AMENDMENT TO AGREEMENT FOR THE COMMUNITY CRISIS CENTER

by and between SEDGWICK COUNTY, KANSAS and SOUTH CENTRAL MENTAL HEALTH COUNSELING CENTER

This Amendment entered into thisCounty, Kansas ("County") and the South Cent	day of ral Mental Health	2016, by	and between Sedgwick
WITNESSETH:	tar ivientar i ream.	r Counseling Cente	i, inc. (SCIVINCE).

WHEREAS, SCMHCC is the recipient of a grant award from the Kansas Department for Aging and Disability Services ("KDADS") for a Continuum of Crisis Intervention Services; and

WHEREAS, in accordance with the KDADS grant award, SCMHCC wishes to provide a single location and comprehensive system of care for integrated assessment, triage, stabilization, engagement and referral to ongoing supports and services for those experiencing a behavior health crisis; and

WHEREAS, County warrants that, through its COMCARE Department, it is capable of providing the services hereinafter described; and

WHEREAS, the parties hereto entered into an agreement on March 2, 2016 ("Original Agreement"); and

WHEREAS, the parties now find it necessary to make amendments to the Original Agreement due to additional funding.

NOW, THEREFORE, in consideration of the mutual conditions, covenants and promises contained herein, the parties hereto do agree the Original Agreement shall be amended as follows:

- 2. <u>Term.</u> The term of this Agreement shall commence January 1, 2016, and end June 30, 2017, subject to approved grant funding from KDADS for the entire grant award period.
- 4. <u>Compensation</u>. SCMHCC agrees to pay monthly payments to COMCARE. SCMHCC agrees to pay equal monthly payments for the remainder of this Agreement. County understands and agrees that in the event the amount of funds SCMHCC receives from KDADS is less than anticipated, SCMHCC may adjust the rate to be paid hereunder. County expressly understands and agree that in no event shall the total, full and complete compensation and reimbursement, if any, paid to Contractor for performance of this Agreement exceeds the maximum amount of FIVE HUNDRED THOUSAND DOLLARS (\$500,000.00), which shall be used in accordance with the schedule as set forth in amended Appendix B, which is attached hereto and made a part hereof as if fully set forth herein.

All other terms and conditions of the Original Agreement and all amendments thereto are retained and shall remain in full force and effect and shall govern the actions and obligations of the parties unless specifically accepted or otherwise noted above.

IN WITNESS WHEREOF, County and SCMHCC have executed this Amendment as of the day and year first above written.

SEDGWICK COUNTY, KANSAS:	SOUTH CENTRAL MENTAL HEALTH COUNSELING CENTER, INC.	
James M. Howell, Chairman Commissioner, Fifth District	Dan Rice, Executive Director	
APPROVED AS TO FORM ONLY:	ATTESTED TO:	
Misha C. Jacob-Warren Assistant County Counselor	Kelly B. Arnold	

APPENDIX B BUDGET

Service provided	Amount	Date by which funds must be spent
SACK Detox Services	\$ 200,000.00	July 30, 2017
Crisis Intervention Services (CIS)	\$300,000.00	September 30, 2016
Total	\$500,000.00	

AGREEMENT FOR THE COMMUNITY CRISIS CENTER

by and between SEDGWICK COUNTY, KANSAS and SOUTH CENTRAL MENTAL HEALTH COUNSELING CENTER

This Agreement entered into this 2nd day of March 2016, by and between Sedgwick County, Kansas ("County") and the South Central Mental Health Counseling Center, Inc. ("SCMHCC").

WITNESSETH:

WHEREAS, SCMIJCC is the recipient of a grant award from the Kansas Department for Aging and Disability Services ("KDADS") for a Continuum of Crisis Intervention Services; and

WHEREAS, in accordance with the KDADS grant award, SCMHCC wishes to provide a single location and comprehensive system of care for integrated assessment, triage, stabilization, engagement and referral to ongoing supports and services for those experiencing a behavior health crisis; and

WHEREAS, County warrants that, through its COMCARE Department, it is capable of providing the services hereinafter described.

