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 23rd day of June, 2016, witness my hand at office in the County of DAVIDSON, State of Tennessee.

[Signature]
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02



Supplemental #1
Additional
Information
-Original-

Axelacare Health
Solutions, LLC

CN1606-022

June 24, 2016

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1606-022
AxelaCare Health Solutions, LLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

13f. The tables for “D9-Other Expenses” on page 54 are noted. However, the categories do not match the categories as listed in the three submitted Projected Data Charts. Please revise.

The Projected Data Chart for Nursing Only that was submitted to you on June 23 (p. 51R) had transposed digits in the Other Expenses entry for Year Two. That number should have been \$19,783 rather than \$19,873. Revised page 51R2 is attached to this letter, correcting the transposition. Also attached is revised page 55R2, whose Table Eleven-A needed to be corrected as a result of changing the Projected Data Chart for Nursing.

17. Section C, Contribution to Orderly Development, Item 7d
a. If possible, please provide the latest copy of the Axelacare’s Specialty Pharmacy Program Inc.’s licensure survey and approved plans of correction.

The Tennessee Board of Pharmacy does not inspect the Alexa facility. Only Kansas licensure and inspection are required. That is the reason the Board of Pharmacy has established a non-resident pharmacy license.

June 24, 2016

12:12 pm

Page Two
June 24, 2016

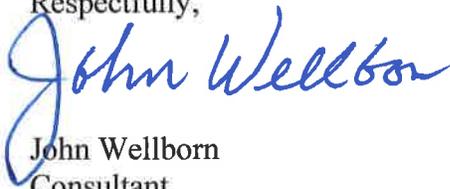
18. Proof of Publication

Please provide copies of the publication of intent of the required 4 newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 21 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication are being submitted to you by Brant Phillips' staff at Bass Berry & Sims. He is the CON legal counsel for this applicant and can serve as joint contact person.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email me at jwdsg@comcast.net or telephone me at 615-665-2022, so that we can respond in time to be deemed complete.

Respectfully,



John Wellborn
Consultant

**PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE 2014, 2016
NURSING AND HOME OFFICE ONLY--PHARMACEUTICALS EXCLUDED**

Give information for the two (2) years following the completion of this proposal.
The fiscal year begins in January.

		CY 2017	CY 2018
	PATIENTS	<u>45</u>	<u>65</u>
A.	Utilization Data VISITS	<u>1,080</u>	<u>1,560</u>
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u> </u>	\$ <u> </u>
2.	Outpatient Services-home health nursing visits	<u>259,200</u>	<u>374,400</u>
3.	Emergency Services	<u> </u>	<u> </u>
4.	Other Operating Revenue (Specify) <u>See notes page</u>	<u> </u>	<u> </u>
	Gross Operating Revenue	\$ <u>259,200</u>	\$ <u>374,400</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u> </u>	\$ <u> </u>
2.	Provision for Charity Care	<u>5,184</u>	<u>7,488</u>
3.	Provisions for Bad Debt	<u>2,592</u>	<u>3,744</u>
	Total Deductions	\$ <u>7,776</u>	\$ <u>11,232</u>
	NET OPERATING REVENUE	\$ <u>251,424</u>	\$ <u>363,168</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>369,840</u>	\$ <u>483,605</u>
2.	Physicians Salaries and Wages	<u> </u>	<u> </u>
3.	Supplies	<u>12,571</u>	<u>18,158</u>
4.	Taxes	<u> </u>	<u> </u>
5.	Depreciation	<u> </u>	<u> </u>
6.	Rent	<u>11,628</u>	<u>12,209</u>
7.	Interest, other than Capital	<u> </u>	<u> </u>
8.	Management Fees	<u> </u>	<u> </u>
	a. Fees to Affiliates	<u> </u>	<u> </u>
	b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9.	Other Expenses (Specify) <u>See notes page</u>	<u>7,798</u>	<u>19,783</u>
	Total Operating Expenses	\$ <u>401,837</u>	\$ <u>533,755</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u> </u>	\$ <u> </u>
	NET OPERATING INCOME (LOSS)	\$ <u>(150,413)</u>	\$ <u>(170,587)</u>
F.	Capital Expenditures		
1.	Retirement of Principal	\$ <u> </u>	\$ <u> </u>
2.	Interest	<u> </u>	<u> </u>
	Total Capital Expenditures	\$ <u>0</u>	\$ <u>0</u>
	NET OPERATING INCOME (LOSS)		
	LESS CAPITAL EXPENDITURES	\$ <u>(150,413)</u>	\$ <u>(170,587)</u>

