

APPENDICES

APPENDIX A – PROPOSAL APPLICATION FORM (SPO-H-200)

STATE OF HAWAII
STATE PROCUREMENT OFFICE
PROPOSAL APPLICATION IDENTIFICATION FORM

STATE AGENCY ISSUING RFP: _____

RFP NUMBER: _____

RFP TITLE: _____

Check one:

Initial Proposal Application

Final Revised Proposal (Completed Items _____ - _____ only)

1. APPLICANT INFORMATION

Legal Name:

Doing Business As:

Street Address:

Mailing Address:

Contact person for matters involving this application:

Name:

Title:

Phone Number:

Fax Number:

e-mail:

2. BUSINESS INFORMATION

Type of Business Entity (*check one*):

Non-Profit Corporation

Limited Liability Company

Sole Proprietorship

For-Profit Corporation

Partnership

If applicable, state of incorporation and date incorporated:

State: _____ Date: _____

3. PROPOSAL INFORMATION

Geographic area(s):

Target group(s):

4. FUNDING REQUEST

FY _____

FY _____

FY _____

FY _____

FY _____

FY _____

Grand Total _____ **\$0**

I certify that the information provided above is to the best of my knowledge true and correct.

Authorized Representative Signature

Date Signed

Name and Title

APPENDIX B – WRITTEN QUESTIONS FORMAT

Appendix B
Written Questions Format
Care Coordination/Case Management for SHOTT
RFP-MQD-2010-003

Applicant Name	Date Submitted	Question #	RFP Section #	RFP Page #	Paragraph #	Question

APPENDIX C - GENERAL CONDITIONS

**GENERAL CONDITIONS FOR HEALTH & HUMAN SERVICES CONTRACTS
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GENERAL CONDITIONS FOR HEALTH & HUMAN SERVICES CONTRACTS**1. Representations and Conditions Precedent****1.1 Contract Subject to the Availability of State and Federal Funds.**

1.1.1 State Funds. This Contract is, at all times, subject to the appropriation and allotment of state funds, and may be terminated without liability to either the PROVIDER or the STATE in the event that state funds are not appropriated or available.

1.1.2 Federal Funds. To the extent that this Contract is funded partly or wholly by federal funds, this Contract is subject to the availability of such federal funds. The portion of this Contract that is to be funded federally shall be deemed severable, and such federally funded portion may be terminated without liability to either the PROVIDER or the STATE in the event that federal funds are not available. In any case, this Contract shall not be construed to obligate the STATE to expend state funds to cover any shortfall created by the unavailability of anticipated federal funds.

1.2 Representations of the PROVIDER. As a necessary condition to the formation of this Contract, the PROVIDER makes the representations contained in this paragraph, and the STATE relies upon such representations as a material inducement to entering into this Contract.

1.2.1 Compliance with Laws. As of the date of this Contract, the PROVIDER complies with all federal, state, and county laws, ordinances, codes, rules, and regulations, as the same may be amended from time to time, that in any way affect the PROVIDER's performance of this Contract.

1.2.2 Licensing and Accreditation. As of the date of this Contract, the PROVIDER holds all licenses and accreditations required under applicable federal, state, and county laws, ordinances, codes, rules, and regulations to provide the Required Services under this Contract.

1.3 Compliance with Laws. The PROVIDER shall comply with all federal, state, and county laws, ordinances, codes, rules, and regulations, as the same may be amended from time to time, that in any way affect the PROVIDER's performance of this Contract, including but not limited to the laws specifically enumerated in this paragraph:

1.3.1 Smoking Policy. The PROVIDER shall implement and maintain a written smoking policy as required by Chapter 32K, Hawaii Revised Statutes, or its successor provision.

1.3.2 Drug Free Workplace. The PROVIDER shall implement and maintain a drug free workplace as required by the Drug Free Workplace Act of 1988.

1.3.3 Persons with Disabilities. The PROVIDER shall implement and maintain all practices, policies, and procedures required by federal, state, or county law, including but not

limited to the Americans with Disabilities Act (42 U.S.C. §12101, et seq.), and the Rehabilitation Act (29 U.S.C. §701, et seq.).

- 1.3.4 Nondiscrimination. No person performing work under this Contract, including any subcontractor, employee, or agent of the PROVIDER, shall engage in any discrimination that is prohibited by any applicable federal, state, or county law.
- 1.4 Insurance Requirements. The PROVIDER shall obtain from a company authorized by law to issue such insurance in the State of Hawai'i commercial general liability insurance ("liability insurance") in an amount of at least TWO MILLION AND NO/100 DOLLARS (\$2,000,000.00) coverage for bodily injury and property damage resulting from the PROVIDER's performance under this Contract. The PROVIDER shall maintain in effect this liability insurance until the STATE certifies that the PROVIDER's work under the Contract has been completed satisfactorily.
- The liability insurance shall be primary and shall cover the insured for all work to be performed under the Contract, including changes, and all work performed incidental thereto or directly or indirectly connected therewith.
- A certificate of the liability insurance shall be given to the STATE by the PROVIDER. The certificate shall provide that the STATE and its officers and employees are Additional Insureds. The certificate shall provide that the coverages being certified will not be cancelled or materially changed without giving the STATE at least 30 days prior written notice by registered mail.
- Should the "liability insurance" coverages be cancelled before the PROVIDER's work under the Contract is certified by the STATE to have been completed satisfactorily, the PROVIDER shall immediately procure replacement insurance that complies in all respects with the requirements of this section.
- Nothing in the insurance requirements of this Contract shall be construed as limiting the extent of PROVIDER's responsibility for payment of damages resulting from its operations under this Contract, including the PROVIDER's separate and independent duty to defend, indemnify, and hold the STATE and its officers and employees harmless pursuant to other provisions of this Contract.
- 1.5 Notice to Clients. Provided that the term of this Contract is at least one year in duration, within ONE HUNDRED AND EIGHTY (180) days after the effective date of this Contract, the PROVIDER shall create written procedures for the orderly termination of services to any clients receiving the Required Services under this Contract, and for the transition to services supplied by another provider upon termination of this Contract, regardless of the circumstances of such termination. These procedures shall include, at the minimum, timely notice to such clients of the termination of this Contract, and appropriate counseling.
- 1.6 Reporting Requirements. The PROVIDER shall submit a Final Project Report to the STATE containing the information specified in this Contract if applicable, or otherwise satisfactory to the STATE, documenting the PROVIDER's overall efforts toward meeting the requirements of this

Contract, and listing expenditures actually incurred in the performance of this Contract. The PROVIDER shall return any unexpended funds to the STATE.

- 1.7 Conflicts of Interest. In addition to the Certification provided in the Standards of Conduct Declaration to this Contract, the PROVIDER represents that neither the PROVIDER nor any employee or agent of the PROVIDER, presently has any interest, and promises that no such interest, direct or indirect, shall be acquired, that would or might conflict in any manner or degree with the PROVIDER's performance under this Contract.

2. Documents and Files

2.1 Confidentiality of Material.

2.1.1 Proprietary or Confidential Information. All material given to or made available to the PROVIDER by virtue of this Contract that is identified as proprietary or confidential information shall be safeguarded by the PROVIDER and shall not be disclosed to any individual or organization without the prior written approval of the STATE.

2.1.2 Uniform Information Practices Act. All information, data, or other material provided by the PROVIDER to the STATE shall be subject to the Uniform Information Practices Act, chapter 92F, HRS, and any other applicable law concerning information practices or confidentiality.

2.2 Ownership Rights and Copyright. The STATE shall have complete ownership of all material, both finished and unfinished that is developed, prepared, assembled, or conceived by the PROVIDER pursuant to this Contract, and all such material shall be considered "works made for hire." All such material shall be delivered to the STATE upon expiration or termination of this Contract. The STATE, in its sole discretion, shall have the exclusive right to copyright any product, concept, or material developed, prepared, assembled, or conceived by the PROVIDER pursuant to this Contract.

2.3 Records Retention. The PROVIDER and any subcontractors shall maintain the books and records that relate to the Contract, and any cost or pricing data for three (3) years from the date of final payment under the Contract. In the event that any litigation, claim, investigation, audit, or other action involving the records retained under this provision arises, then such records shall be retained for three (3) years from the date of final payment, or the date of the resolution of the action, whichever occurs later. During the period that records are retained under this section, the PROVIDER and any subcontractors shall allow the STATE free and unrestricted access to such records.

3. Relationship between Parties

3.1 Coordination of Services by the STATE. The STATE shall coordinate the services to be provided by the PROVIDER in order to complete the performance required in the Contract. The PROVIDER shall maintain communications with the STATE at all stages of the PROVIDER's

work, and submit to the STATE for resolution any questions which may arise as to the performance of this Contract.

- 3.2 Subcontracts and Assignments. The PROVIDER may assign or subcontract any of the PROVIDER's duties, obligations, or interests under this Contract, but only if (i) the PROVIDER obtains the prior written consent of the STATE and (ii) the PROVIDER's assignee or subcontractor submits to the STATE a tax clearance certificate from the Director of Taxation, State of Hawai'i, and the Internal Revenue Service showing that all delinquent taxes, if any, levied or accrued under state law against the PROVIDER's assignee or subcontractor have been paid. Additionally, no assignment by the PROVIDER of the PROVIDER's right to compensation under this Contract shall be effective unless and until the assignment is approved by the Comptroller of the State of Hawai'i, as provided in section 40-58, HRS.
- 3.3 Change of Name. When the PROVIDER asks to change the name in which it holds this Contract, the STATE, shall, upon receipt of a document acceptable or satisfactory to the STATE indicating such change of name such as an amendment to the PROVIDER's articles of incorporation, enter into an amendment to this Contract with the PROVIDER to effect the change of name. Such amendment to this Contract changing the PROVIDER's name shall specifically indicate that no other terms and conditions of this Contract are thereby changed, unless the change of name amendment is incorporated with a modification or amendment to the Contract under paragraph 4.1 of these General Conditions.
- 3.4 Independent Contractor Status and Responsibilities, Including Tax Responsibilities.
- 3.4.1 Independent Contractor. In the performance of services required under this Contract, the PROVIDER is an "independent contractor," with the authority and responsibility to control and direct the performance and details of the work and services required under this Contract; however, the STATE shall have a general right to inspect work in progress to determine whether, in the STATE's opinion, the services are being performed by the PROVIDER in compliance with this Contract.
- 3.4.2 Contracts with Other Individuals and Entities. Unless otherwise provided by special condition, the STATE shall be free to contract with other individuals and entities to provide services similar to those performed by the PROVIDER under this Contract, and the PROVIDER shall be free to contract to provide services to other individuals or entities while under contract with the STATE.
- 3.4.3 PROVIDER's Employees and Agents. The PROVIDER and the PROVIDER's employees and agents are not by reason of this Contract, agents or employees of the State for any purpose. The PROVIDER and the PROVIDER's employees and agents shall not be entitled to claim or receive from the STATE any vacation, sick leave, retirement, workers' compensation, unemployment insurance, or other benefits provided to state employees. Unless specifically authorized in writing by the STATE, the PROVIDER and the PROVIDER's employees and agents are not authorized to speak on behalf and no statement or admission made by the PROVIDER or the PROVIDER's employees or

agents shall be attributed to the STATE, unless specifically adopted by the STATE in writing.

- 3.4.4 PROVIDER's Responsibilities. The PROVIDER shall be responsible for the accuracy, completeness, and adequacy of the PROVIDER's performance under this Contract.

Furthermore, the PROVIDER intentionally, voluntarily, and knowingly assumes the sole and entire liability to the PROVIDER's employees and agents, and to any individual not a party to this Contract, for all loss, damage, or injury caused by the PROVIDER, or the PROVIDER's employees or agents in the course of their employment.

The PROVIDER shall be responsible for payment of all applicable federal, state, and county taxes and fees which may become due and owing by the PROVIDER by reason of this Contract, including but not limited to (i) income taxes, (ii) employment related fees, assessments, and taxes, and (iii) general excise taxes. The PROVIDER also is responsible for obtaining all licenses, permits, and certificates that may be required in order to perform this Contract.

The PROVIDER shall obtain a general excise tax license from the Department of Taxation, State of Hawai'i, in accordance with section 237-9, HRS, and shall comply with all requirements thereof. The PROVIDER shall obtain a tax clearance certificate from the Director of Taxation, State of Hawai'i, and the Internal Revenue Service showing that all delinquent taxes, if any, levied or accrued under state law against the PROVIDER have been paid and submit the same to the STATE prior to commencing any performance under this Contract. The PROVIDER shall also be solely responsible for meeting all requirements necessary to obtain the tax clearance certificate required for final payment under section 103-53, HRS, and these General Conditions.

The PROVIDER is responsible for securing all employee-related insurance coverage for the PROVIDER and the PROVIDER's employees and agents that is or may be required by law, and for payment of all premiums, costs, and other liabilities associated with securing the insurance coverage.

3.5 Personnel Requirements.

- 3.5.1 Personnel. The PROVIDER shall secure, at the PROVIDER's own expense, all personnel required to perform this Contract, unless otherwise provided in this Contract.

- 3.5.2 Requirements. The PROVIDER shall ensure that the PROVIDER's employees or agents are experienced and fully qualified to engage in the activities and perform the services required under this Contract, and that all applicable licensing and operating requirements imposed or required under federal, state, or county law, and all applicable accreditation and other standards of quality generally accepted in the field of the activities of such employees and agents are complied with and satisfied.

4. Modification and Termination of Contract

4.1 Modifications of Contract.

4.1.1 **In Writing.** Any modification, alteration, amendment, change, or extension of any term, provision, or condition of this Contract permitted by this Contract shall be made by written amendment to this Contract, signed by the PROVIDER and the STATE.

4.1.2 **No Oral Modification.** No oral modification, alteration, amendment, change, or extension of any term, provision or condition of this Contract shall be permitted.

4.1.3 **Tax Clearance.** The STATE may, at its discretion, require the PROVIDER to submit to the STATE, prior to the STATE's approval of any modification, alteration, amendment, change, or extension of any term, provision, or condition of this Contract, a tax clearance from the Director of Taxation, State of Hawai'i, and the Internal Revenue Service showing that all delinquent taxes, if any, levied or accrued under state and federal law against the PROVIDER have been paid.

4.2 **Termination in General.** This Contract may be terminated in whole or in part for a reduction in funds available to pay the PROVIDER, or when, in its sole discretion, the STATE determines (i) that there has been a change in the conditions upon which the need for the Required Services was based, (ii) that the PROVIDER has failed to provide the Required Services adequately or satisfactorily, or (iii) that other good cause for the whole or partial termination of this Contract exists. Termination under this section shall be made by a written notice sent to the PROVIDER ten (10) working days prior to the termination date that includes a brief statement of the reason for the termination. If the Contract is terminated under this paragraph, the PROVIDER shall cooperate with the STATE to effect an orderly transition of services to clients.

4.3 **Termination for Necessity or Convenience.** If the STATE determines, in its sole discretion, that it is necessary or convenient, this Contract may be terminated in whole or in part at the option of the STATE upon ten (10) working days' written notice to the PROVIDER. If the STATE elects to terminate under this paragraph, the PROVIDER shall be entitled to reasonable payment as determined by the STATE for satisfactory services rendered under this Contract up to the time of termination. If the STATE elects to terminate under this section, the PROVIDER shall cooperate with the STATE to effect an orderly transition of services to clients.

4.4 **Termination by PROVIDER.** The PROVIDER may withdraw from this Contract after obtaining the written consent of the STATE. The STATE, upon the PROVIDER's withdrawal, shall determine whether payment is due to the PROVIDER, and the amount that is due. If the STATE consents to a termination under this paragraph, the PROVIDER shall cooperate with the STATE to effect an orderly transition of services to clients.

4.5 **STATE's Right of Offset.** The STATE may offset against any monies or other obligations that STATE owes to the PROVIDER under this Contract, any amounts owed to the State of Hawai'i by the PROVIDER under this Contract, or any other contract, or pursuant to any law or other obligation owed to the State of Hawai'i by the PROVIDER, including but not limited to the

payment of any taxes or levies of any kind or nature. The STATE shall notify the PROVIDER in writing of any exercise of its right of offset and the nature and amount of such offset. For purposes of this paragraph, amounts owed to the State of Hawai'i shall not include debts or obligations which have been liquidated by contract with the PROVIDER, and that are covered by an installment payment or other settlement plan approved by the State of Hawai'i, provided, however, that the PROVIDER shall be entitled to such exclusion only to the extent that the PROVIDER is current, and in compliance with, and not delinquent on, any payments, obligations, or duties owed to the State of Hawai'i under such payment or other settlement plan.

