AHCA USE ONLY:
File #: _____
Application #: _____
Check #: _____
Check Amt: _____
Batch #: _____

Health Care Licensing Application
Organ Procurement Organization, Tissue Bank, Eye Bank

The Agency for Health Care Administration (AHCA) has implemented the **ONLINE LICENSING SYSTEM,** which allows the electronic submission of renewal and change during licensure period applications and fees, along with the ability to upload supporting documentation. To submit online please go to: https://ahca.myflorida.com/health-care-policy-and-oversight/online-licensure-information/online-licensing-system

Applications must be received **at least 60 days prior to** the expiration of the current license or effective date of a change of ownership to avoid a late fee. If the renewal application is received by the Agency less than 60 days prior to the expiration date, it is subject to a late fee as set forth in statute. The application will be withdrawn from review if all the required documents and fees are not included with the application or received within 21 days of an omission notice. **Applications will not be considered for review until payment has been received. Renewal and Change During Licensure Period applications: Supporting documentation, responses to omissions and payments may be submitted using the online system even if the application was originally mailed to the Agency.** Please fill in all blanks or mark N/A if not applicable.

Under the authority of Chapters 408, Part II and 765, Part V, Florida Statutes (F.S.), and Chapters 59A-35 and 59A-1, Florida Administrative Code (F.A.C.), an application is hereby made to operate an organ procurement organization, tissue bank or eye bank as indicated below:

1. Provider / Licensee Information

A. PROVIDER INFORMATION – Please complete the following for the OPO/tissue/eye bank name and location. Provider name, address and telephone number will be listed on https://quality.healthfinder.fl.gov/index.html			
License Number (if applicable)	National Provider Identifier (NPI) (if applicable)	Florida Medicaid Number (if applicable)	
Name of OPO/Tissue/Eye Bank (if operated under a fictitious name, enter as it is filed with in the Florida Division of Corporations)			
Street Address			
City	County	State	Zip
Telephone Number	Fax Number		
Email Address	**Note**: By providing your e-mail address, you agree to accept e-mail correspondence from the Agency.		
Provider Website			
Mailing Address or ☐ Same as above			
City	County	State	Zip
Telephone Number	E-mail Address		

B. CONTACT PERSON - For this application	
Contact Person for this application	Contact Telephone Number
Contact e-mail address or ☐ Do not have e-mail	**Note**: By providing your e-mail address, you agree to accept e-mail correspondence from the Agency.

C. **LICENSEE INFORMATION –** Please complete the following for the entity seeking to operate the OPO/tissue/eye bank.			
Licensee Name (This is the owner of the OPO/tissue/eye bank)		Federal Employer Identification Number (EIN)	
Mailing Address or ☐ Same as above			
City		State	Zip
Telephone Number	Fax Number	E-mail Address	

Description of Licensee (check one):

For Profit	Not for Profit	Public
☐ Corporation	☐ Corporation	☐ State
☐ Limited Liability Company	☐ Religious Affiliation	☐ City/County
☐ Partnership	☐ Other	☐ Hospital District
☐ Individual		
☐ Sole Proprietor		
☐ Other		

2. Application Type and Fees

Indicate the type of application with an "X." **Applications will not be processed if not all applicable fees are included. Pursuant to section 408.805(4), F.S., fees are nonrefundable.** Renewal and Change of Ownership applications must be received 60 days prior to the expiration of the license or the proposed effective date of the change to avoid a late fine. If the renewal application is received by the Agency less than 60 days prior to the expiration date, it is subject to a late fee as set forth in statute. The applicant will receive notice of the amount of the late fee as part of the application process or by separate notice.

A. TYPE OF PROCUREMENT ORGANIZATION

Under the authority of sections 408, Part II and 765, Part V, F.S., and Chapters 59A-35 and 59A-1, F.A.C., an application is hereby made to operate as a:

☐ Organ Procurement Organization (OPO) ☐ Tissue Bank ☐ Eye Bank

B. TYPE OF APPLICATION

☐ Initial Licensure **Proposed Effective Date**: _____

If initial application, was this entity previously licensed as an OPO/Tissue Bank/Eye Bank in Florida? YES ☐ NO ☐

If YES, please provide the name of the agency (if different), the EIN # and the date the prior license expired or closed:

NAME:	CLIA #	Date Expired/Closed:

