SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1. CONDITIONS FOR PERFORMANCE

In addition to the performance requirements as set forth under Section C, DESCRIPTION/SPECIFICATIONS/WORK STATEMENT, the QIO is required to comply with the requirements of any revisions in legislation or regulations which may be enacted or implemented during the contract term as they are directly applicable to the performance requirements. Such requirements shall become a part of this contract effort only through the Contracting Officer's execution of a modification to the contract. The Contracting Officer shall afford the QIO an opportunity to consult and participate in negotiations which may be necessary to effect the contract modification.

H.2. EVALUATION, DETERMINATION AND PAYMENT OF AWARD FEE

CMS will evaluate QIO performance at the completion of the 28th month (on or about November 2010) to determine that amount of award fee. The QIO agrees that the amount of the award fee and the award fee methodology are unilateral decisions to be made at the sole discretion of CMS.

QIO performance shall be evaluated according to the Evaluation Criteria contained in Section C of the contract. The QIO will be periodically informed of the quality of its performance and areas in which improvements are expected.

The QIO will be promptly notified, in writing, of the determination and reasons why the award fee was or was not earned. The QIO may submit a performance self-evaluation for each evaluation period. The amount of award fee is at the sole discretion of CMS but any self-evaluation received within 30 days of the end of the evaluation period will be given such consideration, as may be deem appropriate by CMS.

The amount of award fee which can be awarded in the evaluation period is limited to the amount set forth in Contract Sections B.3 and B.4.

In the event of a contract termination, either in whole or in part, the amount of award fee available shall represent a prorate distribution associated with the evaluation period activities or events as determined by CMS.

A formal modification will be executed by CMS modifying the contract to provide for payment of the earned award fee. After contract modification, CMS will promptly make payment of any award fee upon the submission to the payment office of a public voucher or invoice in the amount of the total fee earned for the period evaluated.

H.3. PERFORMANCE EVALUATION /MONITORING

During the term of the contract, the Project Officer, in concert with the necessary GTLs and other CMS personnel, will monitor and conduct reviews of the QIO's performance.

H.4. RENEWAL OF A QIO CONTRACT

A. In-State QIO

The contract of a successful QIO that is an In-State organization, as defined in Section 1153(i) (3)of the Social Security Act (the Act), **may be renewed** for an additional three (3) year term at CMS's discretion.

> **Note:** In accordance with the Act, "…an In-State organization is an organization that has its primary place of business in the State in which review will be conducted (or, which is owned by a parent corporation the headquarters of which is located in such State)."

B. Not In-State QIO

For all QIOs that are not In-State organizations, the following shall apply:

1. Not later than six (6) months before the date on which a contract period ends with respect to an organization that is not an In-State organization, CMS shall publish in the Federal Register—

    a. The date on which the contract period ends; and

    b. The period of time in which an In-State organization may submit a proposal for the contract ending on such date.

2. If one or more qualified In-State organizations submit a proposal within the period of time specified in paragraph 1.b., above, CMS shall not automatically renew the current contract on a noncompetitive basis, but shall provide for competition for the contract in the same manner as a new contract.

3. If no qualified In-State organization submits a proposal in response to the announcement and the current "out-of-State" QIO successfully completed the expiring contract, CMS may elect to renew the current "out-of-State" QIO's contract.

H.5. NON-RENEWAL OF A QIO CONTRACT

In accordance with Section 1153(c)(4) of the Act, if CMS does not intend to renew the contract, the QIO shall be notified in writing at least ninety (90) days prior to the contract expiration date. The QIO shall be given an opportunity to

Final Notice of Termination: CMS will issue a final written notice of termination ninety (90) days prior to the effective date of termination unless a shorter period of time is agreed to by the QIO.

H.8. APPROPRIATE USE AND DISCLOSURE OF DATA

For the purposes of this contract, the different types of data and parties are defined as follows:

Data:

CMS Data: the data and/or information that CMS provides to the QIO to enable it to carry out its functions under this contract. CMS data also includes data housed by CMS that has not been released to the QIO.

QIO Data: any data or information collected, acquired or generated by a QIO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act. All information maintained by the QIO must me stored in a facility in the United States.