5. Indemnification

- 5.1 **Indemnification and Defense.** The PROVIDER shall defend, indemnify, and hold harmless the State of Hawai'i, the contracting agency, and their officers, employees, and agents from and against any and all liability, loss, damage, cost, expense, including all attorneys' fees, claims, suits, and demands arising out of or in connection with the acts or omissions of the PROVIDER or the PROVIDER's employees, officers, agents, or subcontractors under this Contract. The provisions of this paragraph shall remain in full force and effect notwithstanding the expiration or early termination of this Contract.
- 5.2 **Cost of Litigation.** In case the STATE shall, without any fault on its part, be made a party to any litigation commenced by or against the PROVIDER in connection with this Contract, the PROVIDER shall pay any cost and expense incurred by or imposed on the STATE, including attorneys' fees.

6. Publicity

- 6.1 **Acknowledgment of State Support.** The PROVIDER shall, in all news releases, public statements, announcements, broadcasts, posters, programs, computer postings, and other printed, published, or electronically disseminated materials relating to the PROVIDER's performance under this Contract, acknowledge the support by the State of Hawai'i and the purchasing agency.
- 6.2 **PROVIDER's Publicity Not Related to Contract.** The PROVIDER shall not refer to the STATE, or any office, agency, or officer thereof, or any state employee, or to the services or goods, or both provided under this Contract, in any of the PROVIDER's publicity not related to the PROVIDER's performance under this Contract, including but not limited to commercial advertisements, recruiting materials, and solicitations for charitable donations.

7. Miscellaneous Provisions

- 7.1 **Nondiscrimination.** No person performing work under this Contract, including any subcontractor, employee, or agent of the PROVIDER, shall engage in any discrimination that is prohibited by any applicable federal, state, or county law.
- 7.2 **Paragraph Headings.** The paragraph headings appearing in this Contract have been inserted for the purpose of convenience and ready reference. They shall not be used to define, limit, or extend the scope or intent of the sections to which they pertain.

- 7.3 **Antitrust Claims.** The STATE and the PROVIDER recognize that in actual economic practice, overcharges resulting from antitrust violations are in fact usually borne by the purchaser. Therefore, the PROVIDER hereby assigns to the STATE any and all claims for overcharges as to goods and materials purchased in connection with this Contract, except as to overcharges which result from violations commencing after the price is established under this Contract and which are not passed on to the STATE under an escalation clause.
- 7.4 **Governing Law.** The validity of this Contract and any of its terms or provisions, as well as the rights and duties of the parties to this Contract, shall be governed by the laws of the State of Hawai'i. Any action at law or in equity to enforce or interpret the provisions of this Contract shall be brought in a state court of competent jurisdiction in Honolulu, Hawai'i.
- 7.5 **Conflict between General Conditions and Procurement Rules.** In the event of a conflict between the General Conditions and the Procurement Rules or a Procurement Directive, the Procurement Rules or any Procurement Directive in effect on the date this Contract became effective shall control and are hereby incorporated by reference.
- 7.6 **Entire Contract.** This Contract sets forth all of the contracts, conditions, understandings, promises, warranties, and representations between the STATE and the PROVIDER relative to this Contract. This Contract supersedes all prior agreements, conditions, understandings, promises, warranties, and representations, which shall have no further force or effect. There are no contracts, conditions, understandings, promises, warranties, or representations, oral or written, express or implied, between the STATE and the PROVIDER other than as set forth or as referred to herein.
- 7.7 **Severability.** In the event that any provision of this Contract is declared invalid or unenforceable by a court, such invalidity or unenforceability shall not affect the validity or enforceability of the remaining terms of this Contract.
- 7.8 **Waiver.** The failure of the STATE to insist upon the strict compliance with any term, provision, or condition of this Contract shall not constitute or be deemed to constitute a waiver or relinquishment of the STATE's right to enforce the same in accordance with this Contract. The fact that the STATE specifically refers to one provision of the Procurement Rules or one section of the Hawai'i Revised Statutes, and does not include other provisions or statutory sections in this Contract shall not constitute a waiver or relinquishment of the STATE's rights or the PROVIDER's obligations under the Procurement Rules or statutes.
- 7.9 **Execution in Counterparts.** This Contract may be executed in several counterparts, each of which shall be regarded as an original and all of which shall constitute one instrument.

APPENDIX D – BUSINESS ASSOCIATE LANGUAGE

APPENDIX D

Exhibit

Special Conditions

Applicable to CONTRACTORS or PROVIDERS that are Business Associates of STATE under 45 CFR § 160.103

1. **Introduction:** This Agreement has been determined to be a business associate relationship under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 ("HIPAA") and its implementing privacy and security regulations at 45 CFR Part 160 and 164 ("the HIPAA regulations"). The STATE wishes to disclose to Business Associate certain information pursuant to the terms of this Agreement, some of which may constitute Protected Health Information (PHI). Under this Agreement, CONTRACTOR or PROVIDER is the Business Associate of STATE and provides services, arranges, performs, or assists in the performance of functions or activities on behalf of the STATE, and uses or discloses PHI. STATE and Business Associate desire to protect the privacy and provide for the security of PHI disclosed pursuant to this Agreement, in compliance with HIPAA, and the HIPAA regulations.
2. **Definitions:**
 - a. The terms used in these special conditions, but not otherwise defined, shall have the same meanings as those terms in the HIPAA regulations.
 - b. "Agreement" shall mean the agreement between STATE and Business Associate to which these special conditions are attached, and all attachments, exhibits and any special conditions.
 - c. "Individual" means the person who is the subject of Protected Health Information, and shall include a person who qualifies as a personal representative under § 164.502(g) of the HIPAA regulations.
 - d. "Protected Health Information" means any information, whether oral or recorded in any form or medium, that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual. For purposes of this Agreement, the term Protected Health Information is limited to the information created or received by Business Associate from or on behalf of STATE.
 - e. "Secretary" shall mean the Secretary of the U.S. Department of Health and Human Services or designee.
 - f. "Security incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an Information System.

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3. Obligations and Activities of Business Associate. Business Associate agrees:
- a. To not use or disclose PHI other than as permitted or required by this Agreement or as required by law.
 - b. To use appropriate safeguards to prevent use or disclosure of PHI consistent with the requirements of this Agreement.
 - c. To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of the STATE, and to prevent use or disclosure of PHI other than as provided for by this Agreement. This includes adoption of the e-mail encryption solution as defined by the STATE if deemed necessary by the STATE.
 - d. To ensure that any agent, including a subcontractor, to whom Business Associate provides PHI, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such Protected Health Information, and to incorporate, when applicable, the relevant provisions of these special condition into each such subcontract or subaward to such agents or subcontractors.
 - e. To make Business Associate's internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI, available to STATE and/or to the Secretary, at reasonable times and places or as designated by the Secretary or STATE, for purposes of determining STATE's compliance with the HIPAA regulations.
 - f. To document and make available to STATE or, at the direction of STATE, to an individual, such disclosures of PHI and information related to such disclosures necessary for STATE to respond to a request by the subject individual for an accounting of disclosures of PHI in accordance with § 164.528 of the HIPAA regulations.
 - g. To provide access to PHI in the designated record set to STATE or, as directed by STATE, to an individual to the extent and in the manner required by § 164.524 of the HIPAA regulations. "Designated Record Set" means the group of records maintained for the STATE that included medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for STATE health plans; or those records used to make decisions about individuals on behalf of the STATE. Business Associate shall respond to requests for access to records transmitted by the STATE within 10 days of receipt of the request by producing the records or verifying that there are none.
 - h. To make any amendment(s) to PHI that the STATE directs or agrees to in accordance with § 164.526 of the HIPAA regulations individual in the time and manner designated by the STATE.
 - i. To mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of these special conditions.

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- j. To provide written notice to STATE within 2 business days of discovery by Business Associate that PHI has been used or disclosed other than as provided for by these special conditions.
 - k. To immediately report to STATE any security incident of which it becomes aware with respect to PHI that is in the custody of Business Associate by calling the MQD Civil Defense Coordinator at (808) 348-9171. Written notice shall be provided within 2 business days of discovery. Business Associate shall take (1) prompt corrective action to cure any deficiencies and (2) any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations. Business Associate shall investigate such breach and provide a written report of the investigation and resultant mitigation within thirty (30) calendar days of the discovery of the breach.
 - l. Notices: Whenever written notice is required under this Agreement, it should be mailed and/or faxed to:

MQD HIPAA Project Manager
P.O. Box 700190
Kapolei, Hawaii 96709-0190

Fax: (808) 692-8155
 - m. To train and use reasonable measures to ensure compliance with the requirements of these special conditions by employees who assist in the performance of functions or activities on behalf of the STATE under this Agreement and use or disclose PHI; and discipline such employees who intentionally violate any provisions of these special conditions, including by termination of employment.
4. Permitted Uses and Disclosures by Business Associate
- a. General Use and Disclosure Provisions. Except as otherwise limited in this Agreement, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, STATE as specified in this Agreement, provided that such use or disclosure would not violate the HIPAA regulations if done by STATE or the minimum necessary policies and procedures of the STATE.
 - b. Specific Use and Disclosure Provisions
 - (i) Except as otherwise limited in this Agreement, Business Associate may use PHI for the proper management and administration of the Business Associate or to carry out the legal responsibilities of the Business Associate.
 - (ii) Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances

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of which it is aware in which the confidentiality of the information has been breached.

(iii) Except as otherwise limited in this Agreement, Business Associate may use PHI to provide data aggregation services to STATE as permitted by § 164.504(e)(2)(i)(B) of the HIPAA regulations.

(iv) Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1) of the HIPAA regulations.

5. Permissible Requests by STATE. STATE shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by STATE, except if Business Associate will use or disclose PHI for data aggregation or management and administrative activities of Business Associate.

6. Termination for Cause. In addition to any other remedies provided for by this Agreement, upon STATE's knowledge of a material breach by Business Associate of these special conditions, STATE shall either:

a. Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or

b. If neither termination nor cure are feasible, STATE shall report the violation to the Secretary.

7. Effect of Termination.

a. Except as provided in section 7.b, below, upon termination of this Agreement, for any reason, Business Associate shall, at STATE's option, return or destroy all PHI received from STATE, or created or received by Business Associate on behalf of STATE. Business Associate shall retain no copies of the PHI. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

b. In the event that Business Associate determines that returning or destroying the PHI is not feasible, Business Associate shall provide to STATE notification of the conditions that make return or destruction not feasible. For any period of time that return or destruction of PHI is not feasible or not completed, Business Associate shall extend the protections of these special conditions to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

8. Miscellaneous

a. Regulatory References. A reference in these special conditions to a section in the HIPAA regulations means the section in effect or as amended.

b. Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for STATE to comply with the requirements of the HIPAA and the HIPAA Regulations, as the same may be amended.

APPENDIX D

- c. Survival. The respective rights and obligations of Business Associate under Section 7.b, above, shall survive the termination of this Agreement.
- d. Interpretation. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the HIPAA regulations, as amended, the HIPAA regulations shall control. Where provisions of this Agreement are different than those mandated in the HIPAA regulations, but are nonetheless permitted by the HIPAA regulations, the provisions of this Agreement shall control. Any ambiguity in this Agreement shall be resolved to permit STATE to comply with the HIPAA regulations.
- e. Third Party Rights. These Special Conditions are entered into solely between, and may be enforced only by, Business Associate and the STATE. These special conditions shall not be deemed to create any rights in third parties or to create any obligations of Business Associate or the STATE to any third party.

APPENDIX E – STANDARD OF CONDUCT

**PROVIDER'S
STANDARDS OF CONDUCT DECLARATION**

For the purposes of this declaration:

“Agency” means and includes the State, the legislature and its committees, all executive departments, boards, commissions, committees, bureaus, offices; and all independent commissions and other establishments of the state government but excluding the courts.

“Controlling interest” means an interest in a business or other undertaking which is sufficient in fact to control, whether the interest is greater or less than fifty per cent (50%).

“Employee” means any nominated, appointed, or elected officer or employee of the State, including members of boards, commissions, and committees, and employees under contract to the State or of the constitutional convention, but excluding legislators, delegates to the constitutional convention, justices, and judges. (Section 84-3, HRS).

On behalf of:

(Name of PROVIDER)

PROVIDER, the undersigned does declare as follows:

1. PROVIDER is* is not a legislator or an employee or a business in which a legislator or an employee has a controlling interest. (Section 84-15(a), HRS).
2. PROVIDER has not been represented or assisted personally in the matter by an individual who has been an employee of the agency awarding this Contract within the preceding two years and who participated while so employed in the matter with which the Contract is directly concerned. (Section 84-15(b), HRS).
3. PROVIDER has not been assisted or represented by a legislator or employee for a fee or other compensation to obtain this Contract and will not be assisted or represented by a legislator or employee for a fee or other compensation in the performance of this Contract, if the legislator or employee had been involved in the development or award of the Contract. (Section 84-14 (d), HRS).
4. PROVIDER has not been represented on matters related to this Contract, for a fee or other consideration by an individual who, within the past twelve (12) months, has been an agency employee, or in the case of the Legislature, a legislator, and participated while an employee or legislator on matters related to this Contract. (Sections 84-18(b) and (c), HRS).

PROVIDER understands that the Contract to which this document is attached is voidable on behalf of the STATE if this Contract was entered into in violation of any provision of chapter 84, Hawai'i Revised Statutes, commonly referred to as the Code of Ethics, including the provisions which are the source of the

* Reminder to agency: If the “is” block is checked and if the Contract involves goods or services of a value in excess of \$10,000, the Contract may not be awarded unless the agency posts a notice of its intent to award it and files a copy of the notice with the State Ethics Commission. (Section 84-15(a), HRS).

CONTRACT NO. _____

declarations above. Additionally, any fee, compensation, gift, or profit received by any person as a result of a violation of the Code of Ethics may be recovered by the STATE.

PROVIDER

By _____
(Signature)

Print Name _____

Print Title _____

Date _____

APPENDIX F – PROPOSAL LETTER

Appendix F

STATE OF HAWAII Department of Human Services

PROPOSAL LETTER RFP-MQD-2009-002

We propose to furnish and deliver any and all of the deliverables and services named in the attached Request for Proposal. The administrative rates offered herein shall apply for the period of time stated in the said RFP.

It is understood that this proposal constitutes an offer and when signed by the authorized State of Hawaii official will, with the RFP and any amendments thereto, constitute a valid and legal contract between the undersigned Offeror and the State of Hawaii.

It is understood and agreed that we have read the State's specifications described in the RFP and that this proposal is made in accordance with the provisions of such specifications. By signing this proposal, we guarantee and certify that all items included in this proposal meet or exceed any and all such State specifications. We also affirm, by signing this proposal, that we have acknowledged the reference materials in the State's documentation library and that we have used this documentation as a basis for submitting our firm fixed price cost proposal.

It is also understood that failure to enter into the contract upon award shall result in forfeiture of the surety bond, if requested. We agree, if awarded the contract, to deliver goods or services which meet or exceed the specifications.

Authorized Offeror's Signature/Corporate Seal

Date

APPENDIX G – DISCLOSURE STATEMENT

**APPENDIX G
FORMS**

**DISCLOSURE STATEMENT
OWNERSHIP**

Company/Agency Name: _____
Address (City, State, Zip): _____
Telephone: _____

For the period beginning: _____ and ending _____

Type of Entity:

- Sole Proprietorship
- Partnership
- Corporation
- Governmental
- For-Profit
- Non-Profit
- Other (Specify)

455.104 Information on Ownership and Control

- a. List the names and addresses of any individuals or organizations with an ownership or controlling interest in the disclosing entity. "Ownership interest" means the possession of equity in the capital, the stock, or the profits of disclosing entity, directly or indirectly.

<u>Name</u>	<u>Address</u>	<u>Percent of Ownership of Control</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

- b. List the names and addresses of any individuals or organizations with an ownership or controlling interest in any subOfferor in which the disclosing entity has direct or indirect ownership of five (5) percent or more.

<u>Name</u>	<u>Address</u>	<u>Percent of Ownership of Control</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

- c. Names of persons named in (a) and (b) above who are related to another as spouse, parent, child, or sibling of those individuals or organizations with an ownership or controlling interest.