June 24, 2016**12:12 pm**

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$5,760	\$5,760
Average Expected Revenue Per Visit	\$240	\$240
Average Deduction from Operating Revenue per Patient	\$173	\$173
Average Deduction from Operating Revenue per Visit	\$7	\$7
Average Net Charge (Net Operating Revenue) Per Patient	\$5,587	\$5,587
Average Net Charge (Net Operating Revenue) Per Visit	\$233	\$233
Average Net Operating Income after Expenses, Per Patient	-\$3,343	-\$2,624
Average Net Operating Income after Expenses, Per Visit	-\$139	-\$109

	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$101,760	\$101,760
Average Expected Revenue Per Visit	\$4,240	\$4,240
Average Deduction from Operating Revenue per Patient	\$3,053	\$3,053
Average Deduction from Operating Revenue per Visit	\$127	\$127
Average Net Charge (Net Operating Revenue) Per Patient	\$98,707	\$98,707
Average Net Charge (Net Operating Revenue) Per Visit	\$4,113	\$4,113
Average Net Operating Income after Expenses, Per Patient	\$15,985	\$18,110
Average Net Operating Income after Expenses, Per Visit	\$666	\$755

June 24, 2016

12:12 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

AXELACARS -- WEST TN

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 24th day of June, 2016, witness my hand at office in the County of DAVIDSON, State of Tennessee.

[Signature]
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02



**ADDITIONAL
INFORMATION
Supplemental #1
-COPY-**

**AXELAcARE HEALTH
SOLUTIONS**

CN1606-022

June 27, 2016

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1606-022
AxelaCare Health Solutions, LLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit. This replaces the materials delivered on June 24.

13f. The tables for “D9-Other Expenses” on page 54 are noted. However, the categories do not match the categories as listed in the three submitted Projected Data Charts. Please revise.

The Projected Data Chart for Nursing Only that was submitted to you on June 23 (p. 51R) had transposed digits in the Other Expenses entry for Year Two. That number should have been \$10,783 rather than \$10,873. Revised page 51R2 is attached to this letter, correcting the transposition. Also attached is revised page 55R2, whose Table Eleven-A needed to be corrected as a result of changing the Projected Data Chart for Nursing.

**17. Section C, Contribution to Orderly Development, Item 7d
a. If possible, please provide the latest copy of the Axelacare’s Specialty Pharmacy Program Inc.’s licensure survey and approved plans of correction.**

The Tennessee Board of Pharmacy does not inspect the Alexa facility. Only Kansas licensure and inspection are required. That is the reason the Board of Pharmacy has established a non-resident pharmacy license.

Page Two
June 27, 2016

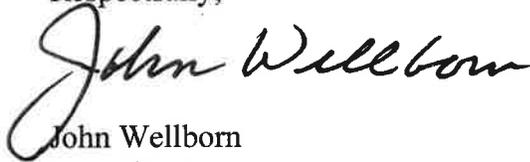
18. Proof of Publication

Please provide copies of the publication of intent of the required 4 newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 21 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication are being submitted to you by Brant Phillips' staff at Bass Berry & Sims. He is the CON legal counsel for this applicant and can serve as joint contact person.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email me at jwdsg@comcast.net or telephone me at 615-665-2022, so that we can respond in time to be deemed complete.

Respectfully,

A handwritten signature in cursive script that reads "John Wellborn". The signature is written in black ink and is positioned above the printed name and title.

