

# Member Center Terms & Conditions

Revised 1/18/22

## 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. "All In" MCs shall enter all Kidney Paired Donation (KPD) pairs and Good Samaritan Donors, into the NKR. KPD Pairs and Good Samaritan Donors must be 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 consider ways to overcome, if possible, such special conditions. MC shall not withhold education or access to standard NKR programs such as paired exchange, voucher, remote donation, Donor Shield, etc.
- D. 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. Requirements to become a PC include:
1. PCs shall execute the ["All In" addendum](#) and be compliant with said addendum.
  2. PCs shall be active voucher participants and shall educate all donors on the voucher option.
  3. PCs shall be active NKR Paired Exchange Program participants.
  4. PCs shall provide education and access to all standard NKR programs.
  5. PCs shall accept any waitlist patient offer (within reason) from the NKR. (e.g. donor age > 65, AB blood types, complex anatomy, etc.)
  6. PCs shall notify the NKR in writing within 15 days if there is a change in the Surgical Director of the kidney transplant program.
  7. PCs shall 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. 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.
- 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 penalized \$2,000 every month, a center with a negative 20 NCS will be penalized \$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 holder exists 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 started.
1. Example A: if the MC has 2 unredeemed Family Voucher chain starts, and an NCS score of -2, there is no MFP.
  2. Example B: if the MC has 2 unredeemed Family Voucher chain starts, and an NCS score of -4, the MFP would be \$2,000.
  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 redeems; the MFP would be \$1,000.

- F. Centers participating in the Donor Care Network (DCN) have been selected as DCN Centers of Excellence (COE) and must adhere to the [commitments](#) and offer all [programs](#) listed on the [DCN website](#). COE who are 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. COE must be approved by the NKR and the NKR reserves the right to revoke COE status at any time.
- G. 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.
- H. NKR will provide advance written notice of any material change to the Member Center Terms and Conditions.

## **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.

#### 4a. STANDARD REIMBURSEMENTS

1. Transplant Services	KFL <sup>1</sup> Internal Direct	All Other NKR Facilitated TXPs			
a) Matching <sup>2</sup>	\$796/ TXP	\$4,484/ TXP			
b) Logistics Support	\$250/ TXP	\$2,932/ TXP			
c) Research	\$25/ TXP	\$483/ TXP			
d) CT Scan	\$0/ TXP	\$342/ TXP			
e) Medicaid Out of State Physician Reimbursement	\$0/ TXP	\$256/ TXP			
f) Donor Shield <sup>3</sup>	\$995/ TXP	\$995/ TXP			
g) Microsite Support <sup>2</sup>	\$0/ TXP	\$0/ TXP			
2. Donor Shield Direct <sup>3</sup>		Quote			
3. Kidney shipping					
a) Ground shipment < 400 miles		\$2,548 per shipment			
b) Commercial air + ground shipment < 400 miles		\$2,548 per shipment			
c) Onboard courier + commercial air + ground shipment < 400 miles		\$7,300 per shipment			
d) Charter Aircraft + commercial air and/or ground shipment <400 miles		Quote			
4. Center Connectivity					
a) Within the routine MCRs <sup>2</sup>		\$325/ month			
b) Outside of the routine MCRs		\$1,000 per event			
c) Avoidable Swap Failure		\$5,000 per event			
5. Automated Donor Intake (DASH) <sup>2</sup>					
Prior Year LD Transplants	<25	25-49	50-74	75-99	>99
<i>\$1,500/ month discount for centers fully utilizing follow-up module.</i>	\$2,000/ month	\$3,000/ month	\$4,000/ month	\$5,000/ month	\$6,000/ month
6. Donor Organ Packaging					\$1,639/ shipped kidney
7. Donor Testing					
a) Pre-Evaluation Labs using Cystatin C or 24-hour urine jug					\$276/ request
b) 24 Hour Urine Jug Only					\$33/ request
8. Tissue Typing & Blood Processing					
a) Donor HLA, ABO, A2 and cryopreservation ( <i>billed to donor center</i> )					\$723/ request
b) Overnight shipment of donor cryo cells for cross matching					\$1,295/ request
c) Recipient HLA and ABO					\$681/ request
d) 'Kidney for Life' Recipient Cheek Swab HLA and ABO (within ratio)					No Cost <sup>4</sup>
e) 'Kidney for Life' Donor Cheek Swab HLA and ABO (within ratio)					No Cost <sup>4</sup>
f) 'Kidney for Life' Recipient Cheek Swab HLA and ABO (outside ratio)					\$681/ request
e) 'Kidney for Life' Donor Cheek Swab HLA and ABO (outside ratio)					\$681/ request
9. Streamlined Billing Service (SBS) <sup>5</sup>					
a) Physician fees for donor nephrectomy					\$4,390/ TXP
b) Physician fees for anesthesia					\$2,342/ TXP
c) Hospital Nephrectomy					\$21,069/ TXP
d) Donor Evaluation (Standard Tests including CT)					\$12,688/ evaluation
10. Donor Protection for centers without an executed <a href="#">Donor Protection Addendum</a>					
a) Medicare is primary or secondary					\$138/ TXP
b) Medicare is not primary or secondary					\$1,379/ TXP
11. NKR Center annual membership					
a) With Signed " <a href="#">All In</a> " Addendum					No Cost
b) No Signed " <a href="#">All In</a> " Addendum					\$20,000/ year

