Quality Improvement Organization
11th Statement of Work

MEMORANDUM OF AGREEMENT

between

KEPRO

and

_____

(Please Print Provider Name)

I. AGREEMENT

A. Parties:

The parties to this Memorandum of Agreement (herein referred to as MOA) are KEPRO (herein referred to as "KEPRO" or "QIO"), the federally designated BFCC-QIO (Quality Improvement Organization) for Areas 2, 3 and 4, and the Provider named above (herein referred to as the "Provider").

B. Statutory Specification

The Social Security Act (the Act) requires QIOs to review services furnished to Medicare beneficiaries by physicians, other health care professionals, providers and suppliers as specified in the contract with the Secretary of Health and Human Services (§1154(a)(1)).

The Act requires that a QIO conduct an appropriate review of all written complaints from beneficiaries about the quality of services not meeting professionally recognized standards of care (§1154(a)(14)).

The Act requires that each Medicare Advantage Organization, for each plan it operates, have an agreement with an independent quality review and improvement organization to perform functions of the type described in §§ 1154(a)(4)(B), 1154(a)(14) and 1852(e)(3)(A).

The Act requires QIOs to conduct a fast-track review of continuing services for Medicare beneficiaries enrolled in a Medicare Advantage plan who have been notified of their impending termination of services or discharge from a skilled nursing facility, home health agency, or comprehensive outpatient rehabilitation facility where the beneficiary makes appeal to the QIO (§1852 (f) and (g)).

The Act requires hospitals (both short-term and long-term acute care) which provide inpatient hospital services, paid under the Prospective Payment System (PPS), to maintain an agreement with a QIO to review the validity of diagnostic information provided by such hospital, the

completeness, adequacy, and quality of care provided, the appropriateness of admissions and discharges, and the appropriateness of care provided for which the hospital is seeking payment (§1866(a)(1)(F)(i)).

The Act requires hospitals, critical access hospitals (CAHs), hospices, skilled nursing facilities (SNFs), and home health agencies (HHAs) to maintain an agreement with the QIO to perform certain functions listed in §1866(a)(3)(A) and §1866(a)(1)(F)(ii).

The Act requires QIOs, under the MOA, to perform functions described under the third sentence in §1154(a)(4)(A) related to quality of services and under §1154(a)(14) related to beneficiary complaints (§1866(a)(3)(A)).

The Benefits Improvement and Protection Act (BIPA), effective July 1, 2005, requires QIOs to review continuing service provision for Medicare fee-for-service beneficiaries who have been notified of their impending termination of services or discharge from a comprehensive outpatient rehabilitation facility, home health agency, hospice, or skilled nursing facility where the beneficiary makes appeal to the QIO (P.L. 106-554, Sec. 521).

II. QIO PROGRAM

In 1982, Congress established Utilization and Quality Control Peer Review Organizations (now known as QIOs) to perform two broad functions: (a) promote quality health care services for Medicare beneficiaries, and (b) determine whether services rendered are medically necessary, appropriate, and meet professionally recognized standards of care. The Centers for Medicare & Medicaid Services (CMS) also contracts with QIOs to validate provider-coding assignments, which may affect reimbursement. The goal of the QIO program is to improve the processes and outcomes of care for Medicare beneficiaries. The QIO is to achieve this goal through performance of various directives promulgated by CMS in the QIO contract, as discussed below.

III. PURPOSE OF AGREEMENT

The purpose of this Agreement is to define the administrative relationship that will exist between parties in the exchange of data and information. This Memorandum of Agreement (MOA) is required by the Medicare statute and regulations as well as the QIO manual and certain QIO contract directives. It is also intended to be informational. KEPRO wants to inform hospitals, nursing homes (SNFs), home health agencies (HHAs), hospices, Medicare Advantage organizations and comprehensive outpatient rehabilitation facilities (CORF) of (a) KEPRO's procedures with respect to certain contract obligations, (b) review and appeal rights which providers have with respect to these obligations, and (c) opportunities providers have to collaborate with KEPRO in local and national quality improvement projects.

IV. EFFECTIVE DATE

This Agreement shall be effective for the Eleventh Statement of Work (11th SOW), beginning on August 1, 2014, and shall remain in effect until July 31, 2019, or so long as KEPRO is the BFCC-QIO, under contract with CMS, for Areas 2, 3 and 4, unless the Agreement is terminated

in accordance with Section VIII of this Agreement or the provider withdraws or is terminated from the Medicare program.