☐ Renewal Licensure

☐ Change of Ownership **Proposed Effective Date**: _____

- ☐ Licensee sale or transfer of ownership to a different individual/entity
- ☐ Transfer or assignment of 51% or more ownership, shares, membership, or controlling interest of the licensee

☐ Change During Licensure Period – select all that apply: **Proposed Effective Date**: _____

Fee Required

- ☐ Provider Name
- ☐ Provider Address

Services/Qualifications:

- ☐ Services Performed

No Fee Required

- ☐ Personnel
- ☐ Hours of Operation
- ☐ Management Company
- ☐ Management Company Controlling Interest

Services/Qualifications:

- ☐ Donor Testing Performed
- ☐ Transfer or assignment of less than 51% ownership, shares, membership, or controlling interest of the licensee

C. LICENSURE FEES

ACTION	FEE	TOTAL FEES
License Fee (Initial or Change of Ownership only): NOTE: No fee is required for renewal applications	OPO/Tissue Bank $1,000.00 Eye Bank $500.00	$
Change During Licensure Period	$25.00	$
TOTAL FEES INCLUDED WITH APPLICATION:		**$**
Please make check or money order payable to the Agency for Health Care Administration (AHCA)		

3. Controlling Interests of Licensee

AUTHORITY:

Pursuant to sections 408.806(1)(a) and (b), F.S., an application for licensure must include: the name, address and social security number (SSN) of the applicant and each controlling interest, if the applicant or controlling interest is an individual; and the name, address, and federal employer identification number (EIN) of the applicant and each controlling interest, if the applicant or controlling interest is not an individual. Disclosure of social security number(s) is mandatory. The Agency for Health Care Administration shall use such information for purposes of securing the proper identification of persons listed on this application for licensure. However, in an effort to protect all personal information, **do not include social security numbers on this form. All social security numbers must be entered on the Health Care Licensing Application Addendum, AHCA Form 3110-1024.**

DEFINITIONS:

Controlling interests, as defined in section 408.803(7), F.S., are the applicant or licensee; a person or entity that serves as an officer of, is on the board of directors of, or has a 5% or greater ownership interest in the applicant or licensee; or a person or entity that serves as an officer of, is on the board of directors of, or has a 5% or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider. The term does not include a voluntary board member.

Note: For each controlling interest an AHCA screening through the Care Provider Background Screening Clearinghouse is needed or the Attestation of Compliance with Background Screening Requirements, AHCA Form 3100-0008 if background screening was conducted by the Department of Financial Services for an applicant for a certificate of authority to operate a continuing care retirement community under Chapter 651, F.S. To verify who is to be screened, visit Background Screening (myflorida.com)

INSTRUCTIONS:

For new individual – complete all fields except the End Date.
For existing individuals – complete all fields except the Effective and End Date.
To remove an individual – complete all fields including the End Date.

A. Individual and/or Entity Ownership of Licensee as listed in Section 1C above – Provide the information for each individual or entity (corporation, partnership, association) with 5% or greater ownership interest in the licensee. Attach additional sheets if necessary. This excludes Not-for-Profit and Publicly held licensees. **Note**: A written explanation will be required if the percentage of ownership interest indicated below does not equal 100%.

FULL NAME OF INDIVIDUAL OR ENTITY	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EIN (NO SSN)	% OWNERSHIP	EFFECTIVE DATE	END DATE

B. Board Members and Officers of Licensee as listed in Section 1C above – Provide the information for each individual that serves as an officer or is on the board of directors. Do not include voluntary board members.

TITLE	FULL NAME	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EFFECTIVE DATE	END DATE
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					

4. Management Company

Does a company other than the licensee manage the licensed provider?

If ☐ NO, **skip to Section 6 - Personnel**
If ☐ YES, provide the following information:

Name of Management Company		EIN (No SSN)	Telephone Number / Fax	
Street Address		E-mail Address		
City		County	State	Zip
Mailing Address or ☐Same as above				
City			State	Zip
Contact Person	Contact E-mail		Contact Telephone Number	

5. Management Company Controlling Interests

DEFINITION:

Controlling interests, as defined in section 408.803(7), F.S., are the applicant or licensee; a person or entity that serves as an officer of, is on the board of directors of, or has a 5% or greater ownership interest in the applicant or licensee; or a person or entity that serves as an officer of, is on the board of directors of, or has a 5% or greater ownership interest in the management company or other entity, related or unrelated, with which the applicant or licensee contracts to manage the provider. The term does not include a voluntary board member.

