

# Member Center Terms & Conditions

Revised 3/20/2023

## 1. GENERAL

- A. The Member Center (MC) wishes to enroll participants into the National Kidney Registry (NKR) program so the NKR can facilitate transplants and provide services as needed.
- B. MCs agree to abide by the following Terms & Conditions, all [Member Center Requirements \(MCRs\)](#) and all [Medical Board Policies](#) as posted on the NKR web site.
- C. NKR will provide advance written notice of any material change to the Member Center Terms and Conditions.
- D. MCs shall notify NKR within 5 business days of any changes in operational status with the Organ Procurement and Transplantation Network (OPTN), the Center for Medicare Services (CMS) or any other internal or external regulatory body which would prevent acceptance of a match offer or the completion of an NKR kidney transplant or NKR donor surgery.
- E. MCs shall not have Net Chains Started (NCS) less than 0. The Monthly Financial Penalty (MFP) for MCs with a negative NCS shall accrue on a 1:1 ratio according to the MC's NCS. For example, a center with a negative 2 NCS will be billed \$2,000 every month, a center with a negative 20 NCS will be billed \$20,000 every month, etc. This provision and the related MFP shall survive the termination of the Service Contract, as the moral obligation to the Voucher holders exist in perpetuity. Notwithstanding the foregoing, the MFP is waived for MCs that are PCs in good standing. Additionally, the MFP is reduced on a 1:1 ratio for each unredeemed Family Voucher (FV) chain start. FV chain start donors have no Standard Voucher holders listed on the informed consent documents.
  1. Example A: if the MC has 2 unredeemed FV chain starts and an NCS score of -2, there is no MFP.
  2. Example B: if the MC has 2 unredeemed FV chain starts and an NCS score of -4, the MFP would be \$2,000/ month.
  3. Example C: if the MC has 10 unredeemed FV chain starts and an NCS score of -10, but in the next month, a FV holder redeems and is transplanted; the MFP would be \$1,000/ month.
- F. **All In** MCs shall execute the ["All In" addendum](#) and must:
  1. Enter all Kidney Paired Donation (KPD) pairs and Good Samaritan Donors into the NKR.
  2. Perform a minimum of one NKR facilitated transplant per year.
  3. Make KPD Pairs and Good Samaritan Donors exportable for at least two weeks before they can be removed for non-NKR exchanges, unless there is a special condition that precludes participation. Special conditions must be communicated via email to the NKR so that the NKR can overcome these special conditions.
  4. Not withhold education or access to standard NKR programs such as paired exchange, voucher, remote donation, Donor Shield, etc.
- G. **Partner Centers** (PC) have been designated to absorb the chain end kidneys resulting from the Voucher Program and to facilitate living donor kidney transplants for voucher patients if / when they return for transplants. PCs must be approved by the NKR and the NKR reserves the right to revoke PC status at any time. All PCs shall:
  1. Execute the ["All In" addendum](#) and be compliant with said requirements.
  2. Be active Voucher participants and shall educate all donors on the Voucher option.
  3. Be active NKR Paired Exchange Program participants.
  4. Provide education and access to all standard NKR programs.
  5. Accept any waitlist patient offer (within reason) from the NKR. (e.g. donor age > 65, AB blood types, etc.)
  6. Notify the NKR in writing within 15 days if there is a change in the Surgical Director of the kidney transplant program.
  7. Use best efforts to coordinate with MCs to adhere to the spirit of the Voucher program, by facilitating living donor kidney transplants for Voucher recipients if / when they return for transplants. In the event that the NKR becomes insolvent and/or ceases operations, PCs shall continue to use best efforts to coordinate with NKR MCs to adhere to the spirit of the Voucher program, by facilitating living donor kidney transplants for Voucher recipients if / when they return for transplants. These obligations are vital so that Voucher donors and recipients are not

irreparably harmed. These obligations are irrevocable, exist in perpetuity, and shall survive the termination of this agreement.