V. RESPONSIBILITIES OF PARTIES

MOAs with hospitals, home health agencies, skilled nursing facilities, critical access hospitals, hospices, comprehensive outpatient rehabilitation facilities, and other providers reflect the specific QIO review responsibilities referenced in §1866(a)(3)(A), §1154(a)(4)(A) and §1154 (a)(14) of the Act, BIPA §521 as well as the responsibilities of each provider regarding 11th SOW activities. Additional information, including relevant portions of the QIO Manual can be found at www.cms.hhs.gov.

It is understood that at a minimum, the MOA stipulates that a reasonable proportion of BFCC-QIO activities are involved in reviewing, under §1154(a)(1)(B) of the Act, the quality of services and that a reasonable allocation of these activities be made among different settings. In addition, §1154(a)(14) of the Act requires that QIOs conduct an appropriate review of written complaints from beneficiaries to determine if the quality of services provided meet professionally recognized standards of care.

In addition, KEPRO agrees that it will assume responsibility for performing the following activities described in the 11th SOW for Medicare:

A. QIO Responsibilities

The stated BFCC-QIO responsibilities in the areas below are not all-inclusive. Many of the BFCC-QIO's activities are provided in the SOW, which change with each five-year QIO/CMS contract period. KEPRO shall assume the federally mandated responsibility for performing the following activities for Title XVIII (Medicare):

1) Conduct timely mandatory case review that involves non-physician screening and physician review of medical records that require review under the SOW. Mandatory case review categories include certain Emergency Medical Treatment and Labor Act (EMTALA, a.k.a. anti-dumping violations); beneficiary complaints; hospital notices of non-coverage, important message appeals notice of discharge and Medicare appeal rights; Medicare Advantage fast-track appeals, Medicare fee-for-service expedited reviews; termination of services or discharge from a comprehensive outpatient rehabilitation facility, home health agency, hospice, or skilled nursing facility; other notices of discharge and Medicare appeal rights; hospital requested higher-weighted diagnosis related group (DRG) adjustments; potential concerns identified during project data collections; and referrals made by the Office of Inspector General (OIG), Medicare Administrative Contractor (MAC), state agency and CMS.

2) Other Review Activities including but not limited to an annual monitoring of Medicare physician attestations.

3) Provide information regarding federal regulations, transmittals, program changes and/or instructions received from CMS, which specifically pertain to the review process. Changes in this MOA will be instituted as necessary to reflect changes in federal regulations and transmittals.

4) Communication activities, consistent with the SOW, which result in providing information for education of health care providers, beneficiaries, and others to improve quality of care and to promote early detection and prevention of disease.

5) Permissible disclosures for health oversight activities in accordance with the Privacy Rule. The Privacy Rules permit a covered entity to disclose protected health information to a health oversight agency for oversight activities authorized by law, 45 CFR § 164.512(d)(1). KEPRO's oversight activities are authorized by law. *See, e.g.*, 42 USC § 1320c-5(a)(3); 42 CFR §§480.111, 480.112, 480.113. Accordingly, HIPAA permits you to disclose protected health information to the QIO.

6) In addition, the Privacy Rules require covered entities to "make reasonable efforts to limit [disclosure of] protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request" (45 CFR §164.502(b)(1)). A covered entity is entitled to rely on a request from a health oversight agency being for the minimum necessary protected health information if (a) the agency represents the request is for the minimum necessary, and (b) the request is reasonable under the circumstances (45 CFR §164.514(d)(3)(iii)(A)). You may rely on any request KEPRO makes for protected health information to be the minimum necessary for our oversight activities.

7) Offer, in accordance with §1154(a)(6)(B)(i) of the Act, to send a clinician representing the QIO to meet with medical and administrative staff of each provider of services which it reviews.

B. Provider Responsibilities

The list of Provider responsibilities in the areas below is not all-inclusive. Many of the Provider activities in the SOW change with each five-year BFCC-QIO/CMS contract period.

1) The Provider shall submit medical records and other information to the BFCC-QIO that are required for conducting off-site review, quality improvement activities and cooperative project activities, consistent with the timeframes established by CMS. Including the submission of relevant medical records, documentation, and other information to KEPRO within thirty (30) calendar days after KEPRO's written request, in order for KEPRO to conduct a retrospective review. Although providers are obligated to forward all required information within 30 calendar days of the request, there are some instances in

which providers must submit medical records within 21 calendar days. See 42 CFR §476.78(b)(2).

For immediate reviews (e.g., concurrent beneficiary complaints and circumstances in which delay would jeopardize the health or safety of a patient), KEPRO must receive the complete medical record from the Provider within one (1) working day of KEPRO's request.