Note: For each controlling interest an AHCA screening through the Care Provider Background Screening Clearinghouse is needed or the Attestation of Compliance with Background Screening Requirements, AHCA Form 3100-0008 if background screening was conducted by the Department of Financial Services for an applicant for a certificate of authority to operate a continuing care retirement community under Chapter 651, F.S. To verify who is to be screened, visit Background Screening (myflorida.com)

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INSTRUCTIONS:
For new individual – complete all fields except the End Date.
For existing individuals – complete all fields except the Effective and End Date.
To remove an individual – complete all fields including the End Date.

A. Individual and/or Entity Ownership of Management Company: Provide the information for each individual or entity (corporation, partnership, association) with 5% or greater ownership interest in the management company. Attach additional sheets if necessary.

FULL NAME OF INDIVIDUAL OR ENTITY	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EIN (NO SSN)	% OWNERSHIP	EFFECTIVE DATE	END DATE

B. Board Members and Officers of Management Company: Provide the information for each individual that serves as an officer or is on the board of directors. Do not include voluntary board members.

TITLE	FULL NAME	PERSONAL/PRIMARY ADDRESS	TELEPHONE NUMBER	EFFECTIVE DATE	END DATE
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					
Board Member/Officer					

6. Personnel

Please provide information for the individual(s) who perform the following roles. **Note:** For the administrator, financial officer, and director, an AHCA screening through the Care Provider Background Screening Clearinghouse is needed or the Attestation of Compliance with Background Screening Requirements, AHCA Form 3100-0008, if background screening was conducted by the Department of Financial Services for an applicant for a certificate of authority to operate a continuing care retirement community under Chapter 651, F.S. To verify who is to be screened, visit Background Screening (myflorida.com)/.

INSTRUCTIONS:
For new individual – complete all fields except the End Date.
For existing individuals – complete all fields except the Effective and End Date.
To remove an individual – complete all fields including the End Date.

A. **Administration**

INFORMATION	ADMINISTRATOR	FINANCIAL OFFICER
Full Name		
Effective Date		
End Date		
Telephone Number		
Email Address		
Personal Address		

INFORMATION	DIRECTOR
Full Name	
Effective Date	
End Date	
Telephone Number	
Email Address	
Personal Address	
Florida Dept of Health License Number	
Business Degree	
Board Certified By	
Lab Experience (Years)	
Hours Spent in Lab (Per week)	

B. Advisory Board

NAME	AREA OF EXPERTISE

7. Required Disclosure

The following disclosures are required:

A. Pursuant to section 408.809, F.S., the applicant shall submit to the Agency a description and explanation of any convictions of offenses prohibited by sections 435.04 and 408.809(4), F.S., for each controlling interest.

Has the applicant or any individual listed in Sections 3 and 4 of this application been convicted of any level 2 offense pursuant to section 408.809, F.S.? YES ☐ NO ☐

If YES, provide the following information:

☐ The full legal name of the individual and the position held

☐ A description/explanation of any convictions

B. Pursuant to section 408.810(2), F.S., the applicant must provide a description and explanation of any exclusions, suspensions, or terminations from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment (CLIA) programs.

Has the applicant or any individual/entity listed in Sections 3 and 4 of this application been excluded, suspended, terminated or involuntarily withdrawn from participation in Medicare or Medicaid in any state? YES ☐ NO ☐

If YES, enclose the following information:

☐ The full legal name of the individual (and the position held) or the entity

☐ A description/explanation of the exclusion, suspension, termination or involuntary withdrawal.

C. Pursuant to section 408.815(4), F.S., has the applicant or a controlling interest in the applicant, or any entity in which a controlling interest of the applicant was an owner or officer when the following actions occurred ever been:

Convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, chapter 893, 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, Medicaid fraud, Medicare fraud, or insurance fraud, within the previous 15 years prior to the date of this application? YES ☐ NO ☐

Terminated for cause from the Medicare program or a state Medicaid program? YES ☐ NO ☐

If YES, has applicant been in good standing with the Medicare program or a state Medicaid program for the most recent five (5) years and the termination occurred at least twenty (20) years before the date of the application. YES ☐ NO ☐

8. Provider Fines and Financial Information

Pursuant to section 408.831(1)(a), F.S., the Agency may take action against the applicant, licensee, or a licensee which shares a common controlling interest with the applicant if they have failed to pay all outstanding fines, liens, or overpayments assessed by final order of the agency or final order of the Centers for Medicare and Medicaid Services (CMS), not subject to further appeal, unless a repayment plan is approved by the agency.