- H. **Donor Care Network** (DCN) Centers of Excellence (COE) and must adhere to the [commitments](#) and offer all [programs](#) listed on the [DCN website](#). COEs unable to support any of the DCN commitment or programs must provide written notification in advance describing the DCN commitment(s) or program(s) that cannot be supported. COEs must be approved by the NKR and the NKR reserves the right to revoke COE status at any time.
- I. **Kidney For Life** (KFL) participating centers shall abide by the [commitments](#) made to the patients on the [KFL website](#). As part of these commitments, the NKR shall provide post-transplant antibody screening for all KFL patients at no cost to the patient or to the KFL center. This testing is consistent with KFL quality metrics which may include home blood draws for DSA monitoring. The KFL center shall be responsible for the final decision related to de novo DSA identification based on antibody screening data provided by the NKR and other information.
- J. **Donor Referral Network** (DRN) centers receive highly qualified donor referrals (online screening, medical history and labs completed) from the NKR which includes the NKR web site, the NKR Microsites and other NKR partner organizations. To participate in the DRN, Member Centers must:
  - 1. Fully participate in the NKR Voucher program.
  - 2. Maintain an 8% NKR donor referral conversion rate.
  - 3. Ensure all NKR referred donors who donate their kidney receive the living donor prioritization (internal direct donations must donate as NKR Internal Direct to receive the prioritization).
  - 4. Be an NKR Member Center in good standing.
- K. **Microsite** participating centers must:
  - 1. Be a member of the Donor Referral Network.
  - 2. Assist NKR referred patients with setting up a microsite.
  - 3. Be an NKR Member Center in good standing.

## 2. INSTITUTIONAL REVIEW BOARD EXEMPTION

- A. The MC acknowledges that the National Research Act of 1974 as governed by Title 45 of the Code of Federal Regulations, Part 46 permits an exemption to Institutional Review Board approval for research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- B. NKR may conduct data analysis and research using information that is recorded by the investigator in such a manner that subjects cannot be identified, without seeking Institutional Review Board approval.

## 3. INDEMNIFICATION AND WARRANTIES

- A. The MC acknowledges that NKR is not a health care provider and is not responsible for any evaluation of the health of any donor or recipient, choice of treatment, or medical services rendered. NKR does not provide any medical services, nor does it endorse any particular health care provider or procedure.
- B. The Parties agree to indemnify and hold harmless, each other, as well as the Parties' subsidiaries, affiliates, officers, board of directors, agents, partners, licensors, employees, successors, and assigns, from and against any claim or demand arising from this Agreement, services provided by NKR, or any actions taken by NKR on behalf of participants, including any damages, judgment, settlement costs, litigation costs, and attorneys' fees, fines and penalties of any kind.
- C. The MC warrants that NKR shall not be liable for damages of any kind, including, but not limited to, personal injuries, wrongful death, patient complications, economic losses, incidental or consequential damages, or any other such damages.
- D. The MC warrants that if NKR is named as a defendant in any legal action based on MC provided medical or surgical services, the MC will pay for NKR's legal defense and make best efforts to remove NKR as a defendant from said legal action.
- E. The MC agrees to indemnify NKR against any lawsuit pertaining to any circumstance involving a donor or recipient who was not fully informed by the MC of the NKR Donor Support & Protections including but not limited to [Donor Shield](#), prioritization for a living donor kidney transplant should they ever need one, vouchers, or the 90-day replacement policy.
- F. The MC warrants that they shall make timely payments for any and all invoices received from NKR. In the event of a Material Dispute to any particular line-item charge, MC shall tender timely payment for

said invoice, less the amount of the particular item in dispute. A Material Dispute must be emailed to the NKR within 30 days of the invoice date.

- G. The Parties agree that no breach of this agreement shall be deemed material unless the party alleging such a breach shall have given written notice of said breach to the other party, via certified mail, return receipt requested, or via email where the receiving party confirms receipt, and then such receiving party fails to cure the breach within ten (10) days, after receipt of said notice. Waiver of a breach of any provision of this agreement shall not be deemed or construed to be a waiver of any subsequent breach. In the event NKR brings an action to enforce a breach of this agreement, it is mutually agreed that a reasonable attorneys fee is 33 1/3% (thirty-three and one-third percent) of the amount due and owing, with interest to be calculated and compounded at a rate of 1 1/2% (one and one-half percent) per month, per annum.