NOW, THEREFORE, in consideration of the mutual covenants, conditions and promises contained herein, the parties hereto do agree as follows:

- 1. <u>Contractual Relationship</u>. It is agreed that the legal relationship between SCMHCC and County is of a contractual nature. Both parties assert and believe that County is acting as an independent contractor in providing the services and performing the duties required by SCMHCC hereunder.
- 2. <u>Term.</u> The term of this Agreement shall be for one (1) year commencing January 1, 2016, and ending December 31, 2016, subject to approved grant funding from KDADS for the entire grant award period.
- 3. Purpose and Scope of Work. County shall do, perform and carry out in a satisfactory and proper manner the Agreement purpose, goals and objectives as set forth in Appendix Λ .
- 4. <u>Compensation</u>. SCMHCC agrees to pay monthly payments to COMCARE. SCMHCC agrees to pay equal monthly payments for the remainder of this Agreement. County understands and agrees that in the event the amount of funds SCMHCC receives from KDADS is less than anticipated, SCMHCC may adjust the rate to be paid hereunder. County expressly understands and agree that in no event shall the total, full and complete compensation and reimbursement, if any, paid to Contractor for performance of this Agreement exceeds the maximum amount of \$200,000.00.
- 5. Incorporation of Documents. Appendix A (Purpose, Goals and Objectives), Appendix B (Budget), and Appendix C (HIPAA Business Associate Addendum) are attached hereto and made a part hereof as if fully set forth herein.

IN WITNESS WHEREOF, County and SCMHCC have executed this Agreement as of the day and year first above written.

SEDGWICK COUNTY, KANSAS:

SOUTH CENTRAL MENTAL HEALTH COUNSELING CENTER, INC.

Dy R. M. Mil, LEP

Dan Rice, Executive Director

James M. Howell, Chairman Commissioner, Fifth District

APPROVED AS TO FORM ONLY:

Misha C. Jacob-Warren

Assistant County Counselor

ATTESTED TO:

Kelly B. Arnold County Clerk

APPENDIX A PURPOSE, GOALS AND OBJECTIVES

SECTION 1: PROGRAM MANAGEMENT PLAN

The CCC will be accessible to individuals living in the greater Wichita metropolitan area and its surrounding communities. The specific geographic area served by this grant will be Butler, Sedgwick and Sumner Counties. The target population includes children, adolescents and adults who are at risk of needing a higher level of care, including voluntary or involuntary local and state hospitalization or jail, due to a mental health crisis and/or a crisis related to a co-occurring substance use disorder. The target population includes those who are uninsured, under insured, or who have no known payer source.

The goal of the CCC is to successfully divert individuals not appropriate for the hospital emergency department or jail. Working closely with hospital emergency departments and law enforcement, the CCC will also reduce the strain and expense on those facilities.

SECTION 2: GENERAL PROVISIONS

- **2.1** County agrees that any services provided under this Agreement must be pre-approved by SCMHCC.
- 2.2 It is understood that County's records used in the preparation of all reports are subject to review by SCMHCC to insure the accuracy and validity of the information reported.
- 2.3 It is mutually agreed by and between County and SCMHCC that this Agreement will be evaluated by SCMHCC in terms of obtaining goals and objectives.
- 2.4 County shall provide written notice to the Director of SCMHCC if it is unable to provide the required quantity or quality of service. This written notice shall include a plan to address the issues affecting quantity and/or quality of services being provided.
- 2.5 County is required to notify SCMHCC of any critical incidents related to programming funded by this Agreement within 24 hours of the time County becomes aware of the occurrence. SCMHCC's Director of Quality Management must be notified by County as soon as possible, but no later than 24 hours after County is aware of the incident. As outlined in the MCO Provider Manual, the following incidents must be reported immediately:
 - a) Death of a consumer receiving services from County
 - b) Suicide attempt
 - c) Medication error
 - d) Any event requiring the services of the fire department or law enforcement agency beyond the scope of County's routine delivery of services
 - e) Abuse or alleged abuse involving a consumer

- f) An injury or illness (non-psychiatric) of a consumer that requires medical treatment more intensive than first aid
- g) A consumer who is out of contact with staff for more than 24 hours without prior arrangement, or a consumer who is in immediate danger because he/she is missing for any period of time
- h) Any fire, disaster, flood, earthquake, tornado, explosion, or unusual occurrence that necessitates the temporary shelter or relocation of residents
- i) Seclusion of restraint
- j) Other incidents identified by SCMHCC as critical, adverse or unusual
- 2.6 County will meet with representatives from SCMHCC on a yearly basis to discuss successes, concerns, improvements and changes to be implemented.
- 2.7 Consistent with good patient care and State of Kansas mental health licensing requirements, County and SCMHCC agree it is their mutual intent to comply with the provisions of state and federal regulations in regard to confidentiality of eligible participant records.