Are there any incidences of outstanding fines, liens or overpayments as described above? YES ☐ NO ☐

If YES, please complete the following for each incidence (attach additional sheets if necessary):

AHCA CASE NUMBER	CMS	ASSESSED AMOUNT	DATE OF RELATED INSPECTION, APPLICATION, OR OVERPAYMENT	PAYMENT DUE DATE	PENDING APPEAL OF FINAL ORDER	
					YES	NO
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐
	☐				☐	☐

Please attach a copy of the approved repayment plan if applicable.

9. Accreditation

The applicant participates in the accrediting organization below or ☐ Not accredited:

ACCREDITING ORGANIZATION	ACCREDITATION ID	ACCREDITATION STATUS		SURVEY END DATE
		EFFECTIVE DATE	END DATE	
☐ Association of Organ procurement Organizations (AOPO)				
☐ American Association of Tissue Banks (AATB)				
☐ Eye Bank Association of America (EBAA)				

Note: If accredited, provide a copy of the full accreditation survey, award letter and any follow up letters to or from the accrediting organization.

☐ I understand that the complete accreditation report must be submitted to the Agency for review if the accreditation report is to be accepted in lieu of a complete licensure inspection and such reports used to meet licensure requirements are considered public documents subject to disclosure per Chapter 119, F.S. A complete accreditation report includes correspondence from the accrediting organization containing the dates of the survey, any citations to which the accreditation organization requires a response, the facility's response to each citation, the effective date of accreditation and verification of Medicare (CMS) deemed status, if applicable.

10. Donor Testing

List all laboratory tests performed on donors and/or donated organs and/or tissues and indicate site of testing. If tests are performed by the applicant, indicate "on-site." For any testing laboratory outside of Florida, please supply evidence of current CLIA certification. Attach additional sheets if needed.

LOCATION	LABORATORY TESTS PERFORMED

11. Equipment and Site Location

A. Equipment: List and briefly describe the equipment used (attach additional sheets if needed):

EQUIPMENT	DESCRIPTION

B. Site Description

Is the space contiguous? YES ☐ NO ☐

Is there more than one site? YES ☐ NO ☐

If YES, list all sites, except for the main site (attach additional sheets if needed):

NAME OF SITE	LOCATION

Is the agency sharing the site(s) with another health provider? YES ☐ NO ☐
If yes, please explain: _____

12. Type of Service

Please check all that apply:

☐	Recovery/Retrieval	☐	Storage	☐	Distribution	☐	Processing

13. Hours of Operation

List the regular operating hours. **Note:** Site inspections by surveyors will occur during the business hours submitted. Failure to be open during the listed hours may result in a fine.

DAY OF THE WEEK	OPENING TIME	CLOSING TIME	BY APPOINTMENT
☐ Monday			☐
☐ Tuesday			☐
☐ Wednesday			☐
☐ Thursday			☐
☐ Friday			☐
☐ Saturday			☐
☐ Sunday			☐

14. Supporting Documents

Applicants must include the following attachments as stated in Chapters 408, Part II and 765, Part V, F.S., and Chapters 59A-35 and 59A-1, F.A.C. Note: Required documents listed below are dependent on the type of application submitted. (Initial, Renewal, Change of Ownership, Change during licensure period)

