

W. Brantley Phillips, Jr.
bphillips@bassberry.com
(615) 742-7723

October 13, 2016

VIA HAND DELIVERY

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

Re: AxelaCare Health Solutions LLC (CN1606-022)

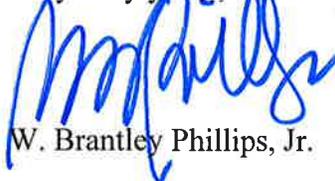
Dear Ms. Hill:

In connection with the above-referenced application, please find attached several letters of support from national research institutions, physician practice groups and patients. Please include this group of support letters in the materials that are provided to the Agency members. We will look forward to being present on October 26th to discuss the many merits of this application.

Thank you for your attention in this matter, and please let us know if you have any questions about the attached.

With kind regards, I remain,

Very truly yours,



W. Brantley Phillips, Jr.

WBP:
Attachment
cc: Michele Hartman Tamene

20628468.1

10/12/2016

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

Re: AxelaCare Health Solutions LLC (CN1606-022)

Dear Ms. Hill:

I want to express my support for AxelaCare Health Solutions LLC's certificate of need application to expand its services in West Tennessee. From personal experience, I can attest that the work AxelaCare does with patients around the country makes an important and positive contribution to patient care and medical research.

Many rare and complex diseases lack evidence based treatment guidelines. My practice entails the diagnosis and management of such diseases, many of which are treated with IVIg (intravenous immunoglobulin). The increased acceptance and use of home infusions for IVIg creates a unique opportunity to collect and measure patient outcomes data. With AxelaCare's unique "CareExchange" technology, physicians and nurses are able to capture valuable patient data easily and securely. This data offers in site into the way rare disease are diagnosed and treated, thereby improving our understanding of diagnostic and treatment shortcomings. AxelaCare's CareExchange technology also allows physicians to use that data to potentially help understand how any individual patient responds to treatment. This is critically important when attempting to individualize or optimize therapy for rare diseases in which there is no standard long term treatment guideline.

I value the research partnership with AxelaCare, and appreciate efforts they have made to improve patient monitoring during long-term IVIg therapy. I strongly endorse AxelaCare's application for a Certificate of Need. Thank you for your consideration in this matter. Please do not hesitate to contact me with any questions.

Sincerely,



Jeffrey Allen MD
University of Minnesota
Department of Neurology



DeKalb Medical Physicians Group
Neurology Specialists of Decatur

2665 North Decatur Road, Ste 450, Decatur, GA 30033
www.neurologyspecialistsofdecatur.com

ph: 404.501.7555
fx: 404.501.7550

Tamara S. Greene, M.D.

October 11, 2016

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

Re: AxelaCare Health Solutions LLC (CN1606-022)

Dear Ms. Hill:

I am a physician at Neurology Specialists of Decatur in Decatur, Georgia and want to express my support for AxelaCare Health Solutions LLC's certificate of need application to expand its services in West Tennessee. From personal experience, I can attest that the work AxelaCare does with patients around the country makes an important and positive contribution to medical research. I am certain that the approval of this project will assist both in improving patient care and the orderly development of healthcare in your state. I urge your agency to approve AxelaCare's application.

Many rare and complex diseases, and the medicines that treat them, lack a robust body 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 hope to patient facing serious long-term medical challenges. The increased acceptance and use of home infusions for IVig (intravenous immunoglobulin) create a unique opportunity to collect and measure patient outcomes data with trained clinicians. With AxelaCare's unique "CareExchange" technology, physicians and nurses are able to capture valuable patient data easily and securely. Research institutions like ours rely on this data as we work to study dose response, dose optimization, drug side effects and variations in treatment results across diverse demographic groups and diagnoses. The goals for improved patient outcomes and reductions in costs are put closer within reach thanks to the research support that the data collected from AxelaCare's patients provides.

I value my partnership with AxelaCare, and am confident that the addition of AxelaCare's services in West Tennessee region will enhance our research efforts. For all of these important reason, I enthusiastically endorse AxelaCare's application for a Certificate of Need. Thank you for your consideration in this matter. Please do not hesitate to contact me with any questions.

Sincerely,


Tamara S. Greene, M.D.

~~Bala Adamolekun, M.D.~~

~~Tullio E. Bertorini, M.D.~~

~~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 Pillai, M.D.~~

Nancy F. Baker
Administrator

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

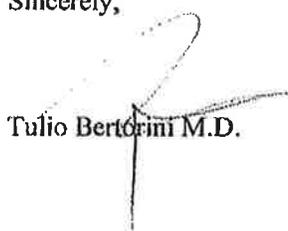
Dear Ms. Hill:

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 Bertorini 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:

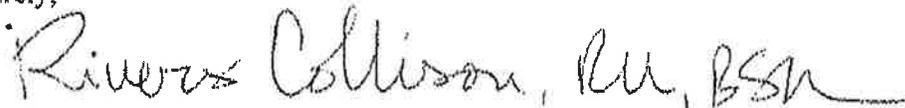
I am a Registered Nurse working for Memphis Neurology. We are a multi-physician specialty medical practice in Memphis treating patients with disorders related to the nervous system. We see patients from Memphis and several counties surrounding Shelby County.

