



**Health Care Regulation and Quality Improvement**  
800 NE Oregon Street, Suite 465  
Portland, Oregon 97232  
971-673-0540  
971-673-0556 (Fax)  
mailbox.inhomecare@odhsoha.oregon.gov

April 24, 2025

Paul Behrends  
Amnion Llc  
14 Pidgeon Hill Dirve, Suite 110  
Sterling, VA 20165

Dear Mr. Behrends:

This letter is to notify you that Amnion Llc has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on January 27th, 2027.

Thank you for your cooperation. Should you have any questions, please contact our office at the above phone number or email address.

Sincerely,

A handwritten signature in blue ink, appearing to read "Mauri Ouel", written over a light blue horizontal line.

Oregon Procurement Organizations/Tissue Bank Registry Staff  
Oregon Health Authority  
Public Health Division  
Health Care Regulation and Quality Improvement

*If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711*

**OREGON REVISED STATUTES  
2007**

**441.079 Eye, organ and tissue transplants.** (1) As used in this section and ORS 441.082:

(a) "Entity" means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.

(b) "Eye bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.

(c) "Health care facility" has the meaning given that term in ORS 442.015.

(d) "Organ procurement organization" means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.

(e) "Tissue bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.

(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.

(3) A health care facility that performs organ transplants must:

(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;

(b) Be regulated by the United States Department of Health and Human Services; and

(c) Use an organ procurement organization to obtain organs for transplants.

(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration. [2007 c.334 §1]

**Note:** 441.079 and 441.082 were enacted into law by the Legislative Assembly but were not added to or made a part of ORS chapter 441 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

**441.080** [Repealed by 1971 c.730 §25]

**441.081** [1979 c.680 §2; repealed by 1981 c.784 §38]

**441.082 Registration of organ procurement organization, tissue bank**



**and eye bank; rules; penalties.** (1) The Department of Human Services shall adopt by rule standards and a system of registration for every organ procurement organization, tissue bank and eye bank doing business in this state.

(2) An organ procurement organization, tissue bank or eye bank may not do business in this state unless it has registered with the department.

(3) Each organ procurement organization, tissue bank and eye bank shall provide to the department at least every three years current documentation of designation, certification and inspection as evidence of compliance with national standards and requirements under federal law.

(4) The department may impose a civil penalty not to exceed \$1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:

(a) Register with the department;

(b) Report loss of designation, accreditation or certification within 60 days of the loss; or

(c) Supply the department with requested current documentation of designation, certification and inspection.

(5) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745. [2007 c.334 §2]

**Note:** 441.082 becomes operative July 1, 2008. See section 4, chapter 334, Oregon Laws 2007.

**Note:** See note under 441.079.

**Note:** Section 3, chapter 334, Oregon Laws 2007, provides:

**Sec. 3.** Each organ procurement organization, tissue bank and eye bank doing business in this state must register with the Department of Human Services within 30 days after the operative date [July 1, 2008] of section 2 of this 2007 Act [441.082]. [2007 c.334 §3]

## Organ Procurement Organization Registration Form

<b>Type of Facility / Organization</b>	
New facility? <input type="radio"/>	Renewal? <input checked="" type="radio"/> Address Update
<input checked="" type="radio"/> Tissue Bank <input type="radio"/> Eye Bank	Please attach evidence of current FDA registration.
<input type="radio"/> Health Care Facility Performing Transplants	Please attach evidence of current organ procurement and transplantation network membership

<b>Facility / Organization Information</b>		
Legal Name: Amnion LLC		
DBA Name (if applicable): NA		
Physical Address, City, State & ZIP: 14 Pidgeon Hill Dr, Suite 110, Sterling, VA 20165		
Phone: (571) 368-6966	Fax: NA	County: United States
Mailing Address (if different from above): NA		
Facility / Organization Email: Amnion LLC@outlook.com		

<b>Administrator Information</b>		
Name of Administrator(s): Paul Behrends		
Address, City, State & ZIP: 14 Pidgeon Hill Dr, Suite 110, Sterling, VA, 20165		
Phone: (571) 239-1997	Fax: NA	County: United States
Email: AmnionQA@outlook.com		

<b>Contact Person for Organ Procurement or Transplant Program (if applicable)</b>		
Name: Brett Miller - Director of Operations		
Phone: 850 694 0371	Email: brett.miller@telagenllc.com	Fax: 850 629 4603

*I declare, under penalties of perjury, that I have examined this application and all attachments and that to the best of my knowledge and belief, this information is true, correct and complete. I will notify Health Care Regulation and Quality Improvement, in writing, of any changes in this information within 30 days of any such change.*

  
 \_\_\_\_\_  
 Administrator's Signature  
 Quality Manager  
 \_\_\_\_\_  
 Print Title

Paul Behrends  
 \_\_\_\_\_  
 Print Name  
 04/16/2025  
 \_\_\_\_\_  
 Date (mm/dd/year)

Mail application to: Oregon Health Authority  
 HFLC  
 800 NE Oregon St., Suite 465  
 Portland, OR 97232

Questions about this application? Phone: 971-673-0540 Email: [mailbox.hclc@state.or.us](mailto:mailbox.hclc@state.or.us)



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 PUBLIC HEALTH SERVICE  
 FOOD AND DRUG ADMINISTRATION  
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  
 TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  
 DESCRIBED IN 21 CFR 1271.10**

FEI: 3017609580

Other FDA Registrations:  
 Blood:  
 Devices:  
 Drugs:

Reason For Last Submission: Change in Information  
 Last Annual Registration Year: 2024  
 Last Registration Receipt Date: 07/24/2024  
 Summary Report Print Date: 10/09/2024

**Legal Name and Location:**  
 Amnion LLC  
 14 Pidgeon Hill Dr  
 Suite 110  
 Sterling, Virginia 20165  
 USA  
 Phone: 571-239-1997  
 Ext.:

**Reporting Official:**  
 Paul E Behrends, Quality Manager  
 14 Pidgeon Hill Dr  
 Suite 110  
 Sterling, Virginia 20165  
 USA  
 Phone: 571-239-1997 Ext.  
 AmnionLLC@outlook.com

**Satellite Recovery Establishment:** No

**Parent Manufacturing Establishment FEI No.:** No

**Testing For Micro-Organisms Only:** No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane					X	X	X	X	X			AmDisc, AmGraft, AmGraft Plus
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** Please disregard using FEI number 301609560. The new FEI number for this establishment is 3017609560.

**Proprietary Name(s):**

**FEI:** 3017609560

**Legal Name:**

Ammon LLC