- d. List the names of any other disclosing entity in which a person with an ownership or controlling interest in the disclosing entity also has an ownership or controlling interest.

455.105 Information Related to Business Transactions

- e. List the ownership of any subcontractor with whom the Offeror has had business transactions totaling more than \$25,000 during the 12-month period ending on the date of the request.

<u>Describe Ownership of Subcontractors</u>	<u>Type of Business Transaction with Provider</u>	<u>Dollar Amount of Transaction</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

- f. List any significant business transactions between the Offeror and any wholly owned supplier or between the Offeror and any subOfferor during the five-year period ending on the date of the request.

<u>Describe Ownership of Subcontractors</u>	<u>Type of Business Transaction with Provider</u>	<u>Dollar Amount of Transaction</u>

455.106 Information on Persons Convicted of Crime

- g. List the names of any person who has ownership or controlling interest in the Offeror, or is an agent or managing employee of the Offeror and has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid or the Title XX services program since the inception of those programs.

<u>Name</u>	<u>Address</u>	<u>Title</u>

CONTROLLING INTEREST FORM

The Offeror must provide the name and address of any individual which owns or controls more than ten percent (10%) of stock or that has a controlling interest (i.e., about to formulate, determine or veto business policy decisions, etc.). Failure to make full disclosure may result in rejection of the Offeror's proposal as unresponsive.

<u>NAME</u>	<u>ADDRESS</u>	<u>OWNER OR CONTROLLER</u>	HAS CONTROLLING INTEREST <u>YES</u>
-------------	----------------	----------------------------	---

GRIEVANCE SYSTEM FORM

The Offeror must complete the form below and submit with this proposal.

I hereby certify that _____
(Offeror Name)

will have in place on the commencement date of this contract a system for reviewing and adjudicating grievances by recipients and providers arising from this contract in accordance with DHS Rules and as set forth in the Request for Proposal.

I understand such a system must provide for prompt resolution of grievances and assure the participation of individuals with authority to require corrective action.

I further understand the Offeror must have a grievance policy for recipients and providers which defines their rights regarding any adverse action by the Offeror. The grievance policy shall be in writing and shall meet the minimum standards set forth in this Request for Proposal.

I further understand evaluation of the grievance procedure shall be conducted through documentation submission, monitoring, reporting, and on-site audit, if necessary, by DHS and deficiencies are subject to sanction in accordance with DHS rules.

Authorized Signature

Date

Printed Name

Title

WAGE CERTIFICATION

Pursuant to Section 103-55, Hawaii Revised Statutes, I hereby certify that if awarded the contract in excess of \$25,000, the services to be performed will be performed under the following conditions:

1. The services to be rendered shall be performed by employees paid at wages or salaries not less than wages paid to the public officers and employees for similar work, if similar positions are listed in the classification plan of the public sector.
2. All applicable laws of the Federal and State governments relating to worker's compensation, unemployment insurance, payment of wages, and safety will be fully complied with.

I understand that all payments required by Federal and State laws to be made by employers for the benefit of their employees are to be paid in addition to the base wages required by Section 103-55, HRS.

Offeror:

Signature:

Title: _____

Date: _____

INSURANCE

Offeror shall provide the following:

1. Commercial General Liability Insurance is provided by:

Insurance Company _____

Coverage _____

2. Reinsurance is provided by:

Insurance Company _____

Coverage _____

3. Other forms of insurance will be provided by:

Type: _____

Insurance Company _____

Coverage _____

Type: _____

Insurance Company _____

Coverage _____

Type: _____

Insurance Company _____

Coverage _____

Offeror: _____

APPENDIX H – BUSINESS PROPOSAL

APPENDIX H

BUSINESS PROPOSAL

I, (Name of Official authorized to commit Firm, copy attached) hereby enter the official proposal prices indicated below on behalf of (Name of Firm entering proposal), and warrant that all terms and conditions of the RFP for the Care Coordination/Case Management Services for the State of Hawaii Organ and Tissue Transplant Program are met.

Potential Transplant Volume	Monthly Administrative Fee
0-30	
31-40	
41-50	

Claims Processed per month	Claims Processing Fee
HCFA-1500/1835 claims or 4216 claim lines	
UB-92/311 claims or 4981 claim lines	
Pharmacy/57 claims or 146 claim lines	
Others/475 claims or 786 claim lines	

All fees listed shall be inclusive of all fees and taxes.

BUDGET

(Period _____ to _____)

Applicant/Provider: _____
 RFP No.: _____
 Contract No. (As Applicable): _____

BUDGET CATEGORIES	Budget Request			
	(a)	(b)	(c)	(d)
A. PERSONNEL COST				
1. Salaries				
2. Payroll Taxes & Assessments				
3. Fringe Benefits				
TOTAL PERSONNEL COST				
B. OTHER CURRENT EXPENSES				
1. Airfare, Inter-Island				
2. Airfare, Out-of-State				
3. Audit Services				
4. Contractual Services - Administrative				
5. Contractual Services - Subcontracts				
6. Insurance				
7. Lease/Rental of Equipment				
8. Lease/Rental of Motor Vehicle				
9. Lease/Rental of Space				
10. Mileage				
11. Postage, Freight & Delivery				
12. Publication & Printing				
13. Repair & Maintenance				
14. Staff Training				
15. Substance/Per Diem				
16. Supplies				
17. Telecommunication				
18. Transportation				
19. Utilities				
20.				
21.				
22.				
23.				
TOTAL OTHER CURRENT EXPENSES				
C. EQUIPMENT PURCHASES				
D. MOTOR VEHICLE PURCHASES				
TOTAL (A+B+C+D)				
SOURCES OF FUNDING		Budget Prepared By:		
(a) Budget Request		Name (Please type or print)		Phone
(b)		Signature of Authorized Official		Date
(c)		Name and Title (Please type or print)		
(d)		For State Agency Use Only		
TOTAL REVENUE		Signature of Reviewer		Date

ORGANIZATION - WIDE BUDGET BY SOURCE OF FUNDS

(Period _____ to _____)

Applicant/Provider: _____
 RFP No.: _____
 Contract No. (As Applicable): _____

BUDGET CATEGORIES	Total Funds (a)	(b)	(c)	(d)
A. PERSONNEL COST				
1. Salaries				
2. Payroll Taxes & Assessments				
3. Fringe Benefits				
TOTAL PERSONNEL COST				
B. OTHER CURRENT EXPENSES				
1. Airfare, Inter-Island				
2. Airfare, Out-of-State				
3. Audit Services				
4. Contractual Services - Administrative				
5. Contractual Services - Subcontracts				
6. Insurance				
7. Lease/Rental of Equipment				
8. Lease/Rental of Motor Vehicle				
9. Lease/Rental of Space				
10. Mileage				
11. Postage, Freight & Delivery				
12. Publication & Printing				
13. Repair & Maintenance				
14. Staff Training				
15. Substance/Per Diem				
16. Supplies				
17. Telecommunication				
18. Transportation				
19. Utilities				
20.				
21.				
22.				
23.				
TOTAL OTHER CURRENT EXPENSES				
C. EQUIPMENT PURCHASES				
D. MOTOR VEHICLE PURCHASES				
TOTAL (A+B+C+D)				
SOURCES OF FUNDING		Budget Prepared By:		
(a) Total Funds		Name (Please type or print)		Phone
(b)		Signature of Authorized Official		Date
(c)		Name and Title (Please type or print)		
(d)		For State Agency Use Only		
TOTAL REVENUE		Signature of Reviewer		Date

ORGANIZATION - WIDE BUDGET BY PROGRAMS

(Period _____ to _____)

Applicant/Provider _____

RFP No. : _____

Contract No. (As Applicable): _____

BUDGET CATEGORIES	(a)	(b)	(c)	(d)
	Contract/RFP#:	Contract/RFP#:	Contract/RFP#:	Contract/RFP#:
	Program:	Program:	Program:	Program:
A. PERSONNEL COST				
1. Salaries				
2. Payroll Taxes & Assessments				
3. Fringe Benefits				
TOTAL PERSONNEL COST				
B. OTHER CURRENT EXPENSES				
1. Airfare, Inter-Island				
2. Airfare, Out-of-State				
3. Audit Services				
4. Contractual Services - Administrative				
5. Contractual Services - Subcontracts				
6. Insurance				
7. Lease/Rental of Equipment				
8. Lease/Rental of Motor Vehicle				
9. Lease/Rental of Space				
10. Mileage				
11. Postage, Freight & Delivery				
12. Publication & Printing				
13. Repair & Maintenance				
14. Staff Training				
15. Substance/Per Diem				
16. Supplies				
17. Telecommunication				
18. Transportation				
19. Utilities				
20.				
21.				
22.				
23.				
TOTAL OTHER CURRENT EXPENSES				
C. EQUIPMENT PURCHASES				
D. MOTOR VEHICLE PURCHASES				
TOTAL (A+B+C+D)				
SOURCES OF FUNDING				
(a) Budget Request				
(b)				
(c)				
(d)				
TOTAL REVENUE				
For State Agency Use Only	Budget Prepared By:			
Signature of Reviewer	Date	Name (Please type or print)	Phone	Signature of Authorized Official
				Date

**BUDGET JUSTIFICATION
PERSONNEL - SALARIES AND WAGES**

**BUDGET JUSTIFICATION
PERSONNEL: PAYROLL TAXES, ASSESSMENTS, AND FRINGE BENEFITS**

Applicant/Provider: _____ Date Prepared: _____
 RFP No.: _____ Period: _____ to _____
 Contract No.: _____
 (As Applicable)

TYPE	BASIS OF ASSESSMENTS OR FRINGE BENEFITS	% OF SALARY	TOTAL
PAYROLL TAXES & ASSESSMENTS:			
Social Security	As required by law	As required by law	
Unemployment Insurance (Federal)	As required by law	As required by law	
Unemployment Insurance (State)	As required by law	As required by law	
Worker's Compensation	As required by law	As required by law	
Temporary Disability Insurance	As required by law	As required by law	
SUBTOTAL:			
FRINGE BENEFITS:			
Health Insurance			
Retirement			
SUBTOTAL:			
TOTAL:			
JUSTIFICATION/COMMENTS:			

APPENDIX H

Summary of Budget Sheets

SPO-H-205 \$ _____

SPO-H-205A \$ _____

SPO-H-205B \$ _____

SPO-H-206A \$ _____

SPO-H-206B \$ _____

SPO-H-206C \$ _____

SPO-H-206E \$ _____

SPO-H-206F \$ _____

SPO-H-206H \$ _____

SPO-H-206I \$ _____

SPO-H-206J \$ _____

APPENDIX I – NOTICE OF INTENT TO PROPOSE

Notification to State Agency of Interest in Responding to an RFP

RFP Number and Title: _____

Organization or Individual: _____

Contact Person Information

First Name: _____ Last Name: _____

Position Title: _____

e-mail address: _____

Phone: _____

Fax _____

Mailing Address

Street or PO Box: _____

City _____ State: _____ Zip code _____

Please download and complete this form and either mail or e-mail to the contact person for the RFP.

Note:

- You must download this form before completing the information.
- Do NOT send this form to the State Procurement Office. Send it to the purchasing agency contact person. You will find contact information:
 - In the RFP Detail on the website, and
 - In the RFP document.

APPENDIX J – SHOTT GUIDELINES

APPENDIX J

ORGAN AND TISSUE TRANSPLANT GUIDELINES

General Guidelines

1. Covered transplants must be non-experimental, non-investigational for the specific organ/tissue and specific medical condition.
 - a. There must be conclusive evidence from published peer-review literature that the specific transplant has a definite positive effect on health outcomes. This evidence must include well-designed investigations that have been reproduced by non-affiliated authoritative sources, with measurable results and with positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.
 - b. Published peer-review medical literature must demonstrate that over time the transplant leads to improvement in health outcomes and that beneficial effects outweigh any harmful effects.
 - c. Published peer-review medical literature must demonstrate that the transplant must, in the least, be as effective in improving health outcomes as other established treatments.
 - d. Published peer-review medical literature must exist that shows improvement in health outcomes is possible in standard conditions of medical practice, outside clinical investigatory settings.
 - e. For adult bone marrow/stem cell transplant, Phase III clinical trials may be considered if the trial protocols have been reviewed and approved by the National Cancer Institute (NCI) or similar national cooperative body and conform to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials.
 - f. For pediatric bone marrow/stem cell transplants (defined as age 21 or younger per EPSDT), since clinical trials are considered the standard of care in most cases when there is no reasonable alternative, Phase II or III clinical trials may be considered if the trial protocols have been reviewed and approved by the NCI or similar national cooperative body (e.g. Pediatric Oncology Group) and conform to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials.
 - g. For both adults and children, the clinical trial must not be a single institution or investigator study (NCI designated Comprehensive Cancer Center trials are exempt from this requirement).
2. Transplants must be performed in facilities certified by Medicare for the specific transplant involved and by physicians knowledgeable in the specific transplantation.

3. Based upon a comprehensive evaluation of the patient and sound medical judgment, the transplant is expected to improve the patient's quality of life and chances for long term survival and:
- a. There is no significant involvement of other organ systems (malignancies in other organ systems or tissues, chronic progressive conditions, etc.)
 - b. There are no significant impairments or conditions that would affect negatively the transplant surgery or supportive medical services and the post-transplantation (outpatient and inpatient) management of the patient. In cases where the patient has a history of current or past alcohol or drug abuse, the patient shall be monitored with random and repeated alcohol and/or drug screening during the assessment process up to the time of transplant.
 - c. There is strong clinical indication that the patient can survive the transplantation procedure and related medical therapy (chemotherapy, immunosuppression).
 - d. The patient's condition has failed to improve with other conventional medical/surgical therapies; or based upon peer-review medical literature, transplantation affords the best chance of long term survival for the specific condition.
 - e. The patient is not HIV-positive.
 - f. The patient has sufficient social support to assure the patient's adherence to pre-transplant requirements by the transplant facility, immunosuppressive therapy and other post-transplant requirements.
 - g. The patient and/or their social support system is able and willing to comply with a lifelong disciplined medical regime (requiring multiple drugs several times a day and close supervision by physicians with the likelihood of serious consequences in the event of non-compliance).

Organ Transplant Guidelines

The transplant insurer has contracted with the State of Hawaii to cover organ/tissue transplants specifically cited below. Coverage of transplants for adults will only be made for those recipients who meet the applicable Medicare criteria, are diagnosed as having a Medicare approved clinical condition for transplantation and transplanted in a CMS/Medicare approved facility for the specific transplant.

LIVER

Conditions for which approval may be given:

1. Primary biliary cirrhosis
2. Primary sclerosing cholangitis
3. Post-necrotic cirrhosis
4. Alcoholic cirrhosis
5. Alpha-1 antitrypsin deficiency disease
6. Wilson's Disease
7. Primary hemochromatosis
8. Protoporphyrin
9. Familial cholestasis (Byler's Disease)
10. Trauma
11. Toxic reactions
12. Extrahepatic biliary atresia, intrahepatic bile duct paucity (Alagill's syndrome)
13. Budd-Chiari Syndrome

Coverage of liver transplants in adults will only be made for those beneficiaries who meet the applicable Medicare criteria and who are diagnosed as having one of the clinical conditions listed above. Medicare has removed the exclusion of Hepatitis B from liver transplantation coverage. Therefore, liver transplants can be covered when Hepatitis B is the beneficiary's underlying cause of end-state liver disease or a concomitant infection is a covered condition. The guidelines for patient selections are:

1. The criteria must be based upon both a critical medical need for a transplantation and a maximum likelihood of successful clinical outcome.
2. The patient must have end-stage liver disease with a life expectancy of less than 12 months and no medical or surgical alternatives to transplantation.
3. In the case of alcoholic cirrhosis, the selection of a patient who needs a liver transplant should include evidence of sufficient social support to assure assistance in alcohol rehabilitation and in immunosuppressive therapy following the operation. Although the center should require abstinence at the time of the operation, Medicare does not specify how long the patient should be abstinent prior to the operation. The hospital and the transplant team should establish such guidelines. Facilities will be required to submit the period of time they require for abstinence in a patient with end-state liver disease due to alcoholic cirrhosis.

That the patient must not have the following:

1. Significant or advanced cardiac, pulmonary, renal, nervous system, or other systemic disease.
2. Systemic infection.
3. Presence of malignancies either hepatic, extrahepatic, or metastatic.
4. Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs.
5. Active alcohol or drug abuse.
6. The need for prior transplantation of a second organ, such as lung, heart, kidney, or marrow if this represents a coexistence of significant disease.
7. A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regime (because a lifelong medical regime is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).