In the past, we have attempted to identify home health agencies that will treat our patients requiring immune globulin (Ivlg) 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.

Neurologists:

- Thomas W. Arnold, M.D.
- Maroun Dlek, M.D.
- Kendrick K. Henderson, M.D.
- Joshua J. Lennon, M.D.
- Barbaca Cape O'Brien, M.D.
- David L. Pritchard, M.D.
- Lihong Shen, M.D.
- Lee S. Stein, M.D.

Chip Harris, Administrator

Germantown Park
 8000 Centerview Pkwy. #300
 Cordova, TN 38018
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 (901) 747-1137 fax

MRI
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 Cordova, TN 38018
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 (901) 309-5160 fax

Sleep Center
 8000 Centerview Pkwy. #115
 Cordova, TN 38018
 (901) 255-7150

Memphis Neuroscience
 Research Center
 8000 Centerview Pkwy. #300
 Cordova, TN 38018
 (901) 866-9252
 (901) 255-1457 fax

Web Site:
www.neurologyclinic.org

Neurology Clinic, P.C.

July 29, 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:

The physicians and staff at the Neurology Clinic recognize the need for Axelacare Health Solutions LLC's certificate of need application to provide comprehensive, integrated home infusion care to residents of West Tennessee.

Neurology Clinic is a multi-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, to avoid needless travel.

The number of patients requiring immune globulin infusion is increasing rapidly as the treatment's effectiveness is explored and demonstrated. We are also seeing many health insurance companies requiring patients to be treated in the home setting rather than in the hospital or infusion suites. Those two factors will steadily increase this region's referrals for IgG home infusion.

We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy for patients who are not able to access infusion suites 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, their inability to staff experienced Ig infusion nurses as soon as needed, and limited ability to transmit real-time clinically detailed and appropriate feedback on our patients' responses during infusion. The latter is available, however, from AxelaCare through its hand-held CareExchange technology. 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,



Dr. Kendrick Henderson



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.

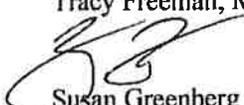
National Integrated Health Associates is a specialty medical practice of six physicians and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in Shelby County. Many of our patients 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

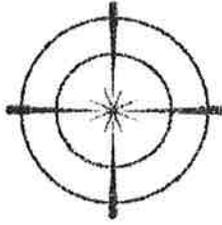


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INTERNATIONAL
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Washington, DC 20037
888-727-6910
Fax 202-765-2456

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.

From: Sandra Frye
Sent: Tuesday, September 09, 2016 10:31 AM
Subject: Recommendation Letter

To whom it may concern, my doctor has ordered that I receive IVIG infusions as I am diagnosed with Myasthenia Gravis. I am ordered to receive this medication at home. I do receive my infusions at home by a contracted nurse. It would be much more stream lined if I was able to receive my medication and nursing from one company. My nurse is good but not an IVIG Nurse. My understanding is that Axelacare nurses are specially trained in IVIG infusions and diseases. If they were licensed in Tennessee it would make things so much easier for people receiving IVIG.
Sincerely, Sandra Frye.

Recommendation letter for CON approval.

Dear State of TN Board of Nursing,
I have been asked to write a letter recommending that ApelaCare obtain a CON so they can provide nursing for Ig patients in the home.

My daughter has Turner's Syndrome and requires Ig every month. The lack of nursing in the area has left her with large gaps of time between infusions due to no one being able to come to our home to infuse her. She works and goes to school so time is precious and infusion suites are not open in the evenings and weekends. I would ask that ApelaCare be granted a CON so people like my daughter can receive their Ig and live their lives to the fullest. — Dana Williams - father of Alexis Williams

TN Recommendation letter for licence in the ~~state~~

To whom it may concern,
I have been going to my doctor
to get my FVIG infusions. It is
a hardship for me to go due to my
condition and I have pain. If
Appalachian was able to have a licence
I could get my IVIG at home
and it would be so much easier
for me. Now there is no nursing that
will be me where I live.

It is my wish that Appalachian have
a licence so I can get my medicines
at home.

Thanks, sincerely
Mrs. Linda Wren

From: AEC
Subject: Tyler
Date: Tuesday, August 30, 2016 1:29:48 PM

Dear Dennis ,

I wanted to reach out to you to thank you for coordinating care for Tyler's infusion . I understand I will be working with a separate nursing service for awhile until Axecare can apply for the proper license . I cannot wait for that as Tyler had Axecare nursing and pharmacy in one when he lived in Florida. Being able to have all of his care under one roof with one company makes things easier and there is less chance for errors and confusion.

Take care ,

April Cohenour