

**HOSPITAL AFFILIATION AGREEMENT**

This Affiliation Agreement (“Agreement”) is made and entered into by the following parties (each a “Party; collectively the “Parties”):

“OneLegacy” OneLegacy 1303 W. Optical Drive Azusa, California 91072	“Hospital” Ventura County Medical Center 300 Hillmont Ave. Ventura, California 93003  Including  Santa Paula Hospital 825 N. 10 <sup>th</sup> Street Santa Paula, California 93061
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**RECITALS**

WHEREAS, OneLegacy is an organ procurement organization (“OPO”) certified in accordance with Part 486 of Subchapter G of Chapter IV of Title 42 of the Code of Federal Regulations (“Conditions for Coverage”) to serve as the designated OPO for certain counties in California (the “Donation Service Area” or “DSA”);

WHEREAS, Hospital is a Medicare and/or Medicaid participating hospital or critical access hospital located within OneLegacy’s DSA and is required by certain federal and state laws, rules and regulations – including Part A of Subchapter XI of Chapter 7 of Title 42 of the United States Code (“Social Security Act”), Parts 482 and 485 of Subchapter G of Chapter IV of Title 42 of the Code of Federal Regulations (“CFR”)(“Conditions of Participation”) and Chapter 3.5 of Part 1 of Division 7 of the California Health and Safety Code (“HSC”)(“Uniform Anatomical Gift Act” or “UAGA”) – to enter into an affiliation or agreement with OneLegacy and collaboratively participate in organ, tissue, and eye procurement; and

WHEREAS, in accordance with the Conditions for Coverage (as amended by CMS-3380-F and CMS-3380-F2; collectively the “CMS Final Rule”) and the Conditions of Participation (collectively with the Conditions for Coverage, the “CMS Conditions”), the Parties are mutually committed to increasing donation and recovery of organs, tissues, and eyes for transplantation, therapy, research, and education (the “Purpose”).

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein and for other good and valuable consideration, the Parties agree as follows:

**I. Term; Termination.**

1. This Agreement will become effective as of the date of the last signature below (the “Effective Date” of this Agreement) and will remain in effect for a period of three (3) years. Unless a Party provides reasonable advance written notice (at least one hundred and eighty (180) days) to the other Party of its intent to amend one or more provisions contained herein, this Agreement will automatically renew for successive three (3) year terms on the anniversary of the Effective Date under the existing provisions until terminated.

2. This Agreement will automatically terminate upon the occurrence of any of the following circumstances:

a. OneLegacy is no longer the designated OPO for Hospital following a decertification, redesignation, or other approved grant of waiver from CMS, effective immediately;

b. Hospital is entirely excluded from or is otherwise no longer required by CMS to cooperate with OneLegacy as its designated OPO, effective immediately; or

c. The Parties mutually agree in writing to terminate this Agreement, effective as mutually agreed upon.

3. In the event of termination, a Party will render advance notice to the other Party in good faith and as soon as practicable to prevent unnecessary loss of usable organ, tissue, and/or eye donations.

## **II. Definitions.**

1. Definition of “imminent death”. A patient’s death is considered imminent according to the criteria established as part of the Donation Protocol (defined below).

2. Definition of “timely referral”. A referral is considered timely according to the criteria established as part of the Donation Protocol.

3. Definition of “Clinical Trigger”. The Parties will mutually agree to Clinical Trigger criteria that must, pursuant to CMS Conditions, effectively promote the opportunity for (i) OneLegacy to determine a potential donor’s suitability for organ, eye, and/or tissue donation, (ii) the family of each potential donor to be informed of its options regarding donation, and (iii) Hospital to maintain each potential donor while necessary testing and placement of potential organ, eye, and/or tissue donation(s) take place.