Many factors must be recognized with regard to an adverse outcome after liver transplantation. The manner and extent to which adverse risk is translated into contraindication varies. For example, presence of insulin-dependent diabetes mellitus may have to be considered in relation to transplantation because of possible adverse effects on outcome as well as complications related to chronic immunosuppressive therapy. Plans for long-term adherence to a disciplined medical regime must be feasible and realistic for the individual patient.

HEART-LUNG

Conditions for which approval may be given for adults and children:

1. Irreversible primary pulmonary hypertension with congestive heart failure.
2. Non-specific pulmonary fibrosis.
3. Eisenmenger complex with irreversible pulmonary hypertension and heart failure.
4. Cystic fibrosis with severe heart failure.
5. Emphysema with severe heart failure.
6. COPD with severe heart failure.

Candidates for heart-lung transplant must meet criteria under both heart transplant and lung transplant.

HEART

Conditions for which approval may be given for adults and children:

1. Ischemic myocardial disease.
2. Idiopathic cardiomyopathy
3. Valvular disease.
4. Congenital cardiac disease.
5. Myocardial disease (e.g. sarcoidosis and amyloidosis).
6. Infection (e.g. Chagas disease)

7. Drug induced myocardial destruction.
8. Class IV cardiac disease when surgical or medical therapy not pertinent and estimated survival is less than 6-12 months without a transplant.

Medicare guidelines for patient selection criteria are:

1. The patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.
2. The patient must have a very poor prognosis (for example, less than a 25 percent likelihood of survival for six months) as a result of poor cardiac status, but must otherwise have a good prognosis for survival with transplant.
3. All other medical and surgical therapies which might be expected to yield both short-and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.
4. Many other factors must be recognized at the present time exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies.

Strongly adverse factors include:

1. Advancing age – the selection of candidates beyond age 50 must be done to ensure an adequately young “physiologic” age and the absence or insignificance of coexisting disease.
2. Severe pulmonary hypertension.
3. Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine).
4. Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).
5. Symptomatic peripheral or cerebral vascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).
6. Chronobstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).
7. Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).
8. Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).
9. Systemic hypertension, either at transplantation or prior to development of end-state heart disease, that required multidrug therapy for even moderate control for patients who would be on cyclosporine protocols.
10. Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.
11. Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).
12. The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow.
13. A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen.

14. The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or preexisting disease.

Other factors include:

1. Insulin-requiring diabetes mellitus.
2. Asymptomatic severe peripheral or cerebrovascular disease.
3. Documented peptic ulcer disease.
4. Current or recent history of diverticulitis
5. Plans for a long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

LUNG

Conditions for which approval may be given for children and adults:

1. Alpha-1 antitrypsin deficiency.
2. Primary pulmonary hypertension.
3. Pulmonary fibrosis, Idiopathic pulmonary fibrosis.
4. Bilateral bronchiectasis*ICD-9-CM code 494.
5. Cystic fibrosis (both lungs to be transplanted)*ICD-9-CM code 518.89
6. Bronchopulmonary dysphasia.
7. Eisenmenger's syndrome.
8. Sarcoidosis lung involvement (135)* ICD-9-CM 517.8.
9. Scleroderma
10. Lymphangiomyomatosis.
11. Emphysema ICD-9-CM codes 492.0,492..8
12. Eosinophilic granuloma
13. Chronic obstructive pulmonary disease.
14. Pulmonary hypertension due to cardiac disease.
15. Idiopathic fibrosing alveolitis*ICD-9-CM code 516.3
16. Respiratory failure *ICD-9-CM code 518.81.

Selection Criteria is based on CMS' National Policy and criteria for the NHLBI of the National Institutes of Health:

- a. A patient is selected based upon both a critical medical need for transplantation and a strong likelihood of successful clinical outcome.
- b. A patient who is selected has irreversible, progressively disabling, end-state pulmonary disease (or, in some instances, end-state cardiopulmonary disease).
- c. The facility has tried or considered all other medically appropriate medical and surgical therapies that might be expected to yield both short and long term survival comparable to that of transplantation.
- d. Plans for long term adherence to a disciplined medical regimen are feasible and realistic for the individual patient.

Conditions for which approval may not be given:

1. End-stage pulmonary disease with limited life expectancy
2. Primary or metastatic malignancies of the respiratory or intrathoracic organs
3. Acute respiratory insufficiency and failure
4. Pneumonia, influenza
5. Emphysema, pleurisy
6. Abscess of lung or mediastinum
7. Recent or chronic therapeutic use of systemic steroids
8. Significant or advanced heart, liver, kidney, gastrointestinal or other systemic or multisystem disease that is likely to contribute to a poor outcome after lung transplantation including significant extra-pulmonary infection
9. Inadequate biventricular cardiac function and/or significant coronary artery disease
10. Evidence of medical non-compliance
11. Contraindications to immunosuppression
12. A history of behavior pattern or psychiatric illness considered likely to interfere significantly with a disciplined medical regimen
13. Non-ambulatory with limited rehabilitation potential
14. Presence of chronic pulmonary infection in candidates for single lung transplant
15. Current significant acute illness that is likely to contribute to a poor outcome if the patient receives a lung transplant or current use of mechanical ventilation for more than a brief period
16. Prior major cardiac or thoracic surgery or pleurodesis
17. Age beyond that at which there has been substantial favorable experience- >60 years for single lung transplant, >50 years for double lung transplant.

Each of the criteria should be addressed with consideration of these procedures, although rational argument may be presented to override single criteria exclusions (e.g., age limitations).

Other adverse factors that should be considered in transplant evaluation:

1. Continued cigarette smoking or failure to have abstained for long enough to indicate low likelihood of recidivism.
2. Systemic hypertension that requires more than two drugs for adequate control.
3. Cachexia, even in the absence of major end-organ failure
4. Obesity

SMALL BOWEL WITH OR WITHOUT LIVER

Generally, small bowel and combined small bowel and liver transplants have been done in children and not adults. Adults will not be covered. Children will be covered through the month of their 21st birthday.

Conditions for which approval may be given:

1. Small bowel syndrome resulting from inadequate intestinal propulsion due to neuromuscular impairment.

2. Small bowel syndrome resulting from post-surgical conditions due to resections for intestinal cysts, mesenteric cysts, small bowel or other tumors involving small bowel, crohn's disease, mesenteric thrombosis, volvulus.
3. Short gut syndromes in which there is liver function impairment (usually secondary to TPN).

KIDNEY

Conditions for which approval may be given:

- Medicaid recipients whose primary and only coverage is Medicaid or QUEST
- Medicaid recipients who do NOT qualify for Medicare coverage of their kidney transplant. Claims for kidney transplants for Medicaid recipients with other health insurances (including Medicare) will continue to be paid through Medicaid's fee-for-service program.
- The following conditions may deteriorate to the point that a kidney transplant may be required:
 - 1) Glomerulonephritis
 - 2) Chronic pyelonephritis
 - 3) Hypertensive nephrosclerosis
 - 4) Toxic reactions (analgesis nephropathy, heavy metal poisoning)
 - 5) Trauma
 - 6) Hereditary (Polycystic disease, Medullary cystic disease, Nephritits)
 - 7) Congential (Hyperplasia, Horseshoe kidney)
 - 8) Irreversible acute renal failure (Cortical necrosis, Acute tubular necrosis)

PANCREAS AND PANCREAS/KIDNEY

Guidelines for Pancreas and Pancreas/Kidney are under review and will be available prior to January 1, 2004.

SOLID ORGAN TRANSPLANTS WHICH ARE NOT CURRENTLY COVERED

- Adrenal to Brain
- Fetal Mesencephalic Transplantation

TISSUE TRANSPLANTS (Bone Marrow-allogeneic and autologous,stem cells)

ALLOGENEIC BONE MARROW TRANSPLANTATION

Conditions for which approval may be given:

1. Severe combined immunodeficiency disease (SCID) *ICD code 279.2.
2. Aplastic Anemia * ICD-9-CM codes 284.0 – 208.91, including Fanconi's anemia.
3. Homozygous beta-thalassemia (Thalassemia major)
4. Wiskott-Aldrich syndrome * ICD-9-CM 279.12.
5. Infantile malignant osteopetrosis (Albers-Schoenbeget syndrome or marble bone disease).
6. Mucopolysaccharidoses (e.g. Gaucher's disease, metachromatic leukodystrophy, adrenoleukodystrophy) for patients who have failed conventional therapy and who are neurologically intact.
7. Myelodysplastic syndromes
8. Chronic myelocytic leukemia (CML)
9. Acute myelocytic leukemia (AML)
10. Follicular Non-Hodgkin's lymphoma in patients who have failed primary therapy without histologic transformation.
11. Acute Lymphocytic Leukemia (ALL), recurrent disease or patients in first remission with poor prognostic factors.
12. Other leukemias when reasonable and necessary and when sufficient medical evidence exists that the transplantation prolongs survival and decreases mortality in patients who have received transplants for the type of leukemia in question.

The above strict conditions are approved for transplantation under Medicare and include leukemia, leukemia in remission * ICD-9-CM codes 204.00 – 208.91 when it is reasonable and necessary.

The following conditions are not covered:

- Multiple myeloma *ICD-9-CM codes 203.0 and 238.6
- Solid tumors *ICD-9-CM codes 140.00-199.1 including breast cancer.
- Fetal (cord blood) transplants are not covered.

AUTOLOGUS BONE MARROW TRANSPLANT

Conditions for which approvals may be given:

1. Neuroblastoma, State III or Stage IV, in patients over 12 months of age.
2. Testicular Germ Cell tumors at initial or subsequent relapse or that is refractory to standard dose chemotherapy with an FDA approved platinum compound. Retractory cases include:
 - a. Patients with advanced disease who fail to achieve a complete response to second-line therapy; or
 - b. Patients with moderate or minimal extent disease who fail to achieve a complete response to third-line therapy for Testicular Germ Cell tumors that meet the above criteria. Standard protocol involves tandem transplant. Germ cell tumor stage is to

be determined using the Indiana University/Einhorn classification or Follicular Non-Hodgkin's lymphoma in patients who have failed primary therapy without histologic transformation.

3. Acute leukemia in remission in patients with a high probability of relapse and who have no HLA matched donor. The leukemia type must meet the general conditions (sensitive to chemotherapy/radiation and incurable with conventional chemotherapy/radiation), and be in one of the following categories:
 - ICD-9-CM 204.01 lymphoid.
 - ICD-9-CM 205.01 myeloid.
 - ICD-9-CM 206.01 monocytic.
 - ICD-9-CM 207.01 acute erythema and erythroleukemia, and
 - ICD-9-CM 208.01 unspecified cell type.
4. Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response *ICD-9-CM codes 200.00 – 200.08, 200.10 – 200.18, 200.20 – 200.28, 200.80 – 200.88, and 202.90 – 202.98.
5. Non-Hodgkin's lymphoma, follicular, in patients who have failed primary therapy without histologic transformation.
6. Hodgkin's Lymphoma, relapse or refractory disease* advanced Hodgkin's disease ICD-9-CM 201.00 – 201.98 who have failed conventional therapy and have no HLA-matched donor.
7. Multiple myeloma ONLY after receipt of a high dose chemotherapy regime. Coverage of autologous stem cell transplantation for multiple myeloma is effective for services provided on or after July 1, 2000.

The above strict conditions are approved for autologous bone marrow transplantation under Medicare.

The following conditions are not covered under Medicare:

- Breast cancer
- Acute leukemia not in remission *ICD-9-CM codes 204.00, 206.00, 207.00, 208.00 except for primary resistant acute myelogenous leukemia.
- Chronic granulocytic leukemia * ICD-9-CM codes 205.10 and 205.11
- Solid tumors (other than neuroblastoma) *ICD-9-CM codes 140.00 – 199.1

APPENDIX K – SHOTT POLICIES AND PROCEDURES

APPENDIX K

STATE OF HAWAII ORGAN AND TISSUE TRANSPLANT PROGRAM ("SHOTT") POLICIES & PROCEDURES (Medical Management)

I. TRANSPLANT REFERRAL

1. Physicians within the community, QUEST health plans, or QExA health plans identify persons who meet the medical conditions for a transplant evaluation. The complete list of information needed for a SHOTT medical review is at the end of the SHOTT Policies and Procedures.
2. **For a QUEST member**, the health plan completes and submits the ADRC application/packet, as required, to the Med-QUEST Division (MQD) ADRC coordinator for disability determination along with a DHS Form 1144:

DHS Form 1180 "ADRC REFERRAL, DETERMINATION or RE-DETERMINATION"
DHS Form 1127 "MEDICAL HISTORY AND DISABILITY STATEMENT"
DHS Form 1128 "DISABILITY REPORT"
DHS Form 1144, "REQUEST FOR MEDICAL AUTHORIZATION"

If determined disabled, the QUEST member is dis-enrolled from QUEST and enrolled into QUEST Expanded Access (QExA).

The health plan notes on the top right corner of the form 1180, "Transplant Candidate".

The physician requesting the transplant(s) should be instructed to follow the Medicaid requirements for the State of Hawaii Organ and Tissue Transplant (SHOTT) program.

In addition to the ADRC application, the physician should complete and submit form DHS 1144 "REQUEST FOR MEDICAL AUTHORIZATION" requesting a transplant evaluation, as well as submit the appropriate medical information documenting the client's medical condition, including results of laboratory tests, studies, clinical notes, etc.

Both the ADRC packet and the 1144 Form to request transplant evaluation should be sent to:

Clinical Standards Office
Med-QUEST Division
P.O. Box 700190
Kapolei, HI 96709-0190

The form and medical information may also be faxed to the MQD-Clinical Standards Office (CSO) at (808) 692-8131.

Once SHOTT approves the client for transplant, the client is disenrolled from the QUEST health plan and enrolled into SHOTT with the effective date being the date of the MQD

medical director's signature on the DHS 1144. SHOTT is to notify CSO and client within 30 days of SHOTT eligibility determination.

3. For a QExA member, the physician should complete a DHS 1144 'Request for Medical Authorization' requesting a transplant evaluation as well as submit appropriate medical information documenting the client's medical condition, including result of lab tests, studies, clinical notes, etc. to the CSO as above.

The physician and QExA health plan requesting the transplant(s) should be instructed to follow the Medicaid requirements for the SHOTT program.

The QExA member will be dis-enrolled from the health plan and enrolled into the SHOTT program once approved for transplantation. The effective date of enrollment into SHOTT is the date the MQD medical director signed the DHS Form 1144.

4. For a Medicaid FFS client, the physician should complete a DHS Form 1144 'Request for Medical Authorization' requesting a transplant evaluation as well as submit appropriate medical information documenting the client's medical condition, including result of lab tests, studies, clinical notes, etc. to the Clinical Standards Office as above.

The physician requesting the transplant(s) should be instructed to follow the Medicaid requirements for the SHOTT program.

The FFS client will be enrolled into SHOTT with the effective date being the date the MQD medical director signed the DHS Form 1144.

5. The MQD transplant coordinator
 - a. Will check client's FFS eligibility in the MQD HPMMIS or HAWI system.
 - b. Will do an initial review to determine that all required documentation is received.
 - 1) If additional information is needed, the MQD transplant coordinator will follow up with the referring party.
 - 2) When all documents are received, the MQD transplant coordinator will then submit the SHOTT packet to the MQD medical director for review.
6. The MQD medical director reviews the DHS Form 1144 and the supporting documentation and makes a determination as to whether or not to forward the request to the SHOTT contractor. If additional information is required, the MQD medical director works with the MQD transplant coordinator to obtain the additional information from the client's health plan/physician. MQD determination to forward the request to the SHOTT contractor is made within one week provided all necessary information is available.
7. The MQD medical director approves or disapproves the transplant evaluation request to move forward to SHOTT.
 - a. If the request for the transplant evaluation is not approved to move forward to SHOTT, the referring health plan/physician is notified by MQD. A Copy of Form 1144 indicating a denial is returned to the referring physician/HP who informs the client.