Parties:

Requestor: person or entity that makes a request to the QIO for de-identified data.

QIO: Quality Improvement Organization

SDPS Contractor: Iowa Foundation for Medical Care (IFMC)

A. The QIO shall collect information relevant to its functions, keep and maintain records, and permit access to and use of (including delivery of) any such information and records as the Contracting Officer may require.

B. Data and information that CMS provides to the QIO, or to any subcontractor under this contract, shall be used, duplicated or disclosed only for the purposes of the contract unless the Contracting Officer specifically permits another use in writing.

C. The QIO shall not disclose confidential information to any person, except as allowed in Section 1160 of the Act, 42 CFR 480, and Section H.8.A and H.8.D of this contract. For purposes of this contract, confidential information is defined at 42 CFR 480.101. The QIO shall refer any questions regarding the appropriate release of confidential information to the Contracting Officer.

D. The QIO shall disclose non-confidential information as required in 42 CFR 480.120 and in accordance with the procedures in 42CFR 480.

E. The QIO may have confidential quality review study information de-identified by the SDPS Contractor and release it as non-confidential if the QIO conforms to the following conditions:

1. The QIO must obtain prior written consent from its Project Officer.

2. Upon request by the QIO, the SDPS Contractor shall prepare the de-identified data set. The QIO shall not perform the de-identification. The SDPS Contractor shall provide the de-identified data set to the QIO for release to the requestor. The QIO shall execute the Agreement for Use of Health Care Data.

3. In accordance with 42 CFR 480.104(c), the QIO may charge a fee for this service which shall not exceed the amount necessary to recover the cost to the QIO and the SDPS Contractor for providing the information.

4. The SDPS Contractor may, at the request of the QIO and with the approval of the QIO's Project Officer, link the data with either CMS data or other data provided by the requestor as long as all explicit and implicit identifiers are removed from the data set.

5. The QIO shall maintain a log of all data requests under this Section of the contract. The SDPS Contractor shall maintain a copy of each data set requested.

6. The QIO shall conclude a new Data Use Agreement, prior to data release, if the same researcher requests to use the data set. The QIO shall provide its Project Officer with a copy of the signed agreement no later than ten (10) working days after signature.

7. The QIO shall ensure that the terms and conditions of the Data Use Agreement are met (e.g., data is returned or destroyed in accordance with the terms of the agreement).

F. The QIO may release to a third party, confidential quality review study information that identifies a practitioner or provider with the consent of the practitioner or provider, or at the request of the practitioner or provider.

The QIO may disclose non-confidential information in a publication, subject to the requirements of this Section. "Publication" is defined as any peer-reviewed, referenced, and/or referenced document which a QIO submits on its own behalf to a professional or trade journal and which

results from a CMS funded quality improvement activity. The definition also includes abstracts submitted for publication or for presentation at professional meetings (excluding CMS, QIO and/or American Health Quality Association sponsored meetings). "Publication" does not refer to press releases, newsletters, brochures, pamphlets or letters to the editor (with the exception of a letter to the editor that includes CMS data that has not been previously published elsewhere). If the QIO is unsure whether a document falls within the definition of "publication," the Project Officer shall make a determination.

Any manuscript that the QIO submits for publication shall meet all requirements specified in Section 1160 of the Act, 42 CFR 480, and Section 16300 of the QIO Manual. It shall also contain the required disclaimer language as set forth in the QIO Manual at Section 16320B.

The QIO shall submit all manuscripts to the Project Officer for approval prior to publication. The QIO shall follow the approval process contained in Section 16300 of the QIO Manual. Within thirty (30) days after publication, the QIO shall provide a copy of all manuscripts or abstracts, as published to its Project Officer.

The QIO shall continue to comply with the requirements of Section 1160 of the Act, regarding the prohibition against disclosure of information, and other applicable laws, and regulations after termination or non-renewal.

Upon the request of the Contracting Officer or the expiration date of this contract, whichever shall come first, the QIO shall, upon instructions from the Contracting Officer, return, destroy or retain all data given to the contractor by the Government. If the Contracting Officer directs that the data be retained by the QIO, the time period for retention will be subject to agreement by the QIO. The Contracting Officer has sole discretion to determine whether the data are to be returned, retained, or destroyed. The QIO shall retain no data, copies of data, or part thereof, in any form, when the Contracting Officer directs that the data be returned or destroyed.