SECTION 3: SERVICE OUTCOMES/GOALS

- 3.1 Performance Measures and Reporting Requirements:
- 1. Performance measures for project services:
 - a) Individuals are triaged in less than 30 minutes 75 percent of the time.
 - b) Assessments and the initial stabilization treatment plan are completed within defined timeframes (not to exceed 24 hours) for 90 percent or higher of all individuals admitted.
 - c) At least 90 percent of the individuals who are discharged for crisis observation will have a documented plan for follow up services that includes utilization of community services (to include intensive case management, substance use disorder treatment, medical follow-up, mental health, peer support and other services as needed).
 - d) Through the satisfaction survey process, at least 80 percent of the individuals will report that they are satisfied with the treatment provided and that the treatment was relevant to their presenting concerns.
 - e) Less than 20 percent of clients discharged from any level of service will be readmitted to this or any other institution within seven days of discharge based on information accessible by the CMHC
- 3.2 Data collected for the following measures within the first year is the baseline:
- 1. Increased percentage of clients whose living arrangements improved, as measured by:
 - a) Number who obtained or maintained permanent housing
 - b) Number who obtained or maintained transitional housing
- Increased percentage of clients who connect to needed mental health or substance use disorder services as measured by:
 - a) Number of clients who actively participate in Recovery Oriented Systems of Care (ROSC)services
 - b) Number of clients who actively participate in mental health services
 - c) Number of clients who actively participate in substance use disorder treatment

- 3. Increased percentage of clients who access needed benefits as measured by:
 - a) Number of clients who received assistance applying for federal disability of benefits and the total number of clients who attained federal disability benefits
 - b) Number of clients who received assistance applying for state or third party benefits and total number who attained state or third party benefits
 - c) Increase in total number of clients who are assisted to secure primary medical care and the number of people who attained primary medical care
- 4. Increased total number of people who had an interest in seeking earned income and the number of people who attain earned income.

SECTION 4: MONTHLY REPORTING

- 4.1 Monthly reports are due by the 20th of the month and shall include the following:
- a) Number of people served
- b) Average time to complete initial assessments
- c) Average length of wait time for triage
- d) Average length of stay in sobering beds
- e) Average length of stay in crisis observation beds
- f) Number of people who received an alcohol and drug evaluation
- g) Number of individuals referred to social detox
- h) Number of individuals referred to Substance Use Disorder (SUD) intensive outpatient treatment and attend first session
- i) Number of individuals referred to SUD outpatient treatment and attend first appointment
- i) Number of individuals who are referred to Medication Assisted Treatment
- k) Number of individuals referred to intermediate SUD treatment and admitted
- l) Number of individuals referred to community based mental health services
- m) Number of individuals referred to short-term stabilization
- n) Number of people who complete an intake at the program(s) to which they were referred
- o) Number of people discharged with community services
- p) Percentage of individuals who report being satisfied with services provided at CCC
- q) Number of people readmitted to services within seven days of discharge
- r) Number of individuals screened and admitted to a state mental health hospital (SMHH)
- s) Number of individuals screened and not admitted to SMHH
- t) Total number of bed days needed for stabilization
- u) Total number of clients who obtained or maintained permanent housing
- v) Total number of clients who obtained or maintained transitional housing
- w) 'Total number of clients who were engaged in ROSC services
- x) Total number of clients who were engaged in mental health services
- y) Total number of clients who were engaged in substance use treatment
- z) Total number of clients who received assistance applying for federal disability benefits
- aa) Total number of clients who attained federal disability benefits
- bb) Total number of clients who received assistance applying for state or third party benefits and total number who attained state or third party benefits
- cc) Total number of clients who were assisted to secure primary medical care and the number of people who attained primary medical care

dd) Total number of people that had an interest in seeking earned income and the number of people who attained earned income

4.2.1 Performance Measure Project Services

- 1. Decrease admissions to SMIIII for Sedgwick, Butler and Sumner Counties by 30 percent by October 2016
- 2. Reduce 30-day readmission rates to SMHH by 20 percent from 2014 data
- 3. Engage peer specialist/recovery coaches with treatment/recovery plans 70 percent of the time
- 4. Have a follow up plan for at least 90 percent of individuals that includes utilization of community services (to include intensive case management, substance use disorder treatment, medical follow-up, mental health and /or other services, as needed)
- 5. Have a least 80 percent of individuals report through the satisfaction survey process that they are satisfied with the treatment provided and the treatment was relevant to their presenting concerns