- b. If the request for the transplant evaluation is approved to move forward to SHOTT:
 - 1) The MQD transplant coordinator notifies the SHOTT program coordinator/case manager as well as the referring health plan/physician of the approval.
 - 2) The MQD transplant coordinator informs MQD Customer Service Branch (CSB) that the Medical Director approved a DHS 1144 on < date> and the client has been referred to SHOTT for transplant evaluation.
 - 3) The MQD coordinator completes the SHOTT Case Information Form (CIF). The CIF, TPL information, the approved and signed Form 1144, and all the supporting documentation to SHOTT is then transmitted by fax or email to SHOTT.
8. Upon receipt of the approved Form 1144, the SHOTT contractor notifies the referring health plan/physician and client that a review is underway. The SHOTT contractor conducts a "paper review" and determines whether the referral meets transplant criteria. If additional information is necessary to make a determination, the SHOTT contractor will request information from the referring health plan/physician.
 - a. If transplant criteria are met, the SHOTT contractor arranges to send the client to a facility for an evaluation.
 - 1) The SHOTT contractor assumes financial responsibility for all transplant related services from the date that Form 1144 was signed by the MQD medical director.
 - 2) The SHOTT contractor is responsible for coordinating care for transplant services, to include a caregiver, transportation, lodging, and translation services.
 - 3) The client will be asked about Social Security Income information if it is not documented on the SHOTT CIF.
 - 4) MQD transplant coordinator processes the ADRC packet and transmits the DHS 1180 to EW, EB Administrator and CSB as much as possible prior to the 5th working day from the end of the month of the possible change to SHOTT/ABD.
 - 5) If in the end of month window (less than 5 working days from the end of the month), then EW will complete a DHS Form 1080 if retro-enrollment to SHOTT is needed.
 - b. If the transplant criteria are not met, the SHOTT medical director notifies by telephone the MQD medical director of the possible denial and request approval.
 - 1) If the MQD medical director approves the denial, the SHOTT medical director may call the referring physician to notify him/her of the denial. The SHOTT contractor will send a standard form letter formally notifying him/her of the denial with a copy to MQD.
 - 2) SHOTT sends a standard form letter to the client notifying him/her of the denial.
 - 3) The MQD transplant coordinator informs MQD CSB that the client was not approved. The client will remain in his/her health plan and will not be enrolled into SHOTT. If a client belongs to QUEST health plan, the ADRC process initiated with the SHOTT 1144 will continue to move forward.

- 4) If the MQD medical director does not agree with the SHOTT contractor's recommendation, he/she may ask SHOTT to send the case out for a peer/secondary review.
- c. Throughout the referral process, the MQD transplant coordinator and the SHOTT coordinator will communicate closely regarding the status of all referred clients.

II. TRANSPLANT EVALUATION

1. The SHOTT contractor selects the facility to evaluate the client and if accepted, to perform the transplant.
 - a. If the facility accepts the client:
 - 1) SHOTT's case management coordinator arranges all needed services for the client and if needed, a caregiver.
 - 2) All claims are sent to the SHOTT contractor who sorts the claims between transplant-related and non transplant-related.
 - a) Transplant-related claims are paid by the SHOTT contractor.
 - b) Non transplant-related claims are sent to MQD FO. After review and approval, the claims are sent to the MQD Fiscal Intermediary for payment.
 - b. If the client is not accepted by the facility for a transplant:
 - 1) Facility notifies the SHOTT contractor.
 - 2) The SHOTT contractor notifies the MQD medical director of the denial. The MQD medical director reviews and either concurs with the decision or requests another evaluation from another facility.
 - a) If MQD medical director concurs with the denial, SHOTT sends a standard form letter to the client and the referring physician.
 - b) If MQD medical director disagrees with the denial, he/she requests that SHOTT send the client to different facility for another evaluation.
 - 3) For those clients denied transplant services by the facility and the MQD medical director is in agreement, the MQD transplant coordinator informs MQD CSB that the transplant was denied as of the date that the client returned home. The client is then disenrolled from SHOTT and placed back into his/her appropriate health plan.

III. AWAITING TRANSPLANT

1. The client remains either in the facility or nearby housing waiting a transplant.
 - a. The client's medical status is monitored by the transplant facility.
 - b. The SHOTT case manager has at least monthly contact (more frequent in certain cases) with the facility and the client/caregiver. The client/care giver can contact the case manager at anytime.
2. The client returns home to await the transplant.
 - a. The transplant facility and the referring physician monitor the client's medical status. The SHOTT case manager coordinates all services.

IV. TRANSPLANT

1. The client/caregiver is transported to a nearby hotel/apartment to await the impending transplant.
2. After the transplant, the client is kept at a nearby apartment/hotel until medically released by the transplant facility.
3. The client and caregiver return home to Hawaii once medically released.
4. The SHOTT contractor, transplant facility case manager, and client's physician(s) all work together to keep the client medically well.
5. The SHOTT case manager remains available to all 24 hours a day.

V. ONE YEAR ANNIVERSARY – AFTER LAST SUCCESSFUL TRANSPLANT

1. The SHOTT case manager arranges with the transplant facility for the client's one-year post transplant follow up visit following the last successful transplant.
2. SHOTT is responsible to evaluate the patient for appropriate health plan placement, either back into QExA or returned to the original QUEST health plan prior to the original SHOTT/ADRC process and paperwork. This will be done through the ADRC process. SHOTT is responsible for submitting a complete ADRC packet to MQD/CSO. The MQD and SHOTT transplant coordinators will work together to ensure that the ADRC process is completed 30 days prior to transitioning from SHOTT to a health plan.
3. A letter is sent to the referring health plan/physician notifying him/her that the SHOTT contractor has successfully completed the transplant process and that the client has returned to Medicaid.
4. A copy of the letter is sent to the MQD transplant coordinator to transfer client out of SHOTT on the date that the client returns home or the date of the one year post transplant follow up visit after the last successful transplant if the facility is on island.
 - a. If SHOTT client remains disabled, the MQD transplant coordinator to notify CSB and CSB Outreach and Education that the SHOTT client is returning to his/her QExA health plan. If the client's pre-SHOTT health plan was QUEST, then the MQD transplant coordinator will also notify CSB Outreach and Education to assist the client in transitioning to a QExA health plan.
 - b. If SHOTT client is determined no longer disabled, then MQD transplant coordinator to notify the EW, EB Administrator and CSB that the SHOTT client is transitioning back to original QUEST health plan. If client entered via FFS medically needy, then CSB Outreach and Education to be notified to assist client transition to a QUEST health plan.

VI. UNSUCCESSFUL TRANSPLANT

1. SHOTT returns client to Hawaii and transitions client back to appropriate health plan.
2. Client is referred to MQD CSB Outreach and Education for transition of care assistance.
3. If a client passes away at any time during the transplant referral, evaluations, procedure, or follow-up, the SHOTT coordinator will inform the MQD transplant coordinator, who will in turn notify the EW and EB Administrator.

VII. MEDICAID AS A SECONDARY PAYOR

1. The SHOTT contractor coordinates with the primary payor's case manager for transportation, lodging, and any deductibles and may have to pay for a caregiver's transportation and lodging if the primary payor will not.
2. Medicare – The client/physician can choose any Medicare approved facility.
 - a. The SHOTT contractor is responsible for transportation and lodging and any deductibles for the client as well as for transportation and lodging for the caregiver.
 - b. If the client becomes eligible for Medicare after the transplant but prior to the one-year anniversary, the SHOTT contractor will continue case management.

VIII. COBRA

1. If the SHOTT contractor discovers that the client is on COBRA, the MQD Finance Officer will be notified.
 - a. With approval, the SHOTT contractor will pay the COBRA premium, making Medicaid secondary.
 - b. SHOTT will then bill Med-QUEST for the COBRA premium payments.

IX. RECORD-KEEPING

The Clinical Standards Office will keep copies of all files as well as a tracking log for all clients evaluated and sent to SHOTT for evaluation and transplant. The log will be accessible from the public drive.

The MQD transplant coordinator, Medical Director, CSO Administrator will have access to SHOTT's database.

Information Needed for SHOTT Medical Review besides typical patient identifiers (name, age, etc.):

Solid Organ Transplant

1. Requesting physician's name and contact info
2. Type of organ(s) needed
3. List of medications the patient is taking
4. List of diagnoses the patient has

5. Laboratory studies from the last six months before application, and a hemoglobin A1C level if the patient is a diabetic
6. Any diagnostic studies done, including: ultrasounds, EKG, CT scans, biopsies, catheterizations, MRI scans, PET scans, etc.
7. Doctor's clinic or office notes from the last six months
8. Results of three (each): urine drug screens, blood alcohol screens and nicotine if the patient is a smoker or has not quit smoking in the last six months
9. Results of HIV testing
10. If the patient has a substance abuse history, a detailed account of the patient's treatment for such
11. Any history of incarceration
12. Any psychosocial evaluation results
13. If the patient has a history of noncompliance, a detailed history of such and what measures have been taken if any to ameliorate it

Stem Cell (Bone Marrow) Transplant

1. Requesting physician's name and contact info plus what type of transplant is anticipated
2. Type of anticipated donor if allogeneic transplant planned
3. List of medications the patient is taking
4. List of diagnoses the patient has and the stage of cancer, if malignancy is the reason for transplant
5. Doctor's clinic or office notes from the last six months
6. Laboratory studies from the last three months before application
7. Any diagnostic studies done, including: ultrasounds, EKG, CT scans, bone marrow biopsies, flow cytometry results, catheterizations, MRI scans, PET scans, etc.
8. Either a summary list or a letter that delineates the patient's full treatment history for either cancer or a genetic disorder (not just what the patient is currently getting or has gotten recently)
9. Results of HIV testing
10. If the patient has a substance abuse history, a detailed account of the patient's treatment for such
11. If the patient has a history of noncompliance, a detailed history of such and what measures have been taken, if any, to ameliorate it

APPENDIX L – SHOTT EMERGENCY REFERRAL PROCEDURE

APPENDIX L

EMERGENCY REFERRAL PROCEDURE FOR SHOTT

These procedures should be followed for an Emergency Referral into the State of Hawaii Organ and Tissue Transplant (SHOTT) Program. If the referral is not an emergency, please follow the procedures outlined in QUEST Memorandum BEN-0101.

When a recipient is with a QUEST Health Plan (HP):

1. The referring HP physician and/or HP must complete the Department of Human Services (DHS) Form 1180 Aid to Disabled Review Committee (ADRC) for disability determination and the DHS Form 1144 Request for Medical Authorization. To help expedite the routing of Form 1180 and Form 1144, please print on the top right corner "Transplant Candidate." Fax the forms to the "MQD Medical Consultant" in the Medical Standards Branch (MSB) at 692-8131. Please call, Mr. Ron Iwata at 692-8109, when faxing to notify staff that you are requesting an emergency disability determination for referral into SHOTT.

The HP is responsible to coordinate the submission of the required forms and medical information with the referring HP provider.

2. If you are unable to contact Mr. Ron Iwata, please call Mr. Gary Ojiri, Contract Specialist, in the Health Coverage Management Branch (HCMB) at 692-8161.
3. This emergency process is to be followed during State of Hawaii work hours (Monday–Friday; 7:45 a.m. – 4:30 p.m.). If the recipient is critically ill and the ADRC nor the Form 1144 has not been approved due to it being after work hours, a holiday or the weekend, the HP is responsible for providing and authorizing required medical services for the recipient's care until the process can be completed.
4. If an air ambulance is needed to transport the recipient, the HP should start the process. It will take approximately forty-eight (48) hours for SHOTT to have the recipient transported via air ambulance from the time the request for the evaluation is approved by MQD and sent to SHOTT. Waiting for the disability determination or medical authorization may adversely jeopardize the recipient and therefore the HP is responsible for providing and authorizing required medical services for the recipient.

APPENDIX L

5. If Form 1144 is approved, MQD/HCMB will work with the Eligibility Worker (EW) to have the recipient disenrolled from QUEST and enrolled into Medicaid Fee-For-Service (FFS) as soon as possible. Until the recipient is disenrolled from the QUEST plan, SHOTT cannot assume responsibility over the case. HCMB will notify the referring HP on the date of enrollment into FFS.
6. The approved Form 1144 will be faxed, with the medical information, to SHOTT. Upon receipt of the approved Form 1144, SHOTT becomes responsible for the coordination and the completion of the transplant evaluation as well as the management of the transplant process.

If the SHOTT program requires additional information, SHOTT will be requesting the information directly from the referring physician.

The SHOTT program is responsible to select the appropriate transplant facility for the evaluation and for the transplant procedure. In addition, SHOTT is also responsible for making the arrangements for travel, lodging and meals where needed.

As a reminder, when Medicaid is the secondary payer to any other health insurer, the SHOTT program is only responsible for authorizing meals, transportation, lodging, and any applicable deductible, co-insurance, or the difference between the primary health insurer's payment and the allowance the SHOTT program extends of the service. When Medicaid is the payer of last resort, the referring physician is responsible to select the appropriate transplant facility for the evaluation and transplant procedure.

APPENDIX M – TRANSPLANT SERVICES (CHAPTER 8- PROVIDER MANUAL

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8.1 General Description

Medicaid covers medically necessary transplantation services and the related immunosuppressant drugs and services. Corneal transplants and kidney transplants do not require authorization and are reimbursed directly by the Medicaid Program. The transplants listed below are provided by the Medicaid Program through the State of Hawaii Organ and Tissue Transplant (SHOTT) Program. The policies for each of the transplantation services are provided separately as follows:

- Liver
- Heart-Lung
- Heart
- Lung
- Small Bowel with or without Liver
- Allogeneic Bone Marrow
- Autologous Bone Marrow

8.2 Amount, Duration and Scope

- a) Covered transplants must be non-experimental, non-investigational for the specific organ/tissue and specific medical condition.
 - There must be conclusive evidence from published peer-review medical literature that the specific transplant has a definite positive effect on health outcomes. This evidence must include well-designed investigations that have been reproduced by nonaffiliated authoritative sources, with measurable results and with positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale.
 - Published peer-review medical literature must demonstrate that over time the transplant leads to improvement in health outcomes and that beneficial effects outweigh any harmful effects.
 - Published peer-review medical literature must demonstrate that the transplant must at the least be as effective in improving health outcomes as other established treatments.

- Published peer-review medical literature must exist that shows improvement in health outcomes is possible in standard conditions of medical practice, outside clinical investigative settings.
- b) Transplants must be performed in facilities certified by Medicare for the specific transplant involved and by physicians knowledgeable in the specific transplantation.
- c) Based upon a comprehensive evaluation of the patient and sound medical judgment, the transplant is expected to improve the patient's quality of life and chances for long term survival and:
 - There is no significant involvement of other organ systems (e.g., malignancies in other organ systems or tissues, chronic progressive conditions, etc.)
 - There are no significant impairments or conditions, which would affect negatively the transplant surgery or supportive medical services and the post-transplantation (outpatient and inpatient) management of the patient. In cases where the patient has a history of current or past alcohol or drug abuse, the patient shall be monitored with random and repeated alcohol and/or drug screening during the assessment process up to the time of transplant.
 - There is strong clinical indication that the patient can survive the transplantation procedure and related medical therapy (e.g., chemotherapy, immunosuppression).
 - The patient's condition has failed to improve with other conventional medical/surgical therapies; or based upon peer-review medical literature, transplantation affords the best chance of long term survival for the specific condition.
 - There is sufficient social support to ensure the patient's compliance with treatment recommendations such as immuno-suppression therapy, other medication regimens and physician visits both before and after transplantation.
 - The patient is not HIV-positive.

8.3 Exclusions

The following transplants are not covered:

- Kidney-Pancreas
- Pancreas

- Adrenal to Brain
- Fetal Mesencephalic Transplantation
- Any other transplants not listed

8.4 Limitations

8.4.1 Organ Transplant Guidelines

The State of Hawaii has contracted with a transplant insurer for coverage of the organ/tissue transplants specifically cited below. Coverage of transplants will only be made for those recipients who meet the applicable Medicare criteria, are diagnosed as having a Medicare approved clinical condition for transplantation and are transplanted in a CMS (formerly HCFA)/Medicare approved facility for the specific transplant.