**4a. STANDARD REIMBURSEMENTS**

| 1. <u>Transplant Services</u>   | <u>KFL Internal Direct<sup>1</sup></u> | <u>NKR Internal Direct<sup>1</sup></u> | <u>Microsite Internal Direct</u> | <u>All Other NKR Facilitated TXPs</u> |                |                  |
|---|--|--|----------------------------------|---------------------------------------|----------------|------------------|
| a) Database Management & Technology Support   | \$860/ TXP                             | \$860/ TXP                             | \$4,843/ TXP                     | \$4,843/ TXP                          |                |                  |
| b) Logistics & Paired Exchange Support  | \$295/ TXP                             | \$295/ TXP                             | \$295/ TXP                       | \$3,460/ TXP                          |                |                  |
| c) Pre-Op Serology Testing  | N/A                                    | N/A                                    | N/A                              | \$1,800/ TXP                          |                |                  |
| d) Research   | \$27/ TXP                              | \$27/ TXP                              | \$27/ TXP                        | \$522/ TXP                            |                |                  |
| e) CT Scan  | \$0/ TXP                               | \$0/ TXP                               | \$0/ TXP                         | \$369/ TXP                            |                |                  |
| f) Medicaid Out of State Physician Reimbursement  | \$0/ TXP                               | \$0/ TXP                               | \$0/ TXP                         | \$276/ TXP                            |                |                  |
| g) Donor Shield <sup>2</sup>  | \$1,375/ TXP                           | \$2,864/ TXP                           | N/A                              | \$1,375/ TXP                          |                |                  |
| h) Microsite Support  | \$0/ TXP                               | \$0/ TXP                               | \$4,037/ TXP                     | \$0/ TXP                              |                |                  |
| 2. Donor Shield Direct <sup>2</sup>   |  |  |                                  |                                       |                |                  |
| a) Kidney   |  |  |                                  | \$2,864/ donor                        |                |                  |
| b) Liver  |  |  |                                  | \$3,500/ donor                        |                |                  |
| 3. Kidney shipping & Organ Packaging  |  |  |                                  |                                       |                |                  |
| a) Donor Organ Packaging  |  |  |                                  | \$1,770/ shipment                     |                |                  |
| b) Ground and/or Commercial Air   |  |  |                                  | \$2,752/ shipment                     |                |                  |
| c) Onboard courier + Commercial Air + Ground  |  |  |                                  | \$8,468/ shipment                     |                |                  |
| d) Charter Aircraft + Commercial Air and/or Ground  |  |  |                                  | Quote                                 |                |                  |
| 4. Center Connectivity  |  |  |                                  |                                       |                |                  |
| a) Database Management & Technology Support   |  |  |                                  | \$375/ month                          |                |                  |
| b) <a href="#">Routine Member Center Requirement</a> Non-Compliance                                   |  |  |                                  | \$1,000 per event                     |                |                  |
| c) Avoidable Swap Failure   |  |  |                                  | \$5,000 per event                     |                |                  |
| 5. Automated Donor Intake (DASH) <sup>3</sup>   |  |  |                                  |                                       |                |                  |
| a) Kidney   |  |  |                                  |                                       |                |                  |
| Prior Year LD Transplants   | <13                                    | 13-24                                  | 25-49                            | 50-74                                 | 75-99          | >99              |
|   | \$1,000/ month                         | \$2,000/ month                         | \$3,000/ month                   | \$4,000/ month                        | \$5,000/ month | \$6,000/ month   |
| b) Liver  |  |  |                                  |                                       |                | No Cost          |
| 6. Donor Testing  |  |  |                                  |                                       |                |                  |
| a) Pre-Workup Labs using Cystatin C or 24-hour urine jug  |  |  |                                  |                                       |                | \$364/ request   |
| b) 24 Hour Urine Jug Only   |  |  |                                  |                                       |                | \$36/ request    |
| 7. High Resolution Tissue Typing & Blood Processing   |  |  |                                  |                                       |                |                  |
| a) Donor HLA, ABO, and cryopreservation ( <i>billed to donor center</i> )                             |  |  |                                  |                                       |                | \$891/ request   |
| b) Overnight shipment of donor cryo cells for cross matching  |  |  |                                  |                                       |                | \$1,399/ request |
| c) Cheek Swab HLA and ABO   |  |  |                                  |                                       |                | \$735/ request   |
| d) Cheek Swab HLA and ABO (If ≥ 30% of MCs High Resolution Typed TXPs are Low Eplet Mismatch TXPs)    |  |  |                                  |                                       |                | No Cost          |
| 8. Center to Center Billing (CCB) excludes internal 1-ways  |  |  |                                  |                                       |                |                  |
| a) Hospital Nephrectomy   |  |  |                                  |                                       |                | \$20,878/ TXP    |
| b) Donor Workup   |  |  |                                  |                                       |                | \$13,703/ TXP    |
| 9. Donor Protection for centers without an executed <a href="#">Donor Protection Addendum</a>         |  |  |                                  |                                       |                |                  |
| a) Medicare is primary or secondary   |  |  |                                  |                                       |                | \$149/ TXP       |
| b) Medicare is not primary or secondary   |  |  |                                  |                                       |                | \$1,489/ TXP     |
| 10. Annual Memberships  |  |  |                                  |                                       |                |                  |
| a) NKR "All In" Member Center   |  |  |                                  |                                       |                | No Cost          |
| b) NKR Member Center  |  |  |                                  |                                       |                | \$20,000/ year   |
| c) Donor Care Network Center of Excellence  |  |  |                                  |                                       |                | \$9,500/ year    |
| 11. Kit Fulfillment (2 Way shipping plus kits for Cryopreservation, Serology, XM, Tissue Typing, ABO) |  |  |                                  |                                       |                | \$216/ request   |