For expedited Provider issued notice of non-coverage appeal reviews, the Provider must provide a copy of the generic notice of non-coverage and detailed notice and medical record information by close of business of the day KEPRO notifies the Provider of the request for an expedited determination.

2) Other requirements relating to the Provider's submission of medical records to KEPRO are:

- The entire medical record or requested portions thereof are required to be submitted for KEPRO's review;
- Any record that requires review must be copied by the Provider and forwarded to KEPRO. All copies of medical records reviewed by KEPRO will be retained by the BFCC- QIO according to federal regulations;
- When a medical record requested for case review, originating from Beneficiary Protection activity or the Health Care Quality Improvement activity, is not received from a provider within the allotted time frame, KEPRO will issue a technical denial or notice of noncompliance. See 42 CFR 476.90.
- For retrospective reviews, when KEPRO is unable to make a review determination due to any incomplete or illegible medical record, the Provider will be allowed fifteen (15) days to provide the required information. If the Provider is unable to provide the required information, a technical denial may be issued.

3) The Provider shall develop, implement and complete improvement plans to address patterns of confirmed utilization and/or quality concerns and/or case specific quality concerns.

4) The Provider will adhere to applicable federal laws, regulations and guidelines that protect the confidentiality of medical review information, as well as applicable laws and regulations.

5) The Provider may, as part of beneficiary protection projects, request technical assistance from the QIO or accept technical assistance offered by the QIO.

6) The Provider agrees to provide written notices to Medicare beneficiaries at the time of admissions and/or discharge consistent with CMS directives advising them of their rights as a patient and that the care for which payments is or may be sought will be subject to QIO review by KEPRO.

7) The Provider shall designate, on the information sheet accompanying this MOA, BFCC- QIO liaison person(s) who shall be the representative of the Provider for purposes of correspondence and communications between the Provider and KEPRO under this Agreement.

8) The person(s), serving as a liaison between the Provider and KEPRO, will be responsible for the maintenance of correspondence, the dissemination of QIO information, the coordination of responses to KEPRO inquires, and any other duties related to KEPRO's activity as deemed necessary by the Provider. KEPRO shall be notified in writing in the event a change is made in the designation of the QIO liaison staff person.

VI. CONFIDENTIALITY OF RECORDS AND OTHER DATA

Both parties will abide by the applicable federal confidentiality laws and regulations in § 1160 of the Act and 42 CFR Part 480 as well as confidentiality requirements under all other applicable federal statutes, federal regulations, and any applicable law.

None of the confidential information or any data derived from the information shared between the parties will be released by the recipient to any other organization or individual in confidential form without prior approval of the other party except as otherwise provided by law. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the parties to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security that is at least comparable to the level of security described in Office of Management and Budget (OMB) Circular No. A-130, Appendix III -- Security of Federal Automated Systems which sets forth guidelines for security plans for automated information systems in federal agencies.

The Provider will not re-disclose QIO data to other parties within the limitations set forth in 42 CFR Part 480, unless otherwise approved by KEPRO or as provided by law.

KEPRO recognizes the inherent right of the individual to privacy and at the same time acknowledges the medical profession's need for adequate information in order to carry out its activities under this Agreement.

To protect the confidentiality of data acquired by KEPRO in carrying out its responsibilities under this Agreement, KEPRO shall be bound by §1160 of the Act and applicable regulations. The "Standards for Privacy of the Individually Identifiable Health Information," otherwise known as the "HIPAA Privacy Rule" (45 CFR Parts 160 and 164), guarantees certain privacy rights to individuals. In addition, Privacy Rules provide that PHI may not be used and disclosed

without authorization of the subject of that information. Medicare participating providers are required to disclose information to the QIOs under a number of statutory and regulatory provisions, and do not have the discretion to withhold requested information on services for which payment may be made under Medicare. With respect to disclosures required by law, providers and practitioners do not need a business associate agreement with QIOs. Under the definition of business associate in Section 160.103 of the HIPAA Privacy Rule, QIOs are not business associates of the providers or practitioners because they are not performing functions for the provider or practitioner.

The HIPAA Privacy Rule permits a covered entity to disclose protected health information to a health oversight provider for oversight activities authorized by law, 45 CFR §164.512(d)(1). QIO oversight activities are authorized by law. *See, e.g.,* 42 USC § 1320-c-5(a)(3); 42 CFR §§480.111, 480.112, 480.113. Accordingly, the HIPAA Privacy Rule permits you to disclose protected health information to the QIO.