4.2.2 Monthly reports will include:

- 1. Number of people served
- 2. Average length of stay
- 3. Number of people discharged with community services
- 4. Number of people discharged to SMHII
- 5. Percentage of individuals who complete satisfaction surveys
- 6. Number of people readmitted to services within seven days of discharge
- 7. Number of people engaged with peer support/recovery coach

4.3.1 Performance Measures Consumer Service Dollars/Flexible Funding

- 1. Access of all services identified and individual treatment/recovery plans by individuals within seven days 80 percent of the time
- 2. Report of satisfaction with treatment provided and the treatment was relevant to their presenting concerns

4.3.2 Monthly reports will include:

- 1. Number of individuals referred to residential SUD treatment
- 2. Number of individuals who receive medication assistance
- 3. Number of individuals who receive assistance with housing
- 4. Number of individuals who complete satisfaction surveys
- 5. Detailed budget on Flexible Funds Expenditures

APPENDIX B BUDGET

SACK Detox Services	\$ 200,000.00
	Total \$200,000.00

HIPAA RULES BUSINESS ASSOCIATE ADDENDUM

SECTION 1: DEFINITIONS

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

Specific definitions:

- (a) <u>Business Associate</u>. "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103.
- (b) <u>Covered Entity</u>. "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean Sedgwick County.
- (c) <u>111PAA Rules</u>. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

SECTION 2: OBLIGATIONS AND ACTIVITIES OF BUSINESS ASSOCIATE

Business Associate agrees to:

- 2.1 Not Use or Disclose Protected Health Information other than as permitted or required by the Agreement or as Required By Law;
- 2.2 Use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic Protected Health Information, to prevent Use or Disclosure of Protected Health Information other than as provided for by this Agreement;
- 2.3 Report to covered entity any Use or Disclosure of Protected Health Information not provided for by the Agreement of which it becomes aware, including Breaches of Unsecured Protected Health Information as required at 45 CFR 164.410, and any Security Incident of which it becomes aware, as further provided for in Par. 12.1, et seq.;
- 2.4 Mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Agreement;
- 2.5 In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any Subcontractors that create, receive, maintain, or transmit Protected Health Information on behalf of the Business Associate agree to the same restrictions, conditions, and requirements that apply to the Business Associate with respect to such information;

- 2.6 Make available Protected Health Information in a Designated Record Set to the Covered Entity as necessary to satisfy Covered Entity's obligations under 45 CFR 164.524;
- 2.7 Make any amendment(s) to Protected Health Information in a Designated Record Set as directed or agreed to by the Covered Entity pursuant to 45 CFR 164.526 or take other measures as necessary to satisfy Covered Entity's obligations under 45 CFR 164.526;
- 2.8 Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules; and
- 2.9 Maintain and make available the information required to provide an accounting of Disclosures to the Covered Entity as necessary to satisfy covered entity's obligations under 45 CFR 164.528.

SECTION 3: PERMITTED USES AND DISCLOSURES BY ASSOCIATE

Except as otherwise limited in this Agreement, Business Associate may only Use or Disclose Protected Health Information on behalf of, or to provide services to, Covered Entity for the purposes of the contractual relationship, if such Use or Disclosure of Protected Health Information would not violate the Privacy Rule if done by Covered Entity or the Minimum Necessary policies and procedures of the Covered Entity.

SECTION 4: SPECIFIC USE AND DISCLOSURE PROVISIONS

- 4.1 Except as otherwise limited in this Agreement, Business Associate may Use Protected Health Information for the proper management and administration of the Business Associate or to carry out the contractual or legal responsibilities of the Business Associate.
- 4.2 Business Associate may Use or Disclose Protected Health Information as Required By Law.
- 4.3 Business Associate agrees to make Uses and Disclosures and requests for Protected Health Information consistent with Covered Entity's Minimum Necessary policies and procedures.
- 4.4 Business Associate may Disclose Protected Health Information for the proper management and administration of Business Associate or to carry out the legal responsibilities of the Business Associate, provided the Disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and Used or further Disclosed only as Required By Law or for the purposes for which it was Disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been Breached.
- 4.5 Business Associate may provide Data Aggregation services relating to the Health Care Operations of the covered entity.
- 4.6 Business Associate may Use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with § 164.502(j)(1).