## **III. OneLegacy’s Responsibilities.** OneLegacy will:

1. Clearly describe each Party’s responsibilities as it relates to the organ procurement and donation process, particularly with regards to donation after cardiac/circulatory death (“DCD”) and the meanings of the terms “timely referral” and “imminent death” (42 CFR §§ 486.322(a) and 486.344(d));

2. Ascertain, through a reasonable search of available records, whether a potential donor (whether personally or through a duly authorized individual) has made a valid anatomical gift that should be acknowledged and executed (e.g., an individual who has registered with a donor registry, such as the Donate Life California Organ and Tissue Donor Registry, where, “in the absence of an express, contrary indication by the donor, a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor’s body or part if the donor made an anatomical gift of the donor’s body or part...”) unless such a gift is effectively amended, revoked, or refused (HSC § 7150.35; see also HSC §§ 7150.15, 7150.20, 7150.25, 7150.30, 7150.65, and 7150.85);
3. As applicable, offer “designated requestor” training on at least an annual basis to Hospital staff to ensure that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate (42 CFR §§ 486.322(b) and 486.342; HSC § 7150.40);
4. Provide qualified staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research (as applicable) (42 CFR § 486.326; HSC § 7150.65);
5. Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families (42 CFR § 486.342);
6. Implement written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor (42 CFR § 486.344);
7. Employ a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation-related services, including those provided under this Agreement (42 CFR § 486.348); and
8. With respect to every patient accepted by OneLegacy as an organ, eye, or tissue donor, pay Hospital for services it renders related to donor evaluation, donor maintenance, and recovery of organ, eye, and/or tissue donations pursuant to a mutually agreed-upon Fee Schedule (attached hereto as Schedule “A” and incorporated herein by reference) (42 CFR § 413.418).

**IV. Hospital’s Responsibilities.** Hospital will:

1. Notify OneLegacy in a timely manner of individuals whose death is imminent or who have died in a Hospital facility so that OneLegacy can determine medical suitability for donation (42 CFR §§ 482.45(a)(1) and 485.643(a); HSC § 7150.65);
2. Collaborate in the identification, examination, retrieval, processing, preservation, storage and distribution of usable organs, tissues, and eyes (as appropriate) from potential donors (42 CFR §§ 482.45(a)(2) and 485.643(b); HSC § 7150.65);

3. Ensure, in collaboration with OneLegacy, that the family of each potential donor is informed of its options to donate organs, tissues, and eyes or to decline to donate (42 CFR §§ 482.45(a)(3) and 485.643(c); HSC § 7150.40);
4. Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors (42 CFR §§ 482.45(a)(4) and 485.643(d));
5. Cooperate with OneLegacy in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place (42 CFR §§ 482.45(a)(2) and 485.643; HSC §§ 7150.65(d)-(e));
6. Provide OneLegacy with a streamlined and prioritized process to obtain and maintain access to Hospital's electronic health/medical records system (EHR/EMR) and any other relevant information management system(s) necessary to review and report required medical, social, and identifying information of every donor and transplant beneficiary (as applicable) in an accurate and secure manner (42 CFR § 486.330; HSC § 7150.65(e));
7. Grant all OneLegacy staff who will be responding to referrals the necessary accounts, credentials, and privileges required to effectively perform donor evaluation and management – as well as organ placement and recovery – in a manner that meets current standards of practice, maximizes organ quality, and otherwise furthers the Purpose (42 CFR § 486.344; HSC § 7150.65(e)); and
8. Participate in OneLegacy's Quality Assurance and Performance Improvement (QAPI) program for the purpose of monitoring the performance and evaluating opportunities for improvement of donation-related Hospital activities, such as untimely referrals, missed opportunities, and adverse event prevention measures. (42 CFR § 486.348).

**V. Donation Protocol.** To promote consistency and transparency across the DSA, OneLegacy has pre-approved a standard set of policies and procedures (attached hereto as the "Donation Protocol" and incorporated herein by reference) that outlines each Party's responsibilities and obligations regarding the donation process, represents best practices to satisfy federal and state regulatory requirements, and promotes the Purpose.

a. **Policies Adoption.** Upon execution of this Agreement, Hospital agrees to adopt the Donation Protocol in its entirety as-is. The Parties expressly agree that any alternative policy or protocol that does not comply with regulatory requirements, promote donation, or receive OneLegacy's written approval will not be adopted into practice under the terms of this Agreement.