8.4.1.1 Liver

a) Conditions for which approval may be given:

- Primary biliary cirrhosis
- Primary sclerosing cholangitis
- Post-necrotic cirrhosis
- Alcoholic cirrhosis
- Alpha-1 antitrypsin deficiency disease
- Wilson's disease
- Primary hemochromatosis
- Protoporphyrria
- Familial cholestasis (Bylers's disease)
- Trauma
- Toxic reactions

- Extrahepatic biliary atresia, intrahepatic bile duct paucity (Alagill's syndrome)
- Budd-Chiari syndrome

Coverage of liver transplants will only be made for those recipients who meet the applicable Medicare criteria and who are diagnosed as having one of the clinical conditions listed above. Effective December 2, 1999, Medicare removed the exclusion of Hepatitis B from liver transplantation coverage. Therefore, liver transplants can be covered when Hepatitis B is the recipient's underlying cause of end-stage liver disease or a concomitant infection is a covered condition.

b) Conditions for which approval may not be given:

The patient must not have the following:

- 1) Significant or advanced cardiac, pulmonary, renal, nervous system, or other systemic disease.
- 2) Systemic infection.
- 3) Presence or malignancies either hepatic, extrahepatic or metastatic.
- 4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital organs.
- 5) Active alcohol or drug abuse.
- 6) The need for prior transplantation of a second organ, such as lung, heart, kidney, or marrow, if this represents a coexistence of significant disease.
- 7) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regime (because a lifelong medical regime is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).

c) Selection Criteria:

The guidelines for patient selections are:

- 1) That the criteria must be based upon both a critical medical need for a transplantation and a maximum likelihood of successful clinical outcome.

- 2) That the patient must have end-stage liver disease with a life expectancy of less than 12 months and no medical or surgical alternatives to transplantation.
- 3) That in the case of alcoholic cirrhosis, selection of a patient who needs a liver transplant should include evidence of sufficient social support to assure assistance in alcohol rehabilitation and in immunosuppressive therapy following the operation. Although the center should require abstinence at the time of the operation, Medicare does not specify how long the patient should be abstinent prior to the operation. The MQD/MSB requires that the hospital and the transplant team establish such guidelines. Facilities must submit the period of time they require for abstinence in a patient with end-stage liver disease due to alcoholic cirrhosis.

d) Adverse Factors:

Many factors must be recognized with regard to an adverse outcome after liver transplantation. The manner and extent to which adverse risk is translated into contraindication varies. For example, presence of insulin-dependent diabetes mellitus may have to be considered in relation to transplantation because of possible adverse effects on outcome as well as complications related to chronic immunosuppressive therapy. Plans for long-term adherence to a disciplined medical regime must be feasible and realistic for the individual patient.

8.4.1.2 Heart-Lung

a) Conditions for which approval may be given for adults and children:

- Irreversible primary pulmonary hypertension with congestive heart failure.
- Non-specific pulmonary fibrosis.
- Eisenmenger complex with irreversible pulmonary hypertension and heart failure.
- Cystic fibrosis with severe heart failure.
- Emphysema with severe heart failure.
- COPD with severe heart failure.

Conditions for which approval may not be given:

Approvals will be on a case by case basis.

c) Selection Criteria:

Candidates for heart-lung transplant must meet criteria for both heart transplant and lung transplant.

8.4.1.3 Heart

a) Conditions for which approval may be given for adults and children:

- Ischemic myocardial disease.
- Idiopathic cardiomyopathy.
- Valvular disease.
- Congenital cardiac disease.
- Myocardial disease (e.g. sarcoidosis and amyloidosis).
- Infection (e.g. Chagas disease)
- Drug-induced myocardial destruction.
- Class IV cardiac disease when surgical or medical therapy is not pertinent and estimated survival is less than 6 - 12 months without a transplant.

b) Conditions for which approval may not be given:

- Active infection, systemic illness
- Irreversible liver or kidney failure
- Fixed pulmonary hypertension
- Recent or unresolved pulmonary infarction
- Pre-existing malignancy
- Poorly controlled diabetes or retinopathy, neuropathy, or nephropathy
- Morbid obesity (100% over recommended weight)
- Moribund condition, rapidly fluctuating hemodynamic status

- Unresolved neurologic injury, affecting motor or sensory function that impairs ability to participate in care and decision-making
- History of alcohol or drug abuse, heavy smoking, medically non-compliant or psychologically unstable.

c) Selection Criteria:

Medicare guidelines are:

- 1) That the patient selection criteria must be based upon both a critical medical need for transplantation and a maximum likelihood of successful clinical outcome.
- 2) That the patient must have a very poor prognosis (for example, less than a 25% likelihood of survival for six months) as a result of poor cardiac status but must otherwise have a good prognosis for survival with transplant.
- 3) That all other medical and surgical therapies which might be expected to yield both short- and long-term survival (for example, 3 or 5 years), comparable to that of cardiac transplantation, must have been tried or considered.
- 4) That many factors recognized at the present time exert an adverse influence on the outcome after cardiac transplantation. The manner and extent to which adverse risk is translated into contraindication varies.

d) Adverse Factors:

Strongly adverse factors include:

- 1) Advancing age - the selection of candidates not beyond age 50 must be done to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease.
- 2) Severe pulmonary hypertension.
- 3) Renal or hepatic dysfunction not explained by the underlying heart failure and not deemed reversible (because of the nephrotoxicity and hepatotoxicity of cyclosporine).
- 4) Acute severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of one or more vital end-organs (because of a substantially less favorable prognosis for survival than for the average transplant recipient).

- 5) Symptomatic peripheral or cerebral vascular disease (because of accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment).
 - 6) Chronic obstructive pulmonary disease or chronic bronchitis (because of poor postoperative course and likelihood of exacerbation of infection with immunosuppression).
 - 7) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression).
 - 8) Recent and unresolved pulmonary infarction, pulmonary roentgenographic evidence of infection, or abnormalities of unclear etiology (because of the likelihood that this represents pulmonary infection).
 - 9) Systemic hypertension, either at transplantation or prior to development of end-stage heart disease, that required multi-drug therapy for even moderate control for patients who would be on cyclosporine protocols.
 - 10) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.
 - 11) Cachexia, even in the absence of major end organ failure (because of the significantly less favorable survival of these patients).
 - 12) The need for or prior transplantation of a second organ such as lung, liver, kidney, or marrow.
 - 13) A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen.
 - 14) The use of a donor heart, that may have had its effectiveness compromised by such factors as the use of substantial vasopressors prior to its removal from the donor, its prolonged or compromised maintenance between the time of its removal from the donor and its implantation into the patient, or preexisting disease.
- Other factors include:
 - 1) Insulin-requiring diabetes mellitus.
 - 2) Asymptomatic severe peripheral or cerebrovascular disease.
 - 3) Documented peptic ulcer disease.

4) Current or recent history of diverticulitis.

5) Plans for a long-term adherence to a disciplined medical regimen must be feasible and realistic for the individual patient.

8.4.1.4 Lung

a) Conditions for which approval may be given for children and adults:

- Alpha-1 antitrypsin deficiency.
- Primary pulmonary hypertension.
- Pulmonary fibrosis, Idiopathic pulmonary fibrosis.
- Bilateral bronchiectasis.
- Cystic fibrosis (both lungs to be transplanted).
- Bronchopulmonary dysplasia.
- Eisenmenger's syndrome.
- Sarcoidosis lung involvement.
- Scleroderma.
- Lymphangiomyomatosis.
- Emphysema.
- Eosinophilic granuloma.
- Chronic obstructive pulmonary disease.
- Pulmonary hypertension due to cardiac disease.
- Idiopathic fibrosing alveolitis.
- Respiratory failure.

b) Conditions for which approval may not be given:

- **End-stage pulmonary disease with limited life expectancy.**
- **No recent therapeutic use of systemic steroids.**
- **No other systemic disease.**
- **Adequate biventricular cardiac function; no significant coronary artery disease.**
- **Demonstration of medical compliance with medical regimes.**
- **No contraindications to immunosuppression.**
- **No major psychosocial problems.**
- **Ambulatory with rehabilitation potential.**
- **No chronic infectious pulmonary disease.**
- **No prior major thoracic surgery or pleurodesis.**
- **Age <60 years, single lung transplant; <50 years, double lung transplant.**
- **Each of the criteria should be addressed with consideration of these procedures, although rational argument may be presented to override single criteria exclusions (e.g., age limitations).**
- **Reasons for non-coverage: Cancer of the lung, either primary or metastatic; acute respiratory insufficiency; all acute conditions; and chronic infections.**
- **Non covered ICD-9-CM codes.**
- **Malignant neoplasm or respiratory and intrathoracic organs.**
- **Pneumonia and influenza.**
- **Emphysema and pleurisy.**
- **Abscess of lung and mediastinum.**
- **Acute respiratory failure.**

c) Selection Criteria:

CMS' (formerly HCFA's) National Policy: suggested selection criteria of the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health:

- 1) A patient is selected based upon both a critical medical need for transplantation and a strong likelihood of successful clinical outcome.**
- 2) A patient who is selected has irreversible, progressively disabling, end-stage pulmonary disease (or, in some instances, end-stage cardiopulmonary disease).**
- 3) The facility has tried or considered all other medically appropriate medical and surgical therapies that might be expected to yield both short and long-term survivals comparable to that of transplantation.**
- 4) Plans for long term adherence to a disciplined medical regimen are feasible and realistic for the individual patient.**

d) Adverse Factors:

- Primary or metastatic malignancies of the lung.**
- Current significant acute illness that is likely to contribute to a poor outcome if the patient receives a lung transplant or current use of mechanical ventilation for more than a brief period.**
- Significant or advanced heart, liver, kidney, gastrointestinal or other systemic or multi-system disease that is likely to contribute to a poor outcome after lung transplantation including significant extra-pulmonary infection.**
- Chronic pulmonary infection in candidates for single lung transplantation.**
- Continued cigarette smoking or failure to have abstained for long enough to indicate low likelihood of recidivism.**
- Systemic hypertension that requires more than two drugs for adequate control.**
- Cachexia, even in the absence of major end-organ failure.**
- Obesity.**

- Previous thoracic or cardiac surgery or other bases for pleural adhesions.
- Age beyond that at which there has been substantial favorable experience.
- Chronic cortisone therapy.
- A history of behavior pattern or psychiatric illness considered likely to interfere significantly with a disciplined medical regimen.

8.4.1.5 *Small Bowel with or without Liver*

Generally, small bowel and combined small bowel and liver transplants have been done in children and not adults. Adults will not be covered. Children will be covered through the month of their 21st birthday.

- Conditions for which approval may be given:
 - a) Small bowel syndrome resulting from inadequate intestinal propulsion due to neuromuscular impairment.
 - b) Small bowel syndrome resulting from post-surgical conditions due to resections for:
 - 1) Intestinal cysts.
 - 2) Mesenteric cysts.
 - 3) Small bowel or other tumors involving small bowel.
 - 4) Crohn's disease.
 - 5) Mesenteric thrombosis.
 - 6) Volvulus.
 - c) Short gut syndromes in which there is liver function impairment (usually secondary to total parenteral nutrition (TPN)).

8.4.2 *Tissue Transplants (Bone Marrow-Allogeneic and Autologous, Stem Cells)*

8.4.2.1 *Allogeneic Bone Marrow Transplantation*

Conditions for which approval may be given:

- Severe combined immunodeficiency disease (SCID).

- Aplastic Anemia including Fanconi's anemia.
- Homozygous beta-thalassemia (Thalassemia major).
- Wiskott-Aldrich syndrome.
- Infantile malignant osteopetrosis (Albers-Schoenberg syndrome or marble bone disease).
- Mucopolysaccharidoses (e.g., Gaucher's disease, metachromatic leukodystrophy, adrenoleukodystrophy) for patients who have failed conventional therapy and who are neurologically intact.
- Myelodysplastic syndromes
- Chronic myelogenous leukemia (CML).
- Acute myelocytic leukemia (AML).
- Follicular Non-Hodgkin's lymphoma in patients who have failed primary therapy without histologic transformation.
- Acute Lymphocytic Leukemia (ALL), recurrent disease or patients in first remission with poor prognostic factors.
- Other leukemias when reasonable and necessary and when sufficient medical evidence exists that the transplantation prolongs survival and decreases mortality in patients who have received transplants for the type of leukemia in question.

The above strict conditions are approved for transplantation under Medicare and include leukemia, leukemia in remission when it is reasonable and necessary.

a) Conditions for which approval may not be given:

- The following conditions are not covered:
 - 1) Multiple myeloma.
 - 2) Solid tumors including breast cancer.
- Fetal (cord blood) transplants are not covered.

b) Adverse Factors:

- **Active infection**
- **Incapacity to physically or mentally withstand this rigorous procedure.**

8.4.2.2 Autologous Bone Marrow Transplant

a) Conditions for which approvals may be given.

- **Neuroblastoma, Stage III or Stage IV, in patients over 12 months of age.**
- **Testicular Germ Cell tumors at initial or subsequent relapse or that are refractory to standard dose chemotherapy with an FDA approved platinum compound. Refractory cases include:**
- **Patients with advanced disease who fail to achieve a complete response to second-line therapy; or**
- **Patients with moderate or minimal extent disease who fail to achieve a complete response to third-line therapy for Testicular Germ Cell tumors that meet the above criteria. Standard protocol involves tandem transplant. Germ cell tumor stage is to be determined using the Indiana University/Einhorn classification or Follicular Non-Hodgkin's lymphoma in patients who have failed primary therapy without histologic transformation.**
- **Acute leukemia in remission in patients with a high probability of relapse and who have no HLA matched donor. The leukemia type must meet the general conditions (sensitive to chemotherapy/radiation and incurable with conventional chemotherapy/radiation), and be in one of the following categories:**
 - 1) **lymphoid**
 - 2) **myeloid**
 - 3) **monocytic**
 - 4) **acute erythema and erythroleukemia**
 - 5) **unspecified cell type**
- **Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response.**

- Non-Hodgkin's lymphoma, follicular, in-patients who have failed primary therapy without histologic transformation.
- Hodgkin's Lymphoma, relapsed or refractory disease advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.
- Multiple myeloma ONLY after receipt of a high dose chemotherapy regime. Coverage of autologous stem cell transplantation for multiple myeloma is effective for services provided on or after July 1, 2000.

b) Conditions for which approval may not be given:

The following conditions are not covered under Medicare:

- Breast cancer.
- Acute leukemia not in remission except for primary resistant acute myelogenous leukemia.
- Chronic granulocytic leukemia.
- Solid tumors (other than neuroblastoma and testicular germ cell tumors).

c) Adverse Factors:

- Active infection
- Incapacity to physically or mentally withstand this rigorous procedure.

8.4.3 *Coverage of Immunosuppressant Drugs Following Covered Organ Transplants*

- a) Effective December 21, 2000, eligible Medicare beneficiaries who receive drugs used for immunosuppressive therapy to prevent transplant rejections will continue to be eligible for this benefit from Medicare without limitations.
- b) Medicare will also cover currently Medicare eligible beneficiaries who had their drug coverage terminated prior to December 21, 2000 due to previously imposed time limitations.

8.5 Authorization

8.5.1 Determination Process

8.5.1.1 General

- a) Providers within the community or QUEST health plans identify persons who meet the medical conditions for a transplant evaluation.
- b) The provider completes the Form 1144 requesting approval for a transplant evaluation and sends it to the Fiscal Agent for review and processing.
- c) For all transplant candidates, basic medical information is necessary in order to appropriately refer a patient for evaluation by a participating facility. The following information is requested. Please advise with the referral if any of this information is not available:
 - Age
 - Weight
 - Comprehensive diagnoses list
 - Medical history, including medication(s)
 - Hospital discharge summary(ies)
 - NYHA class, cancer stage, or other functional status information
 - Documentation of other organ status (CBC, chem studies, creatinine clearance, pulmonary function tests, chest x-ray, treadmill, cardiac echo or MUGA scan, etc.)
 - History of drug or alcohol abuse (length of abstinence and response to treatment program(s), documentation of six months abstinence via drug/alcohol screens).
 - History of psychiatric illness (documentation of type and response to therapy).
- d) For specific transplants, information in addition to the above is requested.

8.5.1.2 Heart Transplant

- a) Cardiac catheterization report(s)
- b) History of any cerebral or peripheral vascular problems

- c) Echocardiogram and MUGA scan reports, if available

8.5.1.3 Lung Transplant

- a) Lung biopsy results, pulmonary function test, or bronchoscopy reports
- b) Oxygen saturation with exercise
- c) Any previous thoracic surgery

8.5.1.4 Heart/Lung Transplant

Please provide requested information from both the heart and lung categories

8.5.1.5 Liver Transplant

- a) Liver biopsy results (if available)
- b) Liver enzymes (SGPT, SGOT, Bili, etc.) and clotting studies (APTT, PTT, etc.)
- c) Other liver studies such as liver scan, U/S or CT scan results are helpful

8.5.1.6 Small Bowel

- a) History of hyperalimentation and nutritional studies
- b) History of previous abdominal surgery
- c) Colonoscopy reports, CT scans, any type of GI studies

(If a liver transplant is performed in conjunction, please provide the requested information from the liver category as well.)