John Wellborn
Consultant

**PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE
NURSING AND HOME OFFICE ONLY--PHARMACEUTICALS EXCLUDED**

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

		CY 2017	CY 2018
		<u>45</u>	<u>65</u>
PATIENTS			
VISITS		<u>1,080</u>	<u>1,560</u>
A.	Utilization Data		
B.	Revenue from Services to Patients		
1.	Inpatient Services	\$ <u> </u>	\$ <u> </u>
2.	Outpatient Services-home health nursing visits	<u>259,200</u>	<u>374,400</u>
3.	Emergency Services	<u> </u>	<u> </u>
4.	Other Operating Revenue (Specify) <u>See notes page</u>	<u> </u>	<u> </u>
	Gross Operating Revenue	\$ <u>259,200</u>	\$ <u>374,400</u>
C.	Deductions for Operating Revenue		
1.	Contractual Adjustments	\$ <u> </u>	\$ <u> </u>
2.	Provision for Charity Care	<u>5,184</u>	<u>7,488</u>
3.	Provisions for Bad Debt	<u>2,592</u>	<u>3,744</u>
	Total Deductions	\$ <u>7,776</u>	\$ <u>11,232</u>
	NET OPERATING REVENUE	\$ <u>251,424</u>	\$ <u>363,168</u>
D.	Operating Expenses		
1.	Salaries and Wages	\$ <u>369,840</u>	\$ <u>483,605</u>
2.	Physicians Salaries and Wages	<u> </u>	<u> </u>
3.	Supplies	<u>12,571</u>	<u>18,158</u>
4.	Taxes	<u> </u>	<u> </u>
5.	Depreciation	<u> </u>	<u> </u>
6.	Rent	<u>11,628</u>	<u>12,209</u>
7.	Interest, other than Capital	<u> </u>	<u> </u>
8.	Management Fees	<u> </u>	<u> </u>
	a. Fees to Affiliates	<u> </u>	<u> </u>
	b. Fees to Non-Affiliates	<u> </u>	<u> </u>
9.	Other Expenses (Specify) <u>See notes page</u>	<u>7,798</u>	<u>10,783</u>
	Total Operating Expenses	\$ <u>401,837</u>	\$ <u>524,755</u>
E.	Other Revenue (Expenses) -- Net (Specify)	\$ <u> </u>	\$ <u> </u>
	NET OPERATING INCOME (LOSS)	\$ <u>(150,413)</u>	\$ <u>(161,587)</u>
F.	Capital Expenditures		
1.	Retirement of Principal	\$ <u> </u>	\$ <u> </u>
2.	Interest	<u> </u>	<u> </u>
	Total Capital Expenditures	\$ <u>0</u>	\$ <u>0</u>
	NET OPERATING INCOME (LOSS)		
	LESS CAPITAL EXPENDITURES	\$ <u>(150,413)</u>	\$ <u>(161,587)</u>

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Eleven-A: Average Charges, Deductions, Net Charges, Net Operating Income West Tennessee Nursing Operations Only		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$5,760	\$5,760
Average Expected Revenue Per Visit	\$240	\$240
Average Deduction from Operating Revenue per Patient	\$173	\$173
Average Deduction from Operating Revenue per Visit	\$7	\$7
Average Net Charge (Net Operating Revenue) Per Patient	\$5,587	\$5,587
Average Net Charge (Net Operating Revenue) Per Visit	\$233	\$233
Average Net Operating Income after Expenses, Per Patient	-\$3,343	-\$2,486
Average Net Operating Income after Expenses, Per Visit	-\$139	-\$104

Table Eleven-B: Average Charges, Deductions, Net Charges, Net Operating Income Combined W. TN Nursing and Out of State Pharmaceutical Operations		
	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	\$101,760	\$101,760
Average Expected Revenue Per Visit	\$4,240	\$4,240
Average Deduction from Operating Revenue per Patient	\$3,053	\$3,053
Average Deduction from Operating Revenue per Visit	\$127	\$127
Average Net Charge (Net Operating Revenue) Per Patient	\$98,707	\$98,707
Average Net Charge (Net Operating Revenue) Per Visit	\$4,113	\$4,113
Average Net Operating Income after Expenses, Per Patient	\$15,985	\$18,110
Average Net Operating Income after Expenses, Per Visit	\$666	\$755

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

AXELCARE - W.TN

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.



John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 27th day of June, 2016, witness my hand at office in the County of DAVIDSON, State of Tennessee.

Jan M. Danforth
NOTARY PUBLIC

My commission expires July 2, 2018.

The Commercial Appeal Affidavit of Publication

**STATE OF TENNESSEE
COUNTY OF SHELBY**

Personally appeared before me, Patrick Maddox, a Notary Public, Marianne Sheridan, of MEMPHIS PUBLISHING COMPANY, a corporation, publishers of The Commercial Appeal, morning and Sunday paper, published in Memphis, Tennessee, who makes oath in due form of law, that she is Legal Clerk of the said Memphis Publishing Company, and that the accompanying and hereto attached advertisement was published in the following editions of The Commercial Appeal, to-wit:

June 10, 2016

Marianne Sheridan

Subscribed and sworn to before me this 10th day of June, 2016.

Patrick Maddox Notary Public

My commission expires January 20, 2020.