b. **Hospital Staff Credentialing.** Upon Hospital's adoption of the Donation Protocol, Hospital will require that each of its licensed medical staff (including nurses and physicians) agrees to abide by those policies as part of their credentialing process with Hospital. To the extent any such staff member thereafter fails to comply with the policies (or any part thereof), Hospital will assure OneLegacy of Hospital's commitment to the Purpose by assigning a quality liaison

responsible for the implementation of a mutually-agreeable remediation plan that includes (i) a timely collaborative debrief of the policy violation(s), (ii) confirmation that – in response to each compliance violation – the applicable staff have reviewed and reacknowledged their commitment to compliance with the relevant policy(ies), and (iii) a corrective action plan (elaborated below) designed to identify and prevent similar compliance violations in the future.

**VI. Non-Compliance; Corrective Action Plan.** As it relates to the Parties’ organ, eye, and tissue donation and recovery efforts under this Agreement, upon any allegation or finding of a policy violation, contractual breach, regulatory noncompliance, or patient-related grievance (each an “Adverse Event”), Hospital and OneLegacy agree to collaboratively investigate, identify, and resolve the matter as required under the Donation Protocol. Failure or refusal of one Party to participate in good faith to investigate, correct, prevent, or otherwise address an Adverse Event entitles the other Party to report the matter to the appropriate regulatory and/or accrediting body(ies) and to reserve the right to any legal actions and/or remedies it is entitled to pursue.

**VII. Indemnification.**

1. Subject to the provisions of sections 2 and 3 below, each Party (the “Indemnifying Party”) will defend, indemnify, and hold harmless the other Party and its respective directors, officers, employees, subsidiaries, and agents (collectively the “Indemnified Party”) from and against any and all losses, claims, damages, or liabilities (including reasonable costs of investigating or defending any alleged losses, claims, demands, liabilities, and reasonable attorneys’ fees incurred in connection therewith; collectively “Liabilities”) to which the Indemnified Party may become subject to as a result of the active or passive negligence, willful or intentional misconduct, violations of law, or other acts or omissions which arise during the course of the work performed under this Agreement by the Indemnifying Party.

2. OneLegacy will defend, indemnify, and hold harmless Hospital from and against Liabilities to which Hospital may become subject to as a result of the acts or omissions which arise during the course of work Hospital performed under this Agreement:

- a. pursuant to the Donation Protocol;
- b. at the written, express direction of OneLegacy; or
- c. in good faith to reasonably further the Purpose.

3. OneLegacy will neither assume nor be responsible for, and Hospital will defend, indemnify, and hold harmless OneLegacy from and against, Liabilities that arise out of or are related to:

- a. any failure or refusal by Hospital to engage OneLegacy in the timely implementation and/or maintenance of the Donation Protocol;
- b. any act or omission by Hospital that contradicts the Donation Protocol or otherwise hinders OneLegacy’s ability to perform its obligations related to the organ, eye, or tissue donation process; or

c. any failure or refusal by Hospital to collaborate with OneLegacy on QAPI initiatives in good faith.

4. For the purpose of indemnification, Hospital is deemed to be acting not in good faith – and indemnification will not be available to Hospital – if Hospital:

a. within one hundred and eighty (180) days of execution of this Agreement, rejects the implementation of any portion of the Donation Protocol;

b. within thirty (30) days of written request from the OneLegacy, fails to constructively participate in the implementation and/or modification of the Donation Protocol, especially those motivated by data-driven initiatives designed to increase donation or necessitated by unanticipated circumstances (such as regulatory changes or emergencies); or

c. otherwise seeks to modify or disregard any portion of the Donation Protocol in a manner that does not reflect best practices, prevents OneLegacy from complying with its regulatory obligations, or frustrates the Purpose of this Agreement.