<sup>1</sup> Kidney For Life; includes prioritization for living donor kidney for donor

<sup>2</sup> Database Management & Technology Support (DMTS)

<sup>3</sup> Includes \$250 / DMTS & \$25 Donor Protection Contribution

<sup>4</sup> Free kit allowance: KFL centers 8:1 test to NKR TXP ratio, non-KFL centers 4:1 test to NKR TXP ratio; reconciliation period 7/1 – 6/30

<sup>5</sup> Defined section 5.L.4.ii

12. Pre-Op Testing						
a) CMV IgG		\$65/ request	l) HTLV I & II Ab			\$33/ request
b) CMV IgM		\$68/ request	m) HTLV PCR			\$448/ request
c) EBV IgM		\$28/ request	n) Syphilis/ RPR			\$47/ request
d) EBV IgG		\$28/ request	o) Strongyloides			\$190/ request
e) HBc Total Ab		\$23/ request	p) T. cruzi Ab/Chagas			\$142/ request
f) HBs Ab		\$55/ request	q) West Nile Virus NAT			\$166/ request
g) HBs Ag		\$56/ request	r) West Nile Virus WNV IGM			\$82/ request
h) HCV Ab		\$32/ request	s) Toxo IgG			\$150/ request
i) HIV 1 & 2 Ab		\$30/ request	t) CMV PCR-Quant			\$98/ request
j) HIV/HCV/HBV NAT		\$253/ request	u) EBV PCR-Quant			\$98/ request
k) HSV 1-2 PCR		\$450/ request				
13. Fulfillment						
<u>Available to</u>	<u>Application</u>	<u>Outbound fulfillment &amp; Shipping</u>	<u>Return Shipping</u>	<u>Kit</u>	<u>Home Phlebotomy Service</u>	<u>TOTAL</u>
All	Custom Draw	\$84	\$72	\$44	\$95	\$295 / request
Donor	HLA, ABO, A2, & Cryopreservation	\$84	\$72	\$44	\$95	\$295 / request
Donor	Serology	\$84	\$72	\$44	\$95	\$295 / request
Donor	Final XM	\$84	\$72	\$44	\$95	\$295 / request
Recipient	High Res HLA, ABO	\$84	\$72	\$44	\$95	\$295 / Request
Donor	Follow-Ups	TBD	TBD	TBD	\$95	\$TBD / request
14. Microsite Mailing						No Cost
15. Net Terms						Net 45

#### 4b. STANDARD PAYMENTS

1. Donor Services:	
a) Medicaid or Medi-Cal patients	
1) Physician fees for donor nephrectomy	\$2,142/ nephrectomy
2) Physician fees for anesthesiology	\$1,071/ 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	\$67.90/ ASA Unit
c) Streamlined Billing Service (SBS) <sup>5</sup>	
1) Physician fees for donor nephrectomy	\$4,390/ TXP
2) Physician fees for anesthesiology	\$2,342/ TXP
3) Hospital Nephrectomy	\$21,069/ TXP
4) Donor Evaluation (Standard Tests including CT)	\$12,688/ evaluation
2. Donor Organ Packaging	\$1,639/ shipped kidney