The Paris **Post-Intelligencer**

PROOF OF PUBLICATION

State of Tennessee --- Henry County:

This day personally before me the undersigned came **Michael B.**

Williams, Proprietor of **The Paris Post-Intelligencer**, a daily

newspaper published in Paris, Tennessee, who makes oath in due form of

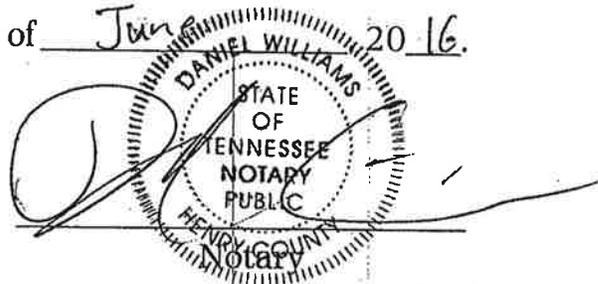
law that the advertisement for Intent to Apply, a copy of which has

been provided, was published in said paper 6-10-16 and

the printer's fee for same is \$ 170.56.

Michael B Williams

Sworn and subscribed to me this 23 day of June 20 16.



My commission expires: August 22, 2017

AFFIDAVIT OF PUBLICATION

0001341971

Newspaper Jackson Sun

State of Tennessee

Account Number NAS-523833

Advertiser BASS, BERRY, & SIMS

BASS, BERRY, & SIMS
BASS BERRY
150 3RD AVE S STE 2800
NASHVILLE, TN 37201

TEAR SHEET
ATTACHED

Jackie Cooper

Sales Assistant for the above mentioned newspaper,

hereby certify that the attached advertisement appeared in said newspaper on the following dates:

✓

06/10/16

Jackie Cooper

Subscribed and sworn to before me this

14

day of

June, 2016

Angela Murray
Notary Public



classifieds

wheels « homes « merch « announce « jobs

ALL CLASSIFIED ADS are subject to the applicable rate card. Lines of ads are established from our Advertising Dept. All ads are subject to standard business practices. The Jackson Sun reserves the right to add, reduce, reject, modify or cancel any ad at any time. Errors must be reported to the print department the day of publication. The Jackson Sun shall not be liable for any loss or damage that results from an error, in whole or in part, or from an omission of an advertisement, for failure to carry out an order, or from any other cause, whether or not such error, omission or failure was caused by negligence. We make no warranties, express or implied, regarding the accuracy of any information contained in any advertisement. We are not responsible for any loss or damage resulting from advertising which may be placed.

Whats Hot
Announce
messages & notices

Adoptions
ADOPTION: Looking for adoptive parents? Call 731-423-0300.

Announcements
ABC Server Permit Classes & Certification Test - 731-717-0022

Found
Found a lost item? Let us know. 731-423-0300

Lost
Lost a pet or item? Let us know. 731-423-0300

Adopt Me
Adopt a pet. 731-423-0300

Domestic Pets
Domestic pets for sale. 731-423-0300

Hollywood Puppies
Hollywood puppies for sale. 731-423-0300

Yorke Pups
Yorke pups for sale. 731-423-0300

Pet Services
Pet services available. 731-423-0300

On The Farm
On the farm items for sale. 731-423-0300

Farm Equipment
Farm equipment for sale. 731-423-0300

Horses and Ponies
Horses and ponies for sale. 731-423-0300

Livestock/Poultry
Livestock and poultry for sale. 731-423-0300

Pigeons for sale
Pigeons for sale. 731-423-0300

Great Buys
Great buys on various items. 731-423-0300

Yard Sale
Yard sale items for sale. 731-423-0300

Madison Central
Madison Central area listings. 731-423-0300

Madison East
Madison East area listings. 731-423-0300

Madison North
Madison North area listings. 731-423-0300

Madison South
Madison South area listings. 731-423-0300

Neighborhood
Neighborhood listings. 731-423-0300

Wanted to Buy
Wanted to buy items. 731-423-0300

Madison Central

Yard Sale

Yard sale items for sale. 731-423-0300

Madison West

Madison West area listings. 731-423-0300

Other Areas

Other areas listings. 731-423-0300

Community

Community listings. 731-423-0300

Assorted

Assorted items for sale. 731-423-0300

General Merchandise

General merchandise for sale. 731-423-0300

Merch

Merchandise for sale. 731-423-0300

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Merchandise for sale. 731-423-0300

General Merchandise

Madison South

Madison South area listings. 731-423-0300

Yard Sale

Yard sale items for sale. 731-423-0300

Madison West

Madison West area listings. 731-423-0300

Other Areas

Other areas listings. 731-423-0300

Community

Community listings. 731-423-0300

Assorted

Assorted items for sale. 731-423-0300

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General merchandise for sale. 731-423-0300

Merch

Merchandise for sale. 731-423-0300

Continued from last column

00012058

NOTICE OF PUBLIC AUCTION

A PUBLIC AUCTION WILL BE HELD TO DISPOSE OF ITEMS WHICH HAVE BEEN DECLARED SURPLUS BY THE JACKSON-MADISON COUNTY SCHOOL SYSTEM. INCLUDED IN THE AUCTION WILL BE SCHOOL BUSES, ONE WRECKER, ONE TRACTOR/BACKHOE, OTHER VEHICLES, ETC.