**VIII. Protected Health Information.** The Parties agree that all protected health information (“PHI”) is considered confidential and OneLegacy will maintain – consistent with applicable federal and state laws – such information disclosed by Hospital to OneLegacy in strict confidence. Hospital acknowledges that certain regulations (specifically §§ 164.512(h) and 482.45 of Titles 45 and 42 of the Code of Federal Regulations, respectively) permit this information to be shared (without patient release) with OneLegacy as the Hospital’s designated OPO for the purpose of facilitating organ, eye and/or tissue donation and transplantation. The Parties expressly acknowledge that OneLegacy is neither a contracted service provider nor vendor of Hospital. Furthermore, Hospital specifically acknowledges OneLegacy is a HIPAA-exempt entity; OneLegacy is not a “business associate” of Hospital (as defined in §160.103 of Title 45 of Code of Federal Regulations) and is not required to enter into or otherwise maintain a “business associate” agreement with Hospital.

a. IT/Technical Support. Hospital will designate specific staff as point(s) of contact to timely address any needs or issues related to (i) retrieving medical, health, and other relevant records of any potential donor, (ii) creating and maintaining credentials and accounts for designated OneLegacy personnel, and (iii) troubleshooting data access and communications errors.

b. Data Integration. Hospital will provide electronic health and medical records (EHR/EMR) access to OneLegacy through either (i) direct system-level HL7 integration or (ii) periodic “data pushes” of required data in a mutually agreed-upon electronic data format.

c. Health and Medical Records Access. Hospital will grant designated OneLegacy personnel unique identification and accounts to monitor and maintain potential donors and ensure timely response and access to relevant potential donor information. Hospital and OneLegacy will collaboratively establish a process that strikes a reasonable balance between efficiently granting designated OneLegacy personnel with reliable and convenient access to Hospital’s EHR/EMR systems and securely maintaining Hospital’s commitment against the unauthorized use and/or

disclosure of PHI. To the extent such access is limited or otherwise restricted in a manner that hinders suitability assessment and/or recovery efforts, Hospital will grant impacted OneLegacy personnel with alternative direct access capabilities (e.g., remote desktop) to view a Potential Donor's health and medical records (including but not limited to relevant medical imaging).

i. Network Account Creation. Hospital will timely provide designated OneLegacy personnel with the appropriate accounts, credentials, and privileges to access (on-site and remotely) a potential donor's information (including relevant PHI). Hospital will not require – and the provision of such accounts, credentials, and privileges will not be contingent upon the completion of – any attestation, training, licensure, or other certification except those (i) required by law or (ii) otherwise mutually agreed upon by OneLegacy and Hospital.

ii. Account Renewal; Recredentialing. Unless otherwise agreed upon, each OneLegacy personnel's accounts, credentials, and privileges will be renewed no more frequently than an annual basis. Hospital will not require – and the renewal of such accounts, credentials, and privileges will not be contingent upon the completion of – any additional attestation, training, licensure, or other certification except those (i) required by law or (ii) otherwise mutually agreed upon by OneLegacy and Hospital.

**IX. Exclusivity.** Hospital hereby designates OneLegacy as its sole eye and tissue recovery agency to fulfill the requirements of the CMS Conditions. To prevent unnecessary loss of usable organ, tissue, and/or eye donations, changes to this designation may be made only upon one-hundred eighty (180) days advance written notice to OneLegacy.

**X. Amendments and Waiver; Regulatory Changes.** This Agreement may not be amended, nor any of its provisions waived, except by an agreement in writing signed by the Party against whom enforcement of such amendment or waiver is sought. The failure of a Party to require the performance of any term or obligation of this Agreement, or the waiver by a Party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. If any applicable rule, statute, or regulation (or any governmental or regulatory agency or accrediting body governing any aspect of either Party's responsibilities as it relates to donation under this Agreement) requires modification of any term or condition of this Agreement, a Party will provide timely notice of such requirement and this Agreement shall be promptly amended to conform to the same; provided, that the Parties will use their respective best efforts to negotiate in good faith and amend this Agreement to the minimum extent necessary so as to establish and/or maintain compliance without undue burden to either Party.

**XI. Severability.** Should any term or condition of this Agreement be determined to be void, invalid, unenforceable or illegal for whatever reason(s), such term or condition shall be null and void; provided, however, that the remaining terms and conditions of this Agreement shall be unaffected thereby and shall continue to be valid and enforceable.