## 5. CENTER TO CENTER AGREEMENT

- A. **Agreement:** Donor Centers (providing donor evaluation and/or nephrectomy) and Recipient Centers (performing recipient transplant) agree to the following:
- B. **General:** In all cases the donor shall not be billed for transplant related medical services including donation evaluation, in-patient stay for donation and post donation complications per Medicare guidelines. All claims must be submitted to the Recipient Center within 120 days from the last day of service. Acknowledgement is due upon receipt of claims. Claims payment is due as soon as possible and no later than 90 days from the receipt of an accurate claim.
- 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. **Pre-Transplant Donor Evaluation Services:** Hospital pre-transplant evaluation costs as well as physician pre-transplant evaluation costs.
1. Member Centers performing pre-transplant donor evaluation services shall be reimbursed by the recipient center for both hospital and physician costs. This will be processed by the NKR according to the Standard Payments for Donor Evaluations, except when donors are evaluated at the same center as the patient receiving the kidney (Internal One-ways). Internal One-way donor evaluation costs shall become acquisition costs of that center.
  2. In a KPD exchange, once the donor is matched with a recipient, any additional tests (Documented in writing by Recipient Center to donor center) requested above and beyond the evaluation tests already performed by the Donor Center to approve that donor should be billed to the Recipient Center requesting the additional tests.
- F. **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.
- G. **Physician Donor Nephrectomy:** Physicians shall bill for the Donor Nephrectomy as follows:
1. If a MC is subject to the SBS<sup>6</sup> then the Donor Center shall be reimbursed by the Recipient Center via the NKR according to the Standard Reimbursements & Payments for the SBS line items unless these costs can be billed to Medicare under [CMS guidelines](#).
  2. If a MC is not subject to SBS and:
    - i. Medicare is primary, then the donor physicians shall bill Medicare utilizing the recipient's Medicare number.
    - ii. Medicaid or Medic-Cal is primary, then NKR shall reimburse the out of state physician fees. The reimbursement rate for the donor surgeon and anesthesiologist is listed in the Standard Payments section.

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<sup>6</sup> Streamlined Billing Service defined section 5.L.4.ii

- iii. 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 Terms and Conditions for a global arrangement.
- iv. Private insurance is primary and there is no global arrangement, then Recipient Center shall make the necessary information available prior to surgery so that the donor physicians can bill the Recipient's insurance directly. If the recipient center does not make the necessary information available, then the donor physician services shall be billed to the Recipient Center according to the Standard Payments Section of the Terms and Conditions for a global arrangement.

**H. Hospital Donor Nephrectomy:**

1. If a MC is not subject to the SBS the Donor Center shall bill the Recipient Center for the donor organ recovery cost by providing a UB-04, a copy of their most recently filed Medicare Cost Report, Worksheet D-4, Part I, which documents the cost per day and the appropriate cost to charge ratios along with a worksheet that reduces the Donor Center bill from charges to cost. ([sample worksheet](#))
2. If a MC is subject to the SBS then the Donor Center shall be reimbursed by the Recipient Center via the NKR according to the Standard Reimbursements & Payments sections for the SBS line items.

**I. 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 reimbursement.
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.

**J. Donor Follow Up:** Shall be the responsibility of the center that performs the donor nephrectomy.

**K. 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 receiving 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.

L. **NKR Center to Center Billing:** The NKR provides the ability for MCs to invoice and pay other NKR MCs through its center-to-center billing (CCB) portal. MCs utilizing CCB agree to:

1. Not decline accurate charges submitted by the donor center.
2. Make necessary remittance information available in the NKR system.
3. Use the CCB portal when a MC requests, or submits payment, through the portal or where NKR is defined as the billing agent.
4. CCB categories are described below:
  - i. **Streamlined Hospital Billing (SHB)** provides the capability for a donor center to bill a recipient center for donation services according to the Physician Donor Nephrectomy and Hospital Donor Nephrectomy sections of this document.
  - ii. **Streamlined Billing Service (SBS)** NKR will act as the billing agent for the center shipping a kidney to, and receiving a kidney from, an SBS center, or for a remote direct donation. NKR will reimburse the Donor Center for the SBS costs, once collected.
  - iii. **Universal Bill Pay (UBP)** provides the capability for a recipient center to pay a donor center through the NKR system.
  - iv. **Donor Evaluation Billing (DEB)** NKR will act as the billing agent for the donor center performing the donor evaluation as defined in the Pre-Transplant Donor Evaluation Services section of this document.
5. CCB remittances will be made per the criteria below:
  - 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 90-100 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 150-160 days of NKR invoicing the services.
  - iii. If a center has a current balance >15 days delinquent, remittances will be delayed until the center is no longer delinquent.

M. **Remote Donation:** Remote Donation Services provide the ability to utilize other MCs to perform an evaluation and / or nephrectomy for a donor whose paired recipient is registered at a different NKR MC. MCs agree to:

1. Provide remote donation services when requested by a donor or another NKR MC.
2. Evaluate and perform the nephrectomy for donors whose paired recipient is listed at a different NKR MC.
3. 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.
4. Accept the donor center's criteria and policies on donor evaluation.
5. Accept the Standard Reimbursements & Payments sections for remote donation services including evaluation and any additional services provided.

## 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.