H.9. GOVERNANCE REQUIREMENTS

The QIOs shall meet certain criteria for contractor governance, including governing body composition, service length and compensation, and compliance plan.

A. Acceptable Compliance Program

The QIO governing body shall develop and implement a compliance program. At a minimum, an acceptable compliance program should consist of the following:

1. Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

2. The designation of a compliance officer and a compliance committee.

3. Effective compliance training and education for the organization's employees, managers and governing body members.

4. Effective lines of communication between the compliance officer and the organization's employees.

5. Enforcement of policies, procedures and standards of conduct through well-publicized disciplinary guidelines.

6. Procedures for periodic internal monitoring and auditing.

7. Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives.

The governing body sets overall policy and direction for the QIO and retains oversight responsibility. The compliance officer handles the day-to-day operations issues that arise in the following areas: compliance, conflict of interest, ethics, program integrity and compensation and travel costs for senior executive staff and governing body members. When appropriate, the compliance officer refers issues in specific areas to the governing body. The governing body should establish a compliance committee comprised of a majority of independent members. The governing body should refer to the compliance committee for review, any concerns, issues and complaints in the above-referenced areas.

Should the QIO governing body be too small to establish, a compliance committee of the board, CMS recommends that it appoint one independent member to work with the Compliance Officer to address the concerns identified above.

present data, interpretations of data, and other information pertinent to its performance under the contract, which will be reviewed in a timely manner. The QIO will be notified of the final decision by the Contracting Officer. Any determinations of non-renewal of a QIO contract made by the Contracting Officer in accordance with Section 1153(f) shall not be subject to judicial review.

H.6. PERFORMANCE EVALUATION CRITERIA

The evaluation criteria are provided in Section C – Statement of Work. The evaluation criteria will also be published in the *Federal Register*. In accordance with 1153(e) (1) of the Act, neither the evaluation criteria nor the application of the evaluation criteria is subject to the Disputes Clause contained in this contract (FAR 52.233-1, Alt I).

H.7. TERMINATION

A. Contractor Initiated Termination

Pursuant to Section 1153(c) (5) of the Social Security Act, the QIO may terminate this contract upon 90 days written notice to the Contracting Officer.

Within five (5) working days of issuing the notice of termination, the QIO shall contact the Administrative Services Group, Division of Property and Space Management, in order to arrange for the disposal of government acquired property under the terms of the contract.

In accordance with the requirements of this contract, all financial records and supporting documents shall be retained three (3) years by a designated responsible individual of the outgoing contract. The three (3)-year period begins on the date CMS makes final payment to the outgoing QIO. If at the end of the three (3)-year period, there are any outstanding litigation claims, unsatisfied judgments or unresolved audit issues, all records shall be retained until the completion of the action.

B. Government-Initiated Termination

Notice of Intent to Terminate: Prior to making any termination under Section 1153(c) (6) of the Act, the Contracting Officer will issue a notice of intent to terminate the contract.[1] The Act defines two distinct authorities for termination: 1153(c) (6) (A) and 1153(c) (6) (B). CMS will follow the processes as stipulated in 1153(c) (6) of the Act depending upon which authority is cited as the basis for the termination.

[1] During the period after CMS has given notice of intent to terminate a contract, and prior to the time that CMS enters into a contract with another Contractor, CMS may transfer review responsibilities of the organization under the contract being terminated to another QIO, or to an FI or carrier having an agreement under Section 1816 or a contract under Section 1842 of the Act.

(**Note:** CMS has provided guidance to its fee-for-service contractors on the development and maintenance of an effective compliance program which can be found at: http://www.cms.hhs.gov/MedicareContractingReform/12_ComplianceProgramGuidance.asp#TopOfPage.)

B. Public Availability of Governing Body Information

The QIO shall make publicly available on its website (at a minimum) information regarding its governing body, including:

1. Number of members;
2. Length of appointment;
3. Cap on service;
4. When appointments are made;
5 What percentage of the governing body is typically appointed each year;
6. Names, affiliation and compensation (unless prohibited by State law) of governing body members.