|                             |                |
|-----------------------------|----------------|
| 12. Home Phlebotomy Service | \$110/ request |
| 13. Net Terms               | Net 45         |

<sup>1</sup> Includes prioritization for living donor kidney for donor

<sup>2</sup> Includes \$250 Database Management & Technology Support (DMTS)

<sup>3</sup> DMTS

#### 4b. STANDARD PAYMENTS

|  |  |
|--|--|
| 1. Donor Services:   |  |
| a) Out of state Medicaid, TRICARE, or Medi-Cal patients            |  |
| 1) Physician fees for donor nephrectomy                            | \$2,313/ nephrectomy                             |
| 2) Physician fees for anesthesiology                               | \$1,157/ nephrectomy                             |
| b) Recipient has private insurance with global case rate at center |  |
| 1) Physician fees for donor nephrectomy                            | 150% of Donor Center Medicare Participating Rate |
| 2) Physician fees for anesthesiology                               | \$71.97/ ASA Unit                                |
| c) Center to Center Billing (CCB) excludes internal 1-ways         |  |
| 1) Hospital Nephrectomy  | \$20,878/ nephrectomy                            |
| 2) Donor Workup  | \$13,703/ nephrectomy                            |
| 2. Donor Organ Packaging   | \$1,770/ shipment                                |

## 5. CENTER TO CENTER AGREEMENT

- A. **Agreement:** Donor Centers (providing donor evaluation and nephrectomy services) and Recipient Centers (performing recipient transplant services) agree to the following:
- B. **General:** In all cases, the donor shall not be billed for transplant related medical services.
- C. **Voucher Program Obligations:** All NKR MCs agree to work with each other in good faith under the leadership of the NKR Surgical Director, should the NKR ever become insolvent and/or cease operations, to facilitate living donor kidney transplants for Voucher recipients if / when they return for transplants. This obligation is irrevocable, exists in perpetuity, and survives the termination of this contract.
- D. **Regulatory Compliance:** This agreement shall serve as written evidence of the required agreement between the Donor Center and Recipient Center outlining the scope of services and the process to:
1. Review the policies and procedures related to donor evaluation, donor selection, informed consent, and multidisciplinary donor management throughout all phases of donation.
  2. Monitor and evaluate these services.
  3. Utilize the NKR standard swap checklists posted on the NKR web site to further ensure regulatory compliance.
  4. Enter swap process issues into the NKR system where appropriate.
  5. Immediately communicate to NKR if the MC is no longer in good standing.
  6. Ensure the donor Center provides the Recipient Center with copies of living donor medical records up to the point of donation.
- E. **Center to Center Billing (CCB):** The NKR shall invoice and reimburse MCs for donor evaluations and donor nephrectomies for all non-internal 1-way transplants facilitated by the NKR.
1. **Donor Evaluation Services:** Hospital pre-transplant donor evaluation costs shall be reimbursed by the Recipient Center according to the Standard Payments Section of the NKR Terms and Conditions.
    - i. Costs incurred from prospective donors who do not donate do not qualify for reimbursement through the NKR. These costs are covered, over time, by the NKR donor evaluation reimbursement which is significantly higher than the specific costs incurred for a single donor evaluation.
  2. **Hospital Donor Nephrectomy:** Hospital donor nephrectomy costs shall be reimbursed by the Recipient Center according to the Standard Payments Section of the NKR Terms and Conditions.
  3. **CCB Payments** shall be made as follows:
    - i. If a center has had no delinquent invoices (no dunning notice sent) during the prior 12-month period, then remittances will be processed in 80-110 days of NKR invoicing the services.
    - ii. If a center has had delinquent invoices (dunning notice sent) during the prior 12-month period, remittances will be processed in 140-170 days of NKR invoicing the services.
    - iii. If a center has a delinquent balance when the CCB remittance cycle is processed, CCB remittances will be delayed until the next CCB remittance cycle, at which time they will be paid if all delinquencies have been resolved.
    - iv. Centers must provide accurate ACH banking information to the NKR before CCB remittances will be paid.
- F. **Donor Physician Fees:** Donor physician fees shall be handled as follows:
1. When Medicare is primary, then the donor physicians shall bill Medicare utilizing the recipient's Medicare number.
  2. When Medicaid, TRICARE, or Medi-Cal is primary and the patient is in-state, then the donor physicians shall bill Medicaid, TRICARE, or Medi-Cal utilizing the recipient's patient number.
  3. When Medicaid, TRICARE, or Medi-Cal is primary and the patient is out of state, then NKR shall reimburse the out of state physician fees via ACH payment according to the Standard Payments section of the NKR Terms and Conditions.
    - a. In order to receive donor physician fee remittances for out of state Medicaid, TRICARE, or Medi-Cal patients, donor centers must forward the NKR swap commencement email

