



State of Tennessee

Health Facilities Commission

665 Mainstream Drive, 2nd Floor, Nashville, TN 37243

www.tn.gov/hfc

Phone: 615-741-7221

August 8, 2024

Sent Via Email

Optigen, Inc
Elizabeth O'Brien
19387 US Highway 19 North
Attn: Licensing Department
Clearwater, Florida 33764

Facility Type: Home Medical Equipment

Dear Nicole McCarney:

It is my pleasure to inform you that your application for Optigen, Inc has been initially approved for providing Home Medical Equipment services in all counties in Tennessee; effective July 11, 2024. The license number shall be 1442. For this initial approval to become final and permanent, your application must be ratified by the commission pursuant to T.C.A. §68-11-206. The Commission will consider your application at its next meeting, scheduled for August 2024. **You are hereby authorized to commence operation pending the final decision of the Commission** No further action is necessary on your part currently.

For certification purposes, please be advised it is your responsibility to contact your Health Facilities Commission regional office for participation in Medicare/Medicaid. The East Tennessee Regional Office phone number is 865-594-9396 .

If the Commission **does** ratify the approval of your application, the license number listed above will become your permanent license number and a letter will be forwarded to you within three (3) business days; notifying you of the Commission final decision.

If the Commission **does not** ratify the initial approval of your application, a letter will be forwarded to you providing an explanation and specific instructions as to any action(s) you may take to have the decision reviewed, at which time this authorization shall cease to be effective.

Please contact me if I can be of further assistance.

Sincerely,

Niraj Soni

Niraj Soni, ASA 3
Phone: (615) 741-7539
Fax: (615) 253-8798
Email: Niraj.Soni@tn.gov

cc: East Tennessee Regional Administrator



State of Tennessee

Health Facilities Commission

665 Mainstream Drive, 2nd Floor, Nashville, TN 37243

www.tn.gov/hfc

Phone: 615-741-7221

June 11, 2024

Sent Via Email

Optigen, Inc.
19387 US Highway 19 North
Attn: Licensing Department
Clearwater, Florida 33764

Facility Type: Home Medical Equipment

Dear Administrator:

It is my pleasure to inform you that your application for licensure of Optigen, Inc. located at 1351 13th Avenue South, Suite 100, Jacksonville Beach, Florida 32250 has been initially approved to provide Home Medical Services to all counties in Tennessee; effective June 10, 2024. The license number shall be 1400. For this initial approval to become final and permanent, your application must be ratified by the Board pursuant to T.C.A. §68-11-206. The Board will consider your application at its next meeting, scheduled for July 31, 2024. **You are hereby authorized to commence operation pending the final decision of the Board.** No further action is necessary on your part currently.

For certification purposes, please be advised it is your responsibility to contact your Health Care Facility's regional office for participation in Medicare/Medicaid. The East Regional Office phone number is 865-594-9396.

If the Board **does** ratify the approval of your application, the license number listed above will become your permanent license number and a letter will be forwarded to you within three (3) business days; notifying you of the Board's final decision.

If the Board **does not** ratify the initial approval of your application, a letter will be forwarded to you providing an explanation and specific instructions as to any action(s) you may take to have the decision reviewed, at which time this authorization shall cease to be effective.

Please contact me if I can be of further assistance.

Sincerely,

Mary Louise Clark

Mary Louise Clark, ASA II



APPROVAL FOR FACILITY LICENSURE OR OCCUPANCY

Facility Type: HME License # (if applicable): _____ County: _____

Initial X Renovation _____ Satellite/Off Campus Location _____

Physical Plant/Services/New Addition _____ Relocation/Replacement Facility _____
(Circle One) (Circle One)

Facility Name: Optigen Inc

Address: 1351 13th Avenue South, Suite 100 City: Jacksonville Beach FL Zip Code: 32250

Application and fee on file in Central Office (CO)? Yes _____ No _____ CON #: _____

Project #: _____ Phase: _____ of _____

Facility approved for (if satellite/off campus site include address): To provide HME services to all counties in Tennessee.