**XII. Counterparts.** This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

**XIII. Applicable Laws.** The Parties agree to perform all obligations under this Agreement in compliance with the applicable federal, state, and local laws, implementing regulations, executive orders, and interpreting authorities (collectively referred to herein as “Applicable Laws”).

**XIV. Prior Agreements.** It is the intention of the Parties hereto that this Agreement shall supersede any prior discussions, commitments, representations, or agreements (whether written or oral) between the Parties hereto related to the subject matter herein.

**XV. Notice.** All notices, requests, demands and other communications under this Agreement will be in writing and will be deemed duly given to the Party(ies) addressed (i) if delivered physically, via facsimile, or sent through electronic mail and receipted for by the Party addressed, on the date of such receipt (as evidenced by a delivery confirmation and/or read receipt, as applicable), or (ii) if mailed by domestic certified or registered mail with postage prepaid, on the third business day after the date postmarked. Addresses for notice to the Parties are as follows:

**To OneLegacy:**  
1303 W. Optical Drive  
Azusa, California 91072  
ATTN: Chief Executive Officer

**To Hospital:**  
Ventura County Medical Center  
300 Hillmont Ave.  
Ventura, California 93003  
ATTN: Chief Eecutive Officer

**With courtesy copy to:**  
1303 W. Optical Drive  
Azusa, California 91072  
ATTN: General Counsel

**With courtesy copy to:**  
HCA Contracts Department  
5851 Thille Street  
Ventura, California 93003

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement effective as of the date of the last signature below.

OneLegacy  
  
By:  
Print: \_\_\_\_\_ Prasad Garimella  
Its: CEO  
Date: \_\_\_\_\_

Hospital  
  
By:  
Print: \_\_\_\_\_  
Its: \_\_\_\_\_  
Date: \_\_\_\_\_

**Schedule A**

**Fee Schedule**

With respect to each patient accepted by OneLegacy as an organ donor, and/or donor of **both** organs and tissues\*, OneLegacy agrees to pay the Hospital for hospital services for donor evaluation and diagnostics, donor treatment, nursing care, and recovery of anatomical gift(s), according to the schedule below:

Hospital will be paid the “ICU Daily Rate” for all services provided by Hospital to a OneLegacy donor, except for those services specifically identified below as “Carve Outs”:

**ICU Daily Rate** \$3,000

**Carve Outs**

Operating Room	
0-5 Hours	\$6,000
Additional Hours	\$2,000
Cardiac Angiograms	\$4,000
Echocardiography	\$1,000
Bronchoscopy	\$1,000

**HBP fees (if provided by hospital)**

Anesthesiologist	\$2,500
Cardiologist for Angiogram	\$2,500
Cardiologist for Echocardiography	\$500
Pulmonologist for Bronchoscopy	\$500

With respect to tissue and/or eye recovery cases only, the Hospital realizes that OneLegacy uses no Hospital staff or materials for these recoveries, and that OneLegacy provides all quality assessment documentation at no charge to the Hospital for compliance inspections, therefore, the Hospital agrees to provide the use of the operating room or other appropriate facility for aseptic recovery of tissues and/or eyes at no charge.

1. Hospital agrees to invoice OneLegacy within sixty (60) days after completion of the donation process.
  - a. In accordance with 42 CFR § 413.418, Hospital agrees that it will bill OneLegacy costs incurred for hospital services authorized by OneLegacy. However, Hospital will not bill – and OneLegacy expressly reserves the right to not reimburse – any such costs (or portions thereof) incurred unnecessarily (e.g., where Hospital’s actions and/or omissions prevent, hinder, or otherwise actually interfere with the donation process).
  
2. OneLegacy agrees to reimburse Hospital within thirty (30) days of receipt of invoice. ICU Daily Rate reimbursements will commence on the day following both declaration of death and consent to donate. OneLegacy will pay Hospital for Carve Out services per rates itemized above.
  
3. Hospital agrees to accept OneLegacy payment in accordance with this Agreement as payment in full for any and all services rendered after both the declaration of brain death and consent to donate.

- 4. Hospital shall not bill the organ donor patient’s family for any charges incurred after the declaration of brain death and consent. \*If tissues are recovered after the recovery of organs, no additional charges will be billed to the family.