DOCUMENTS TO BE PROVIDED:	REQUIRED FOR:
Health Care Licensing Application Addendum, AHCA Form 3110-1024	Initial, Renewal, Change of Ownership and Change of Personnel or Controlling Interest application types
Accreditation documentation, if applicable	Initial, Renewal and Change of Ownership application types
Medical Director Qualifications - Documentation must show laboratory experience/training	Initial, Renewal, Change of Ownership and Change of Personnel application types
A copy of the current CLIA certificate for any labs to be used (*not required for Tissue Banks certified to store and distribute only)*	Initial, Renewal, Change of Ownership application types
Proof of certification by CMS (for OPOs)	Initial, Renewal, Change of Ownership or Change During Licensure application types
FDA Registrations, if applicable	Initial, Renewal, Change of Ownership or Change During Licensure application types
Property Occupancy; Examples; Lease, Mortgage, and Transfer Agreement	Initial, Renewal, Change of Ownership and Address Change application types
Documentation from the appropriate local government office showing that the applicant has met local zoning requirements	Initial, Change of Ownership and Address Change application types
Documentation of change of ownership transaction stating effective date and executed by all parties	Change of Ownership application type
A signed agreement to pay any outstanding payments owed to the Agency. The agreement must include who will pay and when payment will be made	Change of Ownership application type
Required disclosures related to actions taken by Medicare, Medicaid or CLIA, if applicable	All application types, if documentation is required due to responses provided in application
Approved repayment plan, if applicable	All application types

16. Attestation

I, _____, attest as follows:

(1) Pursuant to section 837.06, Florida Statutes, I have not knowingly made a false statement with the intent to mislead the Agency in the performance of its official duty.

(2) Pursuant to section 408.815, Florida Statutes, I acknowledge that false representation of a material fact in the license application or omission of any material fact from the license application by a controlling interest may be used by the Agency for denying and revoking a license or change of ownership application.

(3) Pursuant to section 408.806, Florida Statutes, under penalty of perjury, the applicant is in compliance with the provisions of section 408.806 and Chapter 435, Florida Statutes.

(4) Pursuant to sections 408.809 and 435.05, Florida Statutes, every employee of the applicant required to be screened has attested, subject to penalty of perjury, to meeting the requirements for qualifying for employment pursuant to Chapter 408, Part II, and Chapter 435, Florida Statutes, and has agreed to inform the employer immediately if arrested for any of the disqualifying offenses while employed by the employer.

(5) Pursuant to section 435.05, Florida Statutes, the applicant has conducted a level 2 background screening through the Agency on every employee required to be screened under Chapter 408, Part II, or Chapter 435, Florida Statutes, as a condition of employment and continued employment and that every such employee has satisfied the level 2 background screening standards or obtained an exemption from disqualification from employment.

(6) Pursuant to section 408.810(12), Florida Statutes, the licensee ensures that no person holds any ownership interests, either directly or indirectly, regardless of ownership structure; who has a disqualifying offense pursuant to section 408.809, Florida Statutes or in a provider that had a license revoked or application denied pursuant to section 408.815, Florida Statutes.

(7) Pursuant to sections 408.810(14) and 408.051(3), FS, the licensee ensures that all patient information stored in an offsite physical or virtual environment, including through a third-party or subcontracted computing facility or an entity providing cloud computing services, is physically maintained in the continental United States or its territories or Canada.

(8) Pursuant to section 408.810(15), FS, the licensee ensures that controlling interests of the licensee do not hold, either directly or indirectly, regardless of ownership structure, an interest in an entity that has a business relationship with a foreign country of concern or that is subject to section 287.135, FS.

Signature of Licensee or Authorized Representative	Title	Date

NOTICE: If you are a **Medicaid** provider, you may have a separate obligation to notify the Medicaid program of a name/address change, change of ownership or other change of information. Please refer to your Medicaid handbooks for additional information about Medicaid program policy regarding changes to provider enrollment information.

RETURN THIS COMPLETED FORM WITH FEES AND ALL REQUIRED DOCUMENTS TO:

AGENCY FOR HEALTH CARE ADMINISTRATION
LABORATORY AND IN-HOME SERVICES UNIT
2727 MAHAN DR., MS 32
TALLAHASSEE FL 32308-5407

Questions ? Visit the Agency's website at https://ahca.myflorida.com/ or contact the Laboratory and In-Home Services Unit at (850) 421-4500 or Email : labstaff@ahca.myflorida.com

The Agency for Health Care Administration scans all documents for electronic storage. In an effort to facilitate this process, we ask that you please remember to:

- Please place checks or money orders on top of the application
- Include license number or case number on your check
- Do not submit carbon copies of documents
- Do not fold any of the documents being submitted
- No staples, paperclips, binder clips, folders, or notebooks
- Please ***do not bind any*** of the documents submitted to the Agency.