8.5.1.7 Allogeneic Bone Marrow Transplant

- a) Donor match information
- b) General outline for treatment plan (type of drugs and dosages, TBI or not, etc.)
- c) Pathology reports and marrow analysis are also helpful

8.5.1.8 Autologous Bone Marrow Transplant

(If a scientific study must have full protocol for review plus consent IRB)

- a) Detailed treatment plan (protocol to be used, type of purging (if any), drugs and dosages, timing of stem cell infusion, etc.)
- b) Pathology reports and marrow analysis are also helpful.

8.5.1.9 SHOTT Program Authorization and Reimbursement Procedures

- a) For a QUEST client, the physician also completes an 1128 disability form to submit to Med-QUEST Division for disenrollment from QUEST. Form should have on the top right corner "Transplant Candidate." The physician should coordinate with the recipient's QUEST managed care plan.
- b) For QUEST and Fee-for-service clients, if the MQD/MSB Medical Consultant decides that the medical criteria for the medical need for the transplant is met (appropriate diagnoses and covered transplant), he/she conditionally approves the Form 1144.
 - MQD returns a copy of the Form 1144 to the referring physician. It is the responsibility of the referring physician to notify the recipient.
 - MQD sends a copy of the approved Form 1144 and all attachments to the State of Hawaii Organ and Tissue Transplant (SHOTT) program which then becomes responsible for completion of the transplant evaluation and coordination of the transplant process for MQD.
 - Upon notification by the MQD, the SHOTT program is responsible for the active case management of transplants related services and items for the patient.
- c) If the SHOTT program requires additional information to decide whether the transplant can be approved, the SHOTT program will request information directly from the referring physician.
 - If transplant criteria are met, the SHOTT program makes arrangements to send the patient to a facility for an evaluation. The SHOTT program selects the appropriate transplant facility for the evaluation and for the transplant procedure.
- d) The SHOTT program assumes financial responsibility for transplant related services/items from the date the Form 1144 is signed by the MQD/MSB consultant through the post transplant first anniversary visit. All claims for services performed during this period are submitted to the SHOTT program.
- e) The SHOTT program is responsible for coordinating care for transplant services including arranging for travel, lodging and meals where needed.

- If either the transplant facility or the SHOTT program decides that the recipient does not meet all required transplant criteria, and the MQD concurs, SHOTT program notifies both referring physician and recipient of the denial in writing recommendation.
- f) The recipient may appeal the denial by contacting his/her worker.
- g) If Medicaid is the secondary payer to any other health insurer, the SHOTT program is responsible for authorizing meals, transportation, lodging, and any applicable deductible, coinsurance, or the difference between the primary health insurer's payment and the allowance the SHOTT program extends for the service.
- h) Contact information for the SHOTT Program is listed in Appendix 1.

**APPENDIX N – FORM 208 AIR TRANSPORTATION TRAVEL
REQUEST PROCESS**

APPENDIX N

FORM 208 AIR TRANSPORTATION TRAVEL REQUEST PROCESS

The Med-QUEST Division (MQD) has changed its process for inter-island travel for medical services. In the interest of fiscal responsibility, travel arrangements for eligible Medicaid recipients will now be made by MQD with the assistance of Panda Travel. The purpose is to inform you of additional changes to the process for submitting Form 208.

The following items relating to the Form 208 travel request process:

- Travel must only be for medical reasons (treatments, appointments, follow-up visits, etc.).
- Inter-island travel will only be approved if the medical service associated with the travel request cannot be obtained on the recipient's island of residence. If another Medicaid provider on the recipient's island of residence provides the medical service, the recipient should consult that provider.
- Airlines will not accept approved Form 208s as ticket vouchers.
- Recipients CANNOT make their own travel arrangements and will not be reimbursed for ticket expenses.
- Once a ticket has been issued by MQD, it CANNOT be changed.

The additional changes to the Form 208 process are as follows:

- The Form 208 - Air Transportation Request (refer to attached) has been revised and now includes additional information necessary for processing travel requests. Each section of the Form 208 must be completed.
- The completed Form 208 should be faxed to CSB-208 Processing at (808) 692-8131 if travel is requested at least 14 days before the appointment date.
- If you faxed the 208 Form, you do not need to mail it.
- Incomplete Form 208s will be returned.
- The role and need for companion/attendant travelers must be explained upon submission of travel request. The MQD will approve no more than ONE (1) attendant. Minors require an adult attendant. For adults, the attendant must be an adult and must be able to provide physical assistance to the patient (if needed).
- Special travel needs (seating, gate-to-plane assistance, etc.) must be indicated upon request of travel authorization. Type of oxygen flow device (mask or nasal tube) and the O2 flow rate must be provided upon submission of travel request at least 7 days in advance.

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- ❑ Requests for non-emergent and non-urgent travel received less than 14 days in advance will be returned. Due to the decreasing availability of flights, it is important for travel arrangements to be made in advance so that recipients will be able to travel to their scheduled appointments.
- ❑ If the appointment needs to be rescheduled, submit a new Form 208 at least 14 days from the new appointment date.

The procedure for completing and submitting the Form 208 to CSB for review is described below:

Do not submit more than (1) travel request for each Form 208.

Example: Recipient will have radiation therapy at least (3) times a month and will travel back to the island of residence between each session, then 3 208 Forms must be submitted.

For Non-Emergent and Non-Urgent Conditions (i.e., Regular)

Step 1: Complete each item on the Form 208. Check the “Regular” box at the top right corner of the Form 208. If the patient does not have a telephone, provide the name and telephone number of someone who can relay a message to the patient in Boxes 9 and 10.

Step 2: You should complete the Form 208 at least 14 days before the scheduled appointment. Please fax the Form 208 to:
Department of Human Services
Med-QUEST Division
CSB-208 Processing
FAX: (808) 692-8131

Due to decreases in inter-island flights, the MQD must receive the 208 at least 14 days prior to a scheduled appointment. 208s received less than 14 days prior to an appointment will be returned and the patient will need to reschedule his/her appointment. Also, due to limited flight availability on weekends, please do not schedule any appointments for FRIDAY and MONDAY. Limit appointment to morning and early noon. Example: 8:00 a.m. to 1:00 p.m.

MQD will review the travel request. If the travel request is approved, MQD staff will notify the provider (see attached memorandum). MQD will schedule the flight arrangements and purchase the recipient’s (and companion’s) ticket based on the information provided. MQD staff will notify the recipient of the travel plan. If the travel request is denied, MQD will notify the recipient and provider.

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For Emergency Medical Conditions

Definition: Emergency medical conditions are those conditions that are manifested by ACUTE conditions of sufficient severity (including severe pain) such that a prudent layperson, who possesses average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or with respect to a pregnant woman, the health of the woman and/or her unborn child) in serious jeopardy, or cause serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

If the Medicaid recipient meets the above criteria AND services to treat the emergency conditions are not available on the island of residence AND the recipient can safely travel on a commercial airline, please use the following procedure:

- Step 1:** Please print or type required information. Complete each item on the Form 208. Check the "Emergent" box at the top right corner of the Form 208. If the patient does not have a telephone, provide the name and telephone number of someone who can relay a message to the patient in Boxes 9 and 10.
- Step 2:** Fax the completed Form 208 to (808) 692-8131.
- Step 3:** Direct the Medicaid recipient to his/her Med-QUEST Division Office to obtain Government Airline Coupons (if during working hours). If after working hours or on the weekend, the referring physician must call Dr. Anthea Wang, Medical Director of the Clinical Standards Branch-MQD, at (808) 692-8106 for travel approval and instructions on directing the recipient to the Hawaiian Airlines desk for ticketing.

For Urgent Medical Conditions

Definition: Urgent medical conditions are conditions that require medical care within 2 business days. If the care is not received during this time, a person's life or health may be jeopardized.

If the Medicaid recipient meets the above criteria AND services to treat the urgent medical condition are not available on the island of residence AND the recipient can safely travel on a commercial airline, please use the following procedure:

- Step 1:** Complete the Form 208. Check the "Urgent" box at the top right corner of the Form 208. If the patient does not have a telephone, provide the name and telephone number of someone who can relay a message to the patient in Boxes 9 and 10.
- Step 2:** Fax the completed Form 208 to (808) 692-8131.

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MQD will review the travel request. If the travel request is approved, MQD staff will notify the provider. MQD will schedule the flight arrangements and purchase the recipient's (and companion's) ticket based on the information provided. MQD staff will notify the recipient of the travel plan. If the travel request is denied, MQD will notify the recipient and provider.

Examples of situations that do NOT qualify as EMERGENCY or URGENT medical conditions:

- The Medicaid recipient has a routine appointment (including non-urgent follow-up visit) with a provider and a Form 208 was not submitted timely.*
- The Medicaid recipient has an appointment for an elective procedure scheduled more than 14 days before the date of travel and the Form 208 was not submitted timely.*
- The Medicaid recipient has an appointment with a provider or has changed an appointment date, and a Form 208 has not been submitted at least 14 days before the new appointment.*

In order for an eligible recipient's travel to be covered by the State, this process for submitting the Form 208 must be followed exactly. For your information, a copy of the notice to recipients concerning these changes and a copy of the itinerary format is attached.

Finally, if you become aware of situations where a recipient will be unable to make his appointment, the appointment has been cancelled, the appointment has been rescheduled, or the recipient was a no-show for the appointment, please contact CSB at (808) 692-8124 so that the travel can be cancelled. Recipients will be informed that if they travel to Oahu and fail to show up for their appointment, they will be committing fraud, and the Department will seek repayment of the travel costs.

APPENDIX O - TRANSPLANT ADMINISTRATION SURVEY

APPENDIX O

Transplant Administration Survey

1. Is your institution currently licensed by the State's regulatory agencies? Yes No

2. Are there conditions on the current federal, state, or local licenses, permits, or certifications? Yes No

If yes, explain:

3. Is your institution affiliated with or the parent corporation of other hospitals / institutions? Yes No

If yes, what is the name(s) of the affiliated institutions and the nature of the relationship?

Are transplant services provided at any of the affiliated institutions? Yes No

If yes, please list which affiliate and which service.

4. Is your institution accredited by the JCAHO? Yes No

If yes, are there any contingencies on the accreditation? Yes No

If yes, explain:

On what date does your JCAHO accreditation expire? _____

5. What is your hospital's tax ID number? _____

6. General and Professional Liability Insurance

	Coverage	
	Per Occurrence	Aggregate
General Liability		
Professional Liability		

7. Does your facility's general liability insurance coverage and medical staff professional liability insurance requirements meet state mandates? Yes No

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8. Has your institution ever had or currently has professional or general liability coverage denied, suspended or revoked?

Yes

No

If yes, when and for what reason?

9. Does your institution's Medical Staff Bylaws contain a comprehensive process for credentialing and re-credentialing of physicians participating in the organ and blood/marrow transplant programs including primary verification of:

	Yes	No
Licensure	<input type="checkbox"/>	<input type="checkbox"/>
Previous Appointments	<input type="checkbox"/>	<input type="checkbox"/>
DEA Certificates	<input type="checkbox"/>	<input type="checkbox"/>
Previous State Medicare / Medicaid Sanctions	<input type="checkbox"/>	<input type="checkbox"/>
The National Practitioner Data Bank	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX O

10. Transplant programs available (mark all that apply):

		Type of Transplant		Date Initiated
		Adult	Pediatric	
Blood and Bone Marrow	Allogeneic Related	<input type="checkbox"/>	<input type="checkbox"/>	
	Allogeneic Unrelated	<input type="checkbox"/>	<input type="checkbox"/>	
	Autologous	<input type="checkbox"/>	<input type="checkbox"/>	
	Peripheral Blood Stem Cell	<input type="checkbox"/>	<input type="checkbox"/>	
	Cord Blood	<input type="checkbox"/>	<input type="checkbox"/>	
Heart	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Domino	<input type="checkbox"/>	<input type="checkbox"/>	
Lung	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Living Donor	<input type="checkbox"/>	<input type="checkbox"/>	
Intestine	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Living Donor	<input type="checkbox"/>	<input type="checkbox"/>	
Islet Cell	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Living Donor	<input type="checkbox"/>	<input type="checkbox"/>	
	Autografts	<input type="checkbox"/>	<input type="checkbox"/>	
Kidney	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Living Donor	<input type="checkbox"/>	<input type="checkbox"/>	
Liver	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Living Donor	<input type="checkbox"/>	<input type="checkbox"/>	
Pancreas	Cadaver	<input type="checkbox"/>	<input type="checkbox"/>	
	Living Donor	<input type="checkbox"/>	<input type="checkbox"/>	
Combination	Heart-Lung	<input type="checkbox"/>	<input type="checkbox"/>	
	Heart-Kidney	<input type="checkbox"/>	<input type="checkbox"/>	
	Islet-Kidney	<input type="checkbox"/>	<input type="checkbox"/>	
	Kidney-Pancreas	<input type="checkbox"/>	<input type="checkbox"/>	
	Liver-Kidney	<input type="checkbox"/>	<input type="checkbox"/>	
	Liver-Pancreas	<input type="checkbox"/>	<input type="checkbox"/>	
	Liver-Intestine	<input type="checkbox"/>	<input type="checkbox"/>	
Other		<input type="checkbox"/>	<input type="checkbox"/>	

11. Name and address of immunology laboratory affiliated with transplant program: (State accreditation organization)

APPENDIX O

12. Name and address of procurement organization that hospital contracts with:

13. Facilities and services:

Special Inpatient and Outpatient Facilities:	Yes	No	# Beds
BMT	<input type="checkbox"/>	<input type="checkbox"/>	
Medical Intensive Care Unit	<input type="checkbox"/>	<input type="checkbox"/>	
Surgical Intensive Care Unit	<input type="checkbox"/>	<input type="checkbox"/>	
Neonatal Intensive Care Unit	<input type="checkbox"/>	<input type="checkbox"/>	
Pediatric Intensive Care Unit	<input type="checkbox"/>	<input type="checkbox"/>	
General Pediatric Unit	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiopulmonary/Thoracic Transplant Unit	<input type="checkbox"/>	<input type="checkbox"/>	
Solid Organ Transplant Unit	<input type="checkbox"/>	<input type="checkbox"/>	
BMT Clinic	<input type="checkbox"/>	<input type="checkbox"/>	
Medical and Surgical Transplant Clinics	<input type="checkbox"/>	<input type="checkbox"/>	
Home Health Transplant Nursing Specialists	<input type="checkbox"/>	<input type="checkbox"/>	
Pediatric cardiology or heart transplant clinic	<input type="checkbox"/>	<input type="checkbox"/>	
Available 24 hours/day, 7 days/week	Yes	No	
Anesthesiology	<input type="checkbox"/>	<input type="checkbox"/>	
Pathology	<input type="checkbox"/>	<input type="checkbox"/>	
Blood banking	<input type="checkbox"/>	<input type="checkbox"/>	
Renal dialysis	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiac catheterization and cardiac surgery	<input type="checkbox"/>	<input type="checkbox"/>	
Operating rooms	<input type="checkbox"/>	<input type="checkbox"/>	

14. Are accommodations for living arrangements available for patient(s)/companion(s) for both pre and post transplant period?

Yes

No

If yes, list and provide information:

15. What kind of ongoing training is provided for the transplant staff? What kind of educational services are provided for the community physicians? i.e. conference, workshops, weekly/monthly meetings, etc. Are continuing education credits offered?

APPENDIX O

16. Summarize the unique qualities that add value for patients, referring physicians and payers (attach additional copies as needed). Include such information as ACGME programs, fellowship programs, key accomplishments, future directions. If the institution supports a pediatric program please outline any special programs (i.e. Child Life Program).

17. Summarize efforts to control costs associated with transplantation:

18. Key contacts

		Name	Phone / Fax	E-Mail Address
Person completing Survey				
Transplant Administrator (List all that apply)	Kidney			
	Pancreas			
	Liver			
	Intestine			
	Heart			
	Lung			
	Bone Marrow			
Transplant Data Coordinator				
Transplant Contract Director				

I have investigated and certify that the information contained in this survey and all attachments is accurate, complete and true. I understand that submission of this completed survey does not automatically result in continued participation.