SECTION 5: OBLIGATIONS OF COVERED ENTITY

- 5.1 Covered Entity shall notify Business Associate of any limitation(s) in its Notice of Privacy Practices of Covered Entity in accordance with 45 CFR § 164.520, to the extent that such limitation may affect Business Associate's Use or Disclosure of Protected Health Information.
- 5.2 Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to Use or Disclose Protected Health Information, to the extent that such changes may affect Business Associate's Use or Disclosure of Protected Health Information.
- 5.3 Covered Entity shall notify Business Associate of any restriction to the Use or Disclosure of Protected Health Information that Covered Entity has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's Use or Disclosure of Protected Health Information.

SECTION 6: PERMISSIBLE REQUESTS BY COVERED ENTITY

Covered Entity shall not request Business Associate to Use or Disclose Protected Health Information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by Covered Entity. If necessary in order to meet the Business Associate's obligations under the Agreement, the Business Associate may Use or Disclose Protected Health Information for Data Aggregation, management and administrative activities, or contractual or legal responsibilities of Business Associate.

SECTION 7: TERM

The Agreement shall be effective as of date of execution of the Agreement by the parties, and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, has been returned to Covered Entity or, at Covered Entity's option, is destroyed, or, if it is infeasible to destroy Protected Health Information, the protections are extended to such information, in accordance with the termination provisions in this Agreement.

SECTION 8: MISCELLANEOUS

- 8.1 A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.
- 8.2 The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the HIPAA Rules.
- 8.3 Any ambiguity in this Agreement shall be resolved to permit Covered Entity to comply with the HIPAA Rules.
- 8.4 In addition to any implied indemnity or express indemnity provision in the Agreement, Business Associate agrees to indemnify, defend and hold harmless the Covered Entity, including any employees, agents, or Subcontractors against any actual and direct losses

suffered by the Indemnified Party(ies) and all liability to third parties arising out of or in connection with any breach—of this Agreement or from any negligent or wrongful acts or omissions, including failure to perform its obligations under the HIPAA Rules, by the Business Associate or its employees, directors, officers, Subcontractors, agents, or—other members of its workforce. Accordingly, upon demand, the Business Associate shall—reimburse—the Indemnified Party(ies) for any and all actual expenses (including reasonable attorney's fees) which may be imposed upon any Indemnified Party(ies) by—reason of any—suit, claim, action, proceeding or demand by any third party resulting from the Business Associate's failure to perform, Breach or other action under this Agreement.

SECTION 9: SECURITY RULE REQUIREMENTS

Business Associate agrees, to the extent any Protected Health Information created, received, maintained or transmitted by or in electronic media, also referred to as electronic protected health care information, as defined by 45 CFR § 160.103, that it will only create, maintain or transmit such information with appropriate safeguards in place.

Business Associate shall therefore: implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health care information; ensure that any agent, including Subcontractors, to whom it provides such information shall agree to also implement reasonable and appropriate safeguards to protect the information; and report to the Covered Entity any Security Incident, as that term is defined by 45 CFR § 164.304, of which it becomes aware.

SEECTION 10: TERMINATION

Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement and Business Associate has not cured the breach or ended the violation within the time specified by Covered Entity.

SECTION 11: EFFECT OF TERMINATION

Upon termination of this Agreement for any reason, Business Associate shall return to Covered Entity or, if agreed to by Covered Entity, destroy all Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. Business Associate shall retain no copies of the Protected Health Information.

Provided however, Business Associate may retain Protected Health Information if necessary for management and administration purposes or to carry out its legal responsibilities after termination of the Agreement.

Upon termination of this Agreement for any reason, Business Associate, with respect to Protected Health Information received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, shall:

retain only that Protected Health Information which is necessary for Business Associate to continue its proper management and administration or to carry out its legal responsibilities;

return to Covered Entity or, if agreed to by Covered Entity, destroy the remaining Protected Health Information that the Business Associate still maintains in any form;

continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic Protected Health Information to prevent Use or Disclosure of the Protected Health Information, other than as provided for in this Section, for as long as Business Associate retains the Protected Health Information;

not Use or Disclose the Protected Health Information retained by Business Associate other than for the purposes for which such Protected Health Information was retained and subject to the same conditions set out at in this Agreement which applied prior to termination;

return to Covered Entity or, if agreed to by Covered Entity, destroy the Protected Health Information retained by Business Associate when it is no longer needed by Business Associate for its proper management and administration or to carry out its legal responsibilities; and

provided, however, that nothing in this section 11.1 shall apply in the case of PHI remaining in its possession which Business Associate determines it is not feasible to return or destroy. Business Associate shall extend the protection of this Agreement to such PHI and limit further uses and disclosure of such PHI.