The HIPAA Privacy Rule requires covered entities to "Make reasonable efforts to limit [disclosure of] protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request," 45 CFR § 164.502(b)(1). A covered entity is entitled to rely on a request from a health oversight provider being for the minimum necessary protected health information if (a) the provider represents the request is for the minimum necessary, and (b) the request is reasonable under the circumstances, 45 CFR §164.514(d)(3)(iii)(A). You may rely on any request KEPRO makes for protected health information to be the minimum necessary for our oversight activities.

KEPRO shall ensure the confidentiality and security of the Provider medical records and data from the time the medical records/data are acquired by KEPRO until their destruction in accordance with the statute and regulations.

The Provider shall adhere to the applicable federal and State laws, which protect the confidentiality of medical review information.

VII. MODIFICATION OF AGREEMENT

This Agreement may be amended by KEPRO at any time as necessary to conform with changes or modifications to relevant state or federal laws or applicable regulations, CMS transmittals, program directives, or instructions issued pursuant to applicable laws and regulations. In the event of such an amendment, KEPRO shall provide the Provider with notice of any such new or revised laws, regulations, CMS transmittals, program directives, or instructions, etc.

VIII. TERMINATION OF AGREEMENT

This agreement may be terminated**,** upon advance written notice by one party to the other, as follows:

A. By the Provider without cause with 60-day prior written notice to KEPRO if the Provider determines that it is no longer required to be a party to this agreement as a condition of participation in the Medicare program.

B. In the event that KEPRO's status as a QIO and/or the Provider's status, as a provider qualified and eligible to receive reimbursement for services and items provided under the Medicare program, is terminated by CMS.

In the event that CMS terminates this agreement, KEPRO shall notify the Provider of termination.

C. In the event that the QIO and the Provider cannot agree to a modification to the Agreement, as discussed in Section VII.

IX. MISCELLANEOUS PROVISIONS

A. Severability:

Should any clause, portion, or section of this Agreement be unenforceable or invalid, this shall not affect the enforceability or validity of the remainder of this Agreement. Should any particular provision(s) of this Agreement be held unreasonable or unenforceable for any reason, the provisions shall be given effect and enforced to whatever extent would be reasonable and enforceable.

B. Governing Law:

To the extent procedures for resolving any dispute under this Agreement are not available through the Department of Health and Human Services, this Agreement and any disputes arising under it shall be governed by laws of the state in which your provider resides.

C. Resolution of Disputes:

If problems in the parties' relationship present themselves, or in the event a dispute arises between the parties, the parties shall attempt to resolve those differences in good faith. If a good faith dispute resolution should fail, KEPRO shall notify CMS, and CMS shall advise the parties concerning the matter in dispute.

D. Provider Notices:

The Provider shall designate an individual or individuals to serve as Liaison(s) to be contacted by KEPRO for routine inquiries and substantive issues of program relationships and developments. The Provider is responsible for notifying KEPRO in writing about any change in the person designated to receive such communications.

E. KEPRO Notices:

KEPRO shall designate an individual to act as the Provider Liaison for routine beneficiary claims-related inquiries, quality improvement initiatives and/or regarding program relationships and developments. The names of these individuals shall be furnished to the Provider in Administrative Memoranda distributed by KEPRO. Notices from the Provider in response to KEPRO notices shall be directed to the individual or department specified in KEPRO communications.

Change of Ownership:

In the event of a change of ownership, the new owners will assume all obligations in the current MOA.

X. AGREEMENT TO TERMS

The undersigned acknowledge that this Agreement is made pursuant to §1866(a)(1)(F)(i), §1866 (a)(1)(F)(ii) and §1852(e)(3)(A) of the Act, 42 CFR Part 476; the QIO Manual and certain QIO contract directives, and agree to abide by the terms and conditions set forth.

PROVIDER*		**QIO**
		KEPRO
Provider Name	*CCN Number(Formerly MPN)*	*QIO*
		5700 Lombardo Center Drive
Address		*Address*
		Suite 100
Address		*Address*
		Seven Hills, OH 44131
City, State, Zip Code		*City, State, Zip Code*
		Joseph A. Dougher
Name (Please Print)		*Name (Please Print)*
Signature		*Signature*
		President and CEO
Title		*Title*
		August 1, 2014
Date		*Date (Effective date of 11th SOW)*

***IF SIGNING FOR MULTIPLE PROVIDERS, PLEASE LIST BELOW THE PROVIDERS THAT ARE COVERED UNDER THIS MOA (ADD ADDITIONAL PAGES IF NECESSARY):**

Provider Name & Address	**CMS Certification Number (CCN)** (*formerly Medicare Provider Number [MPN]*)
1.	
2.	
3.	