Name _____ Signature(s) _____
 Title _____ Date _____

APPENDIX P - HEART TRANSPLANT APPLICATION

APPENDIX P

HEART TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:
Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

Data for **Part B: Experience Data** must be obtained from the Scientific Registry of Transplant Recipients (SRTR) secure web site (<https://secure.ustransplant.org>). To download this PDF report, centers may use the same usernames and passwords as are used for the comment and review period for the Center Specific Reports. Please direct questions to the SRTR help-desk (phone: 734-665-4108 x267; email: mail@ustransplant.org).

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2. Scroll down to **2003 OPTN/UNOS Standardized Request for Information (RFI)**. Click on **Part B Version 3.0 PDF Download** to download the self-extracting Adobe PDF file directly onto your local system.
3. Comments or questions about the report should be directed to the SRTR help-desk.

Note: Table B-9 (readmission rates) is not included in the SRTR download and should to be completed by each center.

About the Scientific Registry of Transplant Recipients

The SRTR supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States. With oversight and funding from the Health Resources and Services Administration (HRSA), an agency of the US Department of Health and Human Services, the SRTR is administered by the University Renal Research and Education Association (URREA), a not for profit health research foundation, in collaboration with the University of Michigan.

APPENDIX P

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX P

Table B-9. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

Table B-10. Ventricular Assist Device (VAD) Program

Does your program perform VAD implants? Yes No Start date:

If yes, please provide the number of devices implanted:

Year	Numt						
	HeartMate IP LVAS	HeartMate XVE LVAS	HeartMate SNAP VE LVAS	Thoratec VAD System	Novacor LVAS	AbloMed BVS-5000	Other (please identify)
2003							
2004							
2005							
2006							
2007							
2008							
Total							

APPENDIX P

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Protocols for VAD program if VAD used in an outpatient setting.

C-4. Describe pre- and post-transplant support services.

C-5. Describe pre- and post-transplant patient education.

C-6. Are “Quality of Life” Surveys sent to recipients? Yes No

C-7. Is a “Patient Satisfaction” survey used by the program? Yes No

C-8. Describe patient safety initiatives.

C-9. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX P

Part D: Transplant Team

Table D-1. Adult Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of tx performed	Yrs exp. on team / # of tx performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX P

Table D-2. Pediatric Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of txs performed	Yrs exp. on team / # of txs performed
OPTN/UNOS Primary Surgeon Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX P

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX Q - LIVER TRANSPLANT APPLICATION

APPENDIX Q

LIVER TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:
Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

Data for **Part B: Experience Data** must be obtained from the Scientific Registry of Transplant Recipients (SRTR) secure web site (<https://secure.ustransplant.org>). To download this PDF report, centers may use the same usernames and passwords as are used for the comment and review period for the Center Specific Reports. Please direct questions to the SRTR help-desk (phone: 734-665-4108 x267; email: mail@ustransplant.org).

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3. Comments or questions about the report should be directed to the SRTR help-desk.

Note: Table B-9 (readmission rates) and the donor complications section of Table B-10 (living donor experience) are not included in the SRTR download and should to be completed by each center.

About the Scientific Registry of Transplant Recipients

The SRTR supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation in the United States. With oversight and funding from the Health Resources and Services Administration (HRSA), an agency of the US Department of Health and Human Services, the SRTR is administered by the University Renal Research and Education Association (URREA), a not for profit health research foundation, in collaboration with the University of Michigan.

APPENDIX Q

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX Q

Table B-9. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

Table B-10. Living Donor Experience

	Number of Living Donors	Ave. Age of Donors	% Donor complications within 6 mos after surgery requiring hospitalization
7/2003 – 6/2004	Provided by SRTR	Provided by SRTR	
7/2004 – 6/2005	Provided by SRTR	Provided by SRTR	
7/2005 – 6/2006	Provided by SRTR	Provided by SRTR	
7/2006 – 6/2007	Provided by SRTR	Provided by SRTR	
7/2007 – 6/2008	Provided by SRTR	Provided by SRTR	

APPENDIX Q

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for living donor selection.

C-3. Protocols for rejection identification and treatment.

C-4. Describe pre- and post-transplant support services.

C-5. Describe pre- and post-transplant patient education.

C-6. Are “Quality of Life” Surveys sent to recipients? Yes No

C-7. Is a “Patient Satisfaction” survey used by the program? Yes No

C-8. Does the program offer bio-artificial liver as a bridge to transplant? If yes, number done in last two calendar years: Yes No

Is yes, please provide protocol.

C-9. Describe patient safety initiatives.

C-10. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX Q

Part D: Transplant Team

Table D-1. Adult Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of tx performed	Yrs exp. on team / # of tx performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX Q

Table D-2. Pediatric Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of txs performed	Yrs exp. on team / # of txs performed
OPTN/UNOS Primary Surgeon Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. In transplant	Yrs exp. on team
OPTN/UNOS Primary Physician Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX Q

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX R - LUNG TRANSPLANT APPLICATION

APPENDIX R

LUNG TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:
Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

Data for **Part B: Experience Data** must be obtained from the Scientific Registry of Transplant Recipients (SRTR) secure web site (<https://secure.ustransplant.org>). To download this PDF report, centers may use the same usernames and passwords as are used for the comment and review period for the Center Specific Reports. Please direct questions to the SRTR help-desk (phone: 734-665-4108 x267; email: mail@ustransplant.org).

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3. Comments or questions about the report should be directed to the SRTR help-desk.

Note: Table B-10 (readmission rates) is not included in the SRTR download and should to be completed by each center.

About the Scientific Registry of Transplant Recipients

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APPENDIX R

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX R

Table B-10. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 — 6/2007 and 7/2007 — 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

APPENDIX R

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for living donor selection.

C-3. Protocols for rejection identification and treatment.

C-4. Describe pre- and post-transplant support services.

C-5. Describe pre- and post-transplant patient education.

C-6. Are “Quality of Life” Surveys sent to recipients? Yes No

C-7. Is a “Patient Satisfaction” survey used by the program? Yes No

C-8. Does the Program offer Flolan therapy? Yes No
If yes, please provide protocol.

C-9. Describe patient safety initiatives.

C-10. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX R

Part D: Transplant Team

Table D-1. Adult Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of tx performed	Yrs exp. on team / # of tx performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX R

Table D-2. Pediatric Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of txs performed	Yrs exp. on team / # of txs performed
OPTN/UNOS Primary Surgeon Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX R

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX S - HEART-LUNG TRANSPLANT APPLICATION

APPENDIX S

HEART-LUNG TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:
Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

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Note: Table B-7 (readmission rates) is not included in the SRTR download and should to be completed by each center.

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APPENDIX S

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX S

Table B-7. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

APPENDIX S

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Describe pre- and post-transplant support services.

C-4. Describe pre- and post-transplant patient education.

C-5. Are “Quality of Life” Surveys sent to recipients? Yes No

C-6. Is a “Patient Satisfaction” survey used by the program? Yes No

C-7. Describe patient safety initiatives.

C-8. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX S

Part D: Transplant Team

Table D-1. Adult Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of tx performed	Yrs exp. on team / # of tx performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes No

If yes, provide date(s) of approval.

APPENDIX S

Table D-2. Pediatric Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / # of txs performed	Yrs exp. on team / # of txs performed
OPTN/UNOS Primary Surgeon Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX S

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX T - BONE MARROW CREDENTIALING APPLICATION

APPENDIX T

Credentialing Application
For Bone Marrow/Stem Cell Transplantation

Initial Application _____
Reaccreditation Application _____
Application Date: _____

Please utilize attachments where applicable

General Information

Facility Name

Point of Contact

Point of Contact Mailing Address:

e-mail address: _____

Telephone: _____

Fax: _____

Location/Accessibility to Patients: _____

Number of operating beds: _____

Ownership: _____

Overview of BMT/Stem Cell Committees: _____

Scope and Range of medical services provided internally versus those contracted to vendors: _____

Overview of available medical technologies: _____

Special Capabilities/Experience: _____

Licensure

Has the facility's state license ever been restricted, revoked, surrendered, suspended, stipulated or voluntarily relinquished? ___ Yes ___ No If Yes, please provide details via attachment.

Please provide accreditation documentation for the following:

- JCAHO
- Medicare (overall facility)
- Current State License
- FACT/CLIA/AABB/CAP Accreditation (If applicable)
- Internal Transplant Physician Credentials

Utilization

Please answer the following for allogeneic-related, allogeneic-unrelated and autologous

- Number of admissions
- Number of admission days
- Number of procedures performed each year
- Occupancy Rate
- ALOS
- Number of transplant surgical procedures by inpatient and outpatient
- Retransplant percentages
- Readmit rate
- Overall success rate in percentage for 1 year survival and 2 year survival (broken down by adult vs. pediatric if available)
- Age of Program

Are there special circumstances such as the type of candidates the facility accepts or an ability to handle complicated procedures which would have an impact on success of transplantation?

Medical Staff

- Please attach curriculum vitae for all Board certified Physician Staff
- Number of patient-focused physicians? _____
- Please provide an overview of the transplant team members including years of training and experience
- Please provide an overview of Psychosocial Evaluation criteria (or overview of Evaluation Committee)
- Please provide an overview of Coordination/Outreach staff to include any “inbound patient packets,” etc.

Thank you. Please feel free to provide any additional information which you feel provides an enhanced overview of your facility's capabilities.

APPENDIX U - PEDIATRIC SMALL BOWEL

APPENDIX U

PEDIATRIC SMALL BOWEL TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

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Note: Table B-8 (readmission rates) is not included in the SRTR download and should to be completed by each center.

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APPENDIX U

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX U

Table B-8. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

APPENDIX U

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Describe pre- and post-transplant support services.

C-4. Describe pre- and post-transplant patient education.

C-5. Are “Quality of Life” Surveys sent to recipients? Yes No

C-6. Is a “Patient Satisfaction” survey used by the program? Yes No

C-7. Describe patient safety initiatives.

C-8. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX U

Part D: Transplant Team

Table D-1. Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in KP tx / breakdown of KP txs performed	Yrs exp. on team / breakdown of KP txs performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

APPENDIX U

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX U

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX V - PANCREAS TRANSPLANT APPLICATION

APPENDIX V

PANCREAS TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:
Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

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Note: Tables B-8 (readmission rates) and B-9 (program changes) are not included in the SRTR download and should to be completed by each center.

About the Scientific Registry of Transplant Recipients

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APPENDIX V

administered by the University Renal Research and Education Association (URREA), a not for profit health research foundation, in collaboration with the University of Michigan.

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX V

Table B-8. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 — 6/2007 and 7/2007 — 6/2008.

Primary Complication	Adult				Pediatric			
	PTA		PAK		PTA		PAK	
	N of Readmissions	Total N						
Unplanned Return to OR								
Infection								
Rejection								
Other								

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

B-9. Did the program experience any significant changes in survival rates or other experience outcomes?

Yes

No

If yes, please explain.

APPENDIX V

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Describe pre- and post-transplant support services.

C-4. Describe pre- and post-transplant patient education.

C-5. Are “Quality of Life” Surveys sent to recipients? Yes No

C-6. Is a “Patient Satisfaction” survey used by the program? Yes No

C-7. Describe patient safety initiatives.

C-8. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX V

Part D: Transplant Team

Table D-1. Adult Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in tx / breakdown of PAK/PTA txs performed	Yrs exp. on team / breakdown of PAK/PTA txs performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

APPENDIX V

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX V

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX W - KIDNEY-PANCREAS TRANSPLANT APPLICATION

APPENDIX W

PANCREAS - KIDNEY TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:
Pediatric date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

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APPENDIX W

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX W

Table B-8. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

APPENDIX W

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Describe pre- and post-transplant support services.

C-4. Describe pre- and post-transplant patient education.

C-5. Are “Quality of Life” Surveys sent to recipients? Yes No

C-6. Is a “Patient Satisfaction” survey used by the program? Yes No

C-7. Describe patient safety initiatives.

C-8. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX W

Part D: Transplant Team

Table D-1. Adult Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in KP tx / breakdown of KP txs performed	Yrs exp. on team / breakdown of KP txs performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. In transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

APPENDIX W

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX W

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX X – KIDNEY TRANSPLANT APPLICATION

APPENDIX X

KIDNEY TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date: _____
OPTN/UNOS Yes No Date: _____

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: _____ Volume: _____
Pediatric date of inception: _____ Volume: _____

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

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APPENDIX X

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX X

Table B-8. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

APPENDIX X

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Describe pre- and post-transplant support services.

C-4. Describe pre- and post-transplant patient education.

C-5. Are “Quality of Life” Surveys sent to recipients? Yes No

C-6. Is a “Patient Satisfaction” survey used by the program? Yes No

C-7. Describe patient safety initiatives.

C-8. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX X

Part D: Transplant Team

Table D-1. Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in KP tx / breakdown of KP txs performed	Yrs exp. on team / breakdown of KP txs performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

APPENDIX X

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX X

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____

APPENDIX Y – ADULT INTESTINAL TRANSPLANT APPLICATION

APPENDIX Y

ADULT INTESTINAL TRANSPLANT APPLICATION

Part A: General Information

A-1. Accreditation/certification

Medicare Yes No Date:
OPTN/UNOS Yes No Date:

Have there been any changes in Medicare or OPTN/UNOS status? Yes No

If yes please explain.

A-2. Procedures performed since date of inception through last calendar year. Includes adult and pediatrics, re-transplants and multi-organ transplants.

Adult date of inception: Volume:

A-3. Has the program been closed or suspended for any reasons during the program's history? Yes No

If yes, provide date(s) and explain.

Part B: Experience Data

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APPENDIX Y

ATTACH SRTR PART B: EXPERIENCE DATA HERE.

APPENDIX Y

Table B-8. Readmission Rates within 3 Months of Discharge from the Transplant Hospital Stay for Patients Transplanted in 7/2006 – 6/2007 and 7/2007 – 6/2008.

Primary Complication	Adult		Pediatric	
	N of Readmissions	Total N	N of Readmissions	Total N
Unplanned Return to OR				
Infection				
Rejection				
Other				

Notes: (i) identify only the primary reason for the readmission complication, (ii) patients can be readmitted more than once within the three-month period.

APPENDIX Y

Part C: Protocols

C-1. Protocols for patient selection, including indications or contraindications.

C-2. Protocols for rejection identification and treatment.

C-3. Describe pre- and post-transplant support services.

C-4. Describe pre- and post-transplant patient education.

C-5. Are “Quality of Life” Surveys sent to recipients? Yes No

C-6. Is a “Patient Satisfaction” survey used by the program? Yes No

C-7. Describe patient safety initiatives.

C-8. Please provide a list of research protocols in which transplant patients may be enrolled.

APPENDIX Y

Part D: Transplant Team

Table D-1. Primary Team Composition

Title	Name	Board Certification / Specialty	Yrs exp. in KP tx / breakdown of KP txs performed	Yrs exp. on team / breakdown of KP txs performed
OPTN/UNOS Primary Surgeon [1] Appointment Date Fellowship Location				
Transplant Surgeon(s) Fellowship Location				

Title	Name / Degree	Board Certification / Specialty	Yrs exp. in transplant	Yrs exp. on team
OPTN/UNOS Primary Physician [1] Appointment Date Fellowship Location				
Pre-Transplant Coordinator(s) Contact Phone #				
Post-Transplant Coordinator(s) Contact Phone #				
Social Service				
Financial Coordinator Contact Phone #				
Data Coordinator				
Transplant Administrator				

[1] The OPTN/UNOS primary surgeon or physician is defined as personnel who meet certain minimum levels of commitment to and knowledge of organ procurement and transplantation as specified in the UNOS criteria for formal training and experience.

Has the OPTN/UNOS primary surgeon or physician changed over the past year?

Yes

No

If yes, provide date(s) and explain.

APPENDIX Y

Has the OPTN/UNOS Membership and Professional Standards Committee reviewed and approved the new primary surgeon or physician?

Yes

No

If yes, provide date(s) of approval.

APPENDIX Y

Part E: Quality

E-1. Describe or attach overview of the transplant program's quality improvement process.

E-2. Describe actual quality improvements made over the previous year.

Part F: Summary

F-1. Describe the program's unique qualities.

F-2. Describe initiatives to control costs.

F-3. Provide any other information that you feel is important regarding your program.

I certify that the information contained in this survey and all attachments is accurate, complete and true.

Name		Signature(s)	_____
Title		Date	_____
Name		Signature(s)	_____
Title	Medical Director	Date	_____
Name		Signature(s)	_____
Title	Surgical Director	Date	_____