The obligations of Business Associate under this Agreement shall survive the termination of this Agreement.

SECTION 12: NOTIFICATION OF BREACH

- To the extent Business Associate accesses, maintains, retains, modifies, records, stores, 12.1 destroys, or otherwise holds, Uses, or Discloses Unsecured Protected Health Information, it shall, following the discovery of a Breach of such information, notify the Covered Entity of such Breach. Such notice shall include the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, Used, accessed, acquired, or Disclosed during such Breach. The Business Associate shall provide the Covered Entity with any other available information that the Covered Entity is required to include in notification to the Individual under 45 C.F.R. § 164.404(c) at the time of the required notification to the Covered Entity, or as promptly thereafter as the information is available.
- 12.2 For purposes of this section, a Breach shall be treated as discovered by the Business Associate as of the first day on which such Breach is known to such Business Associate (including any person, other than the Individual committing the breach, that is an employee, officer, or other agent of such associate) or should reasonably have been known to such Business Associate (or person) to have occurred by the exercise of reasonable diligence.

- 12.3 Subject to section 12.4, all notifications required under this section shall be made without unreasonable delay and in no case later than 60 calendar days after the discovery of a Breach by the Business Associate involved in the case of a notification required under section 12.2. The Business Associate involved in the case of a notification required under section 12.2, shall have the burden of demonstrating that all notifications were made as required under this part, including evidence demonstrating the necessity of any delay.
- 12.4 If a law enforcement official determines that a notification or notice required under this section would impede a criminal investigation or cause damage to national security, such notification or notice shall be delayed in the same manner as provided under section 164.528(a)(2) of title 45, Code of Federal Regulations, in the case of a Disclosure covered under such section.

If a law enforcement official states to the Business Associate that any notification or notice would impede a criminal investigation or cause damage to national security, the Business — Associate shall:

- (a) If the statement is in writing and specifies the time for which a delay is required, delay such notification or notice for the time period specified by the official; or
- (b) If the statement is made orally, document the statement, including the identity of the official making the statement, and delay the notification or notice temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in (a) is submitted during that time.

SECTION 13: PROHIBITION ON SALE OF ELECTRONIC HEALTH RECORDS OR PROTECTED HEALTH INFORMATION.

- 13.1 Except as provided in section 13.2, the Business Associate shall not directly or indirectly receive remuneration in exchange for any Protected Health Information of an Individual unless the Covered Entity has obtained from the Individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization that includes, in accordance with such section, a specification of whether the Protected Health Information can be further exchanged for remuneration by the entity receiving Protected Health Information of that Individual.
- 13.2. Section 13.1 shall not apply in the following cases:
 - (a) The purpose of the exchange is for public health activities (as described in section 164.512(b) of title 45, Code of Federal Regulations).
 - (b) The purpose of the exchange is for research (as described in sections 164.501 and 164.512(i) of title 45, Code of Federal Regulations) and the price charged reflects the costs of preparation and transmittal of the data for such purpose.
 - (c) The purpose of the exchange is for the treatment of the Individual, subject to any regulation that the Secretary may promulgate to prevent Protected Health Information from inappropriate access, Use, or Disclosure.

- (d) The purpose of the exchange is the health care operation specifically described in subparagraph (iv) of paragraph (6) of the definition of healthcare operations in section 164.501 of title 45, Code of Federal Regulations.
- (e) The purpose of the exchange is for remuneration that is provided by the Covered Entity to the Business Associate for activities involving the exchange of Protected Health Information that the Business Associate undertakes on behalf of and at the specific request of the Covered Entity pursuant to the Agreement.
- (f) The purpose of the exchange is to provide an Individual with a copy of the Individual's Protected Health Information pursuant to section 164.524 of title 45, Code of Federal Regulations.
- (g) The purpose of the exchange is otherwise determined by the Secretary in regulations to be similarly necessary and appropriate as the exceptions provided in subparagraphs (a) through (f).