LOCATION JACKSON-MADISON COUNTY SCHOOL SYSTEM BUS GARAGE, 59 HARTS BRIDGE ROAD WEST, JACKSON, TN

TIME & DATE OF AUCTION: 9:00AM, TUESDAY, JUNE 14, 2016

ALL ITEMS MAY BE VIEWED & INSPECTED BY THE PUBLIC BEGINNING AT 8:30AM ON THE DAY OF THE AUCTION.

ALL ITEMS WILL BE SOLD "AS IS" AND WITH NO WARRANTIES IMPLIED OR EXPRESSED, & MUST BE REMOVED FROM SCHOOL SYSTEM PROPERTY WITHIN A REASONABLE TIME AS DETERMINED BY THE SCHOOL SYSTEM'S TRANSPORTATION SUPERVISOR.

MADISON COUNTY GOVERNMENT, NOR ANY OF ITS DEPARTMENTS, OFFICES OR AGENCIES, DISCRIMINATES ON THE GROUNDS OF RACE, COLOR, RELIGION, DISABILITY, SEX, AGE OR NATIONAL ORIGIN.

MADISON COUNTY, TN FINANCE DEPT., PURCHASING OFFICE

000130717

NOTICE IS HEREBY GIVEN

That Philip L. Crain has made an application to the Madison County Beer Commission for a permit to sell beer in Madison County. This application is for an On Premise Permit, located at 2174 Highway 70 East, Madison County, Tennessee. Said hearing will be held on June 20, 2016 at 8:00 A.M. at the West Tennessee Center for Agricultural Research and Plant Sciences Conference Room 151, 605 Airways Blvd., Jackson, Tennessee.

Fred Birmingham Secretary MADISON COUNTY BEER COMMISSION

000130733

REQUEST FOR PROPOSALS

Construction Services

Tennessee Housing Development Corporation

Proposals are requested by Tennessee Housing Development Corporation (THDC) from firms capable of providing Construction Services to complete new construction and rehabilitation services for housing as well as to participate in the evolution of plans and specifications with the A/E during the design development work for the project. The work is to be conducted at the existing Kingsfield development on the vacant parcel to the north, located at Kingsfield Drive, just off North Royal Street, Jackson, TN. Submittals will be evaluated according to published criteria. A clearly marked "Construction Services Proposal" in PDF must be received by email at the THDC offices attention Sue Fleming (sflaming@jacksontn.com) by 11:00 am CT on Friday June 24, 2016 in order to be considered. A PDF of the RFP package is available by emailing Ms. Fleming at the above email address. All persons requesting a copy of the RFP package must provide name, mail address, telephone and cell numbers, and email address in case any addenda are issued. There will be a pre-submission conference on Thursday June 16, 2016 beginning at 10:30 a.m. The conference will begin at THDC offices in the JHA buildings at 125 Preston, Jackson, TN. Written inquiries may be submitted no later than 2:30 pm, CT, Monday, June 20, 2016. Inquiries may be sent via email to sflaming@jacksontn.com. All Offerors must be licensed Contractors as required by the Contractors Licensing Act of 1978 TCA Title 42, Chapter 6 of the General Assembly of the State of Tennessee. There will be a Performance and Payment Bond. The right is reserved to reject any or all bids or to waive any informalities in the procurement process. Because certain financing associated with this development involves Federal funds from the U.S. Department of Housing and Urban Development, certain requirements mandated by HUD regulations will apply and are further outlined in the RFP package.

Continued from last column

Public Notices

STATE GAZETTE

294 US Highway 51 Bypass N.
Dyersburg, TN 38024
731-285-4091
Fax: 731-286-6183

I, Jina Jeffries, business manager of the State Gazette, a newspaper published at Dyersburg, Tennessee, hereby certify that the annexed advertisement has been published 1 consecutive/
~~non-consecutive days/weeks~~ in said paper on the following dates: 6/10/2016 and that the fee of \$ 268.80 has ~~not~~ been paid.

Jina Jeffries

This 15th day of June, 2016

Shelia Rouse, Notary Public

Commission expires: February 14, 2018