within 5 business days of donor surgery with ACH payment instructions to the NKR financial contact e-mail address indicated in the email.

4. When Private insurance is primary and there is a global arrangement, then the donor surgeon and anesthesiologist services shall be billed to the Recipient Center according to the Standard Payments section of the NKR Terms and Conditions.
  5. When Private insurance is primary and there is no global arrangement, then the Recipient Center shall make the necessary information available, prior to surgery, so that the donor surgeon and anesthesiologist services can be billed the Recipient's insurance directly. If the recipient center does not make the necessary information available, then the donor surgeon and anesthesiologist services shall be billed to the Recipient Center according to the Standard Payments Section of the NKR Terms and Conditions.
- G. **Recipient Inpatient Services:** The Recipient Center shall bill for services as customary by submitting claims to the recipient's insurance. The physicians shall bill the recipient's insurance for services rendered.
- H. **Donor Complications:** Donor Complications (that arise after the donor nephrectomy that are a direct result of the surgery) shall be billed as follows:
1. If Medicare is primary follow [CMS guidelines](#).
  2. If Medicare is not primary,
    - i. If there is a global arrangement then donor complications shall be billed to the Recipient Center until global end date.
    - ii. If there is no global arrangement then the Donor Center shall work with the Recipient Center for payment.
  3. MCs that have an executed [Donor Protection Addendum](#) on file with the NKR agree to pay for all Uncovered Complications (Donor Complications that are not reimbursable by the recipient insurance, recipient center or recipient) for all donors that undergo donor surgery at the MC's Hospital.
  4. MCs that do not have an executed Donor Protection Addendum on file with the NKR contribute to the [Donor Protection Reserve](#) according to the Standard Reimbursements Section. Uncovered complications documented to the NKR, by the MC, will be covered by the NKR, at the Medicare Rate, up to the amount in the Donor Protection Reserve.
  5. If Medicare is recorded as primary or secondary and the patient does not complete their enrollment in Medicare before the transplant or at the time of transplant, the recipient center shall pay for all Uncovered Complications for the donor who gave a kidney to the patient with the inaccurate financial information recorded in the NKR system.
- I. **Donor Follow Up:** Shall be the responsibility of the center that performs the donor nephrectomy.
- J. **Donor Organ Packaging:** NKR shall bill the Recipient Center for organ packaging on behalf of the OPO or MC. Funds shall be remitted to the OPO or MC twice per calendar year according to the Standard Payments section of the Terms and Conditions for Donor Organ Packaging. If the Recipient center identifies any problems with the Organ Packaging, pictures should be emailed to NKR and the problem(s) must be entered in the swap quality system. If a packaging problem is reported by the receiving center, the OPO or MC responsible for organ packaging will not be reimbursed unless an acceptable Root Cause Corrective Action Plan is provided.
- K. **Remote Donation:** Remote Donation Services provide the ability to utilize other MCs to perform an evaluation and nephrectomy at any MC. To support Remote Donation, MCs shall:
1. Provide remote donation services when requested by a donor or another MC.
  2. Complete the donor evaluation within 6 weeks of donor being transferred from the managing center to the remote center unless there is a special condition. Special conditions must be communicated to the managing center and NKR within 1 business day of confirmation of special condition.
  3. Accept the donor center's criteria and policies on donor evaluation.