Sprinklered: _____ (Full 100%) Partial: _____ (%)

Licensed bed count from: _____ to _____ Number of beds increased/decreased: _____

If secured unit, number of beds in unit: _____ If Alzheimer's unit, number of beds in unit: _____
(NOTE: If this is an increase in the number of beds in a secured Alzheimer's unit, indicate number of beds approved for the increase number only)

Health Surveyor: Robert G. Anderson Date: 6-10-24

Fire Safety: _____ Date: _____

CD Approved: Yes _____ No _____ N/A _____ Health Survey Required: Yes _____ No _____

Facility's Letter of Notification received in Licensure: Yes _____ No ✓
(Completed by Central Office Licensure Staff)

CMS Paperwork (855, etc) approved and received in regional office: Yes _____ No _____
(NOTE: With exception of Initial Licensure Approvals)

Effective date: 6/10/24
(Completed by Central Office Licensure Staff)

Licensure is recommended: Yes X No _____

X Debra Vann
Regional Administrator/Facilities Construction Director or Designee

6/10/24
Date

Mary Louise Clark
Licensure Program Unit Staff

6/14/24
Date



State of Tennessee

Health Facilities Commission

665 Mainstream Drive, 2nd Floor, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-7221

September 6, 2023

Sent Via Email

Elizabeth O'Brien
Optigen, Inc.
1351 13th Avenue South, Suite 100
Jacksonville Beach, Florida 32250

Dear Elizabeth O'Brien:

This is to acknowledge receipt of your application and fee to apply for licensure of Optigen, Inc. Please review the instruction sheet that you received with the application to apply for licensure so that you are aware of the process for obtaining licensure of your facility. If a certificate of need is required to provide services, you will need to contact *Health Services and Developmental Agency* at (615) 741-2364.

Please remember that if you are applying for licensure of a facility that requires an architectural plans review contact Plans Review for complete and details and procedures at (615) 741-6998. You must submit those plans along with the plans review fee prior to scheduling a survey. **For Homes for the Aged facilities specifically; TCA-368-11-202 allows "schematics shall be submitted to the department for approval of plans and specifications, converting and existing single family dwelling" with six (6) or less beds.**

It is your responsibility to contact the East Tennessee Regional Office to request a survey of your facility. Please submit the request in writing to East Tennessee, Regional Administrator, 7175 Strawberry Plains Pike, Suite 103, Knoxville, Tennessee 37914. If you would like to fax the request to Debra Verna) the fax number is 865-594-5739.

Your application and fee will be held in a pending status until you are recommended by the Regional Office for licensure. Once the recommendation for licensure is received from the regional office, your facility will receive a letter for "Initial Approval." Admission of patients MAY NOT occur until the facility's receipt of the "Initial Approval" letter. Your application will be presented before the Board for Licensing Health Care Facilities for ratification and final approval at the next regularly scheduled board meeting. Your facility CAN operate once you receive the "Initial Approval."

This application will only be good for one (1) years from the date of receipt. If the initial licensure has not occurred within that one (1) year period you will be required to submit a new application and fee unless you have contacted our office in writing extending your application.

In the event that a certificate of need is required prior to obtaining a license for this facility the application file will be closed the day following the expiration date of the certificate of need.

Should you have any questions or if I can be of assistance to you please call me at (615) 741-7202 or you may email me at Mary.2.Clark@tn.gov.

Sincerely,

Mary Louise Clark

Mary Louise Clark, ASA 2

115D/ EAST file #1400 App# 22787

Application Summary

9/6/23 7:41 AM

Page 1 of 4

Application Detail

License Type:	Home Medical Equipment: Licensed
Application:	Home Medical Equipment: Initial Application
Application Date:	09/06/2023 (mm/dd/yyyy)

Organization Detail

Organization Name:	OPTIGEN INC
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Addresses

Main Address

Address:	1351 13TH AVE S SUITE 100 DUVAL Jacksonville Beach, FL 32250 US
Phone Number:	800-273-9114
Extension:	
E-mail Address:	LICENSING@LINCARE.COM

Administrative

Name:	OPTIGEN INC
Address:	19387 US HIGHWAY 19 N ATTN: LICENSING DEPT PINELLAS Clearwater, FL 33764 US
Phone Number:	727-530-7700
Extension:	

E-mail Address:

LICENSING@LINCARE.COM

Emergency Contact

Name:

OPTIGEN INC

Address:

1351 13TH AVE S

SUITE 100

DUVAL

Jacksonville Beach, FL

32250

US

Phone Number:

800-273-9114

Extension:

E-mail Address:

LICENSING@LINCARE.COM

Ownership of Building

Name:

AFE, LLC

Address:

3591 3591 WATERCHASE WAY

DUVAL

Jacksonville, FL

32224

US

Phone Number:

904-724-9888

Extension:

E-mail Address:

LICENSING@LINCARE.COM

Legal Entity

Name:

OPTIGEN INC

Address:

19387 US HIGHWAY 19 N

PINELLAS

Clearwater, FL

33764

USPhone Number: **727-530-7700**

Extension:

E-mail Address: **LICENSING@LINCARE.COM****License Attributes Selected**Qualification/Certification **All Counties****Basic License Data**If your facility has branch offices provide the number. If none, enter 00 **00**Provide Administrator's Name: **ELIZABETH O'BRIEN**Provide the Ownership's Name: **LINCARE INC**Is your facility accredited by a federally approved accrediting body? If yes, provide the accrediting body (i.e. JCAHO, CHAP, CARF, DNA, etc.): **Yes**If accredited, provide expiration date of accreditation: **12/15/2024 (mm/dd/yyyy)**What type of Home Care Organization: Hospital Based or Nursing Home Based or Free Standing? **Other**Provide a Yes or No, if your facility is Chain Affiliated: **No**Provide a Yes or No, if your facility has a Holding Company: **No**Do you have Other Licensed Facilities in the state of Tennessee and/or other states? **No**Provide a Yes or No, if your facility has a parent company: **Yes**Provide a Yes or No, if your facility has a Management Firm: **No**Have any owners ever been denied a license, had a license suspended or revoke, had a suspension of admissions or paid any civil monetary penalties for a health care facility in Tennessee or in any other state? **No**

Have any owners ever been denied a license, had a license suspended or revoke, had a suspension of admissions or paid any civil monitory penalties for a health care facility in Tennessee or in any other state?

Does your facility have a physical location in Tennessee?: **No**

File Attachments

RG 50 MRB Marketplace Bank Letter.pdf

Fees

Initial License Fee	\$1404.00
Total Amount Due:	\$1404.00

Attestation

I, being duly sworn and identified as the person referred to in this application attest to the truth of each statement made in said application. I further swear that I have read and understand the law and the Rules and Regulations regarding the practice of my profession, which are posted on the Board's Internet site and/or were provided to me by the Board office, and agree to abide by them in the practice as a Home Medical Equipment facility in the State of Tennessee. I HEREBY: SIGNIFY my willingness to appear to answer such questions as the Board may find necessary, which may include a full Board interview. RELEASE to the Board, its staff, and their representatives, any and all documentation necessary now and in the future to establish my physical and mental capabilities to safely practice as a Home Medical Equipment facility. AUTHORIZE the Board, its staff, and their representatives to consult with my prior and current associates and others who may have information bearing on my professional competence, character, health status, ethical qualifications, ability to work cooperatively with others, and other qualifications. RELEASE from liability the Board, its staff, and all their representatives and any and all organizations which provide information for their acts performed and statements made in good faith and without malice concerning my competence, ethics, character, and/or other qualifications, for certification. ACKNOWLEDGE that I, as an applicant for licensure, have the burden of producing adequate information for a proper evaluation of my professional, ethical, and other qualifications, and for resolving any doubts about such qualifications. AUTHORIZE release, use and disclosure of otherwise HIPAA protected health information to the limited extent necessary for my application to receive full consideration up to and including discussion in a public forum should that become necessary. This certifies that the information submitted by me in this application is true and complete to the best of my knowledge and belief.

Online Payment Receipt

Receipt Issued By:

Board for Licensing Health Care Facilities

Receipt Issued To:

JENNIFER PEDERSEN_OPTIGEN INC

19387 US HWY 19 N

CLEARWATER, FL 33764

Date: 09/06/2023

Transaction Identifier: 3857618488

Trace Number: 1745454

License Type	Licensee	Transaction	Application #	Account #	Amount
Home Medical Equipment	OPTIGEN INC	Home Medical Equipment: Initial Application	548-22787	*****1226	\$1404.00