## 6. BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement ("Agreement") is by and between Covered Entity ("Member Center") and the National Kidney Registry ("Business Associate"). WHEREAS, Covered Entity and Business Associate are parties to the NKR Service Contract pursuant to which Business Associate provides certain services to Covered Entity. In connection with Business Associate's services, Business Associate may receive, maintain or transmit PHI from or on behalf of Covered Entity, which information is subject to protection under the Federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Title XIII of the American Recovery and Reinvestment Act of 2009 (the "HITECH Act"), and related regulations promulgated by the Secretary ("HIPAA Regulations"). Business Associate and Covered Entity agree to the following:

### A. Definitions

1. Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR §160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).
2. Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.
3. Secretary. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his designee.
4. Security Rule. "Security Rule" shall mean the Security Standards at 45 CFR part 160 and part 164.
5. Subcontractor. "Subcontractor" shall have the same meaning as the term "subcontractor" in 45 CFR §160.103.

### B. Obligations and Activities of Business Associate

1. Use and Disclosure. Business Associate agrees to not use or disclose PHI other than as permitted or required by this Agreement or as required by law.
2. Appropriate Safeguards. Business Associate agrees to use appropriate safeguards, and comply, where applicable, with the Security Rule to prevent use or disclosure of the PHI.
3. Reporting. Business Associate agrees to promptly report to Covered Entity any use or disclosure of PHI not permitted by this Agreement.
4. Mitigation. Business Associate agrees 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 or its employees, officers, Subcontractors, or agents in violation of the requirements of this Agreement.
5. Accountings. Business Associate agrees to document and make available to the Covered Entity such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI consistent with HIPAA Regulations.
6. Compliance with HIPAA Standards. When providing its services the Business Associate shall comply with all applicable HIPAA standards and requirements with respect to the transmission of health information in electronic form in connection with any Covered Transactions.
7. Subcontractors. Business Associate agrees to ensure that any Subcontractor receiving PHI from Business Associate on behalf of Covered Entity agrees in writing to the same restrictions and conditions that apply through this Agreement to the Business Associate with the exception of Subcontractors that deliver packages where the patient name and address is required for the delivery of a package.

**C. Permitted Uses and Disclosures by Business Associate**

1. Services Agreement. 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, Covered Entity as specified in the NKR Service Contract, provided that such use or disclosure does not violate HIPAA Regulations.
2. Use for Administration of Business Associate. 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.
3. Reporting Violations of Law. Business Associate may use PHI to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR §164.502(j)(1); provided, however, that Business Associate gives Covered Entity prior written notice of its intention to report any such violation of law and the facts or circumstances related thereto.

**D. Indemnification.**

1. Business Associate agrees to indemnify, defend and hold harmless Covered Entity and its employees, trustees, members, medical staff, representatives and agents (collectively, the "Indemnitees") from and against any and all claims, obligations, actions, causes of action, suits, debts, judgments, losses, fines, penalties, damages, expenses, liabilities, lawsuits and/or costs incurred by the Indemnitees, to the extent arising or resulting from a breach of this Agreement.

**E. Miscellaneous.**

1. No Agency Relationship. It is not intended that an agency relationship be established hereby, between Covered Entity and Business Associate for purposes of liability under HIPAA, HIPAA Regulations, or the HITECH Act.
2. Regulatory References. A reference in this Agreement to a section in HIPAA, HIPAA Regulations, or the HITECH Act, means the section as in effect or as amended or modified from time to time, including any corresponding provisions of subsequent superseding laws or regulations.
3. Interpretation. Any ambiguity in this Agreement shall be resolved to permit Covered Entity and Business Associate to comply with HIPAA, HIPAA Regulations and the HITECH Act.