C. Other Considerations

The QIO shall specify the number of members on its governing body, and shall not exceed 20 members except where appropriate justification is provided.

The QIO should adopt policies ensuring governing body membership includes representatives of a variety of healthcare settings and/or disciplines (e.g., hospitals, nursing homes, home health) as well as of non-healthcare backgrounds, so that the Board is not comprised of a majority of physicians or any other type of practitioner or profession. The QIO shall seek to include (for example) statisticians, epidemiologists, medical records managers and other health professional and information management disciplines, as well as experts from outside the health care field, on the governing body.

Section 1152 (3) of the Act requires a minimum of at least one (1) consumer representative on the QIO governing body. The QIO Manual, Section 2220, will continue to specify minimum qualification criteria for this representative, including that the individual must be a Medicare beneficiary. CMS encourages greater diversity in consumer representation, which would help the QIOs to maintain a focus on the consumer as a customer. Any governing body with more than ten (10) members should have at least two (2) consumer representatives. The second consumer representative, being a contractual requirement rather than a legislative one, need not be a Medicare beneficiary.

The QIO's governing body shall adopt policy ensuring that at least two-thirds (2/3) of the members are independent and have not been compensated by the

QIO within the last year for non-governing body services. The CEO, CFO, CMO and COO shall not receive additional compensation for governing body membership. Officers of the QIO and/or its parent entity should not comprise more than 20% of the governing body. The QIO shall adopt a cap on consecutive governing body member service time of six (6) years in order to ensure new and different perspectives. Governing bodies with 1-5 members may exempt one (1) member from the six (6) year term limit, those with 6-10 members may exempt two (2) members from the six (6) year term limit and those with eleven (11) or more may exempt three (3) members from the six (6) year term limit. No board member may exceed nine (9) consecutive years of board service. This requirement excludes ex-officio members of the board. There shall be a quorum rule of the governing body that states that no business of the governing body can be conducted unless a majority of the present and available membership consists of independent governing body members.

The duties of governing body members shall be delineated in by-laws that are reviewed annually and updated as necessary, and should include: attendance and participation in a minimum of fifty percent of board meetings; participation in an ongoing training plan (development plan) for board members that would include training in ethics, compliance, cultural awareness and other relevant topics, and; participation in sub-committees as appropriate.

The QIO shall develop and implement annual performance evaluations for the body members, including the CEO, COO and CFO, as well as an annual board self-assessment and an overall performance improvement plan.

CMS reserves the right to waive or authorize deviation of the Governance requirements on a case-by-case basis provided the waiver or deviation is in the best interest of the Government.

H.10. DIVERSITY FOR QIOs

In promoting the current federal diversity requirements of Title VI of the Civil Rights Act of 1964, QIOs are encouraged to accept and implement the following guidelines:

Recruit, retain and promote at all levels of the organization a diverse staff and leadership that are representative of the demographic characteristics of the service area.

Define diversity to include demographic variables, including, but not limited to, race, religion, color, gender, national origin, disability, age, education, geographic origin, and professional skills.

Define diversity in staff as being representative of the diverse demographic population of the service area; this includes the leadership of the organization as

well as its governing boards, clinicians, and administrative personnel. Staff refers not only to personnel employed by the organization but also its subcontracted and affiliated personnel.

While CMS acknowledges the practical difficulties in achieving full diversity, this standard emphasizes commitment and a good-faith effort rather than specific outcomes. The focus is not on numerical goals or quotas, but rather on the continuing efforts of an organization to design, implement and evaluate strategies for recruiting and retaining a diverse staff as well as continual quality evaluation of improvements in this area.

H.11. CONFLICT OF INTEREST

A. General

The QIO, and the services provided by the QIO under this contract, shall be free, to the greatest extent possible, of all conflicts of interest in accordance with Subpart 9.5 of the Federal Acquisition Regulation, "Organizational and Consultant Conflicts of Interest." As provided below, the Government will not enter into a contract with a contractor, nor continue a contract with a Contractor, that the Contracting Officer determines has, or has the potential for, an unresolved organizational conflict of interest.

B. Disclosure

QIOs must disclose all actual, apparent and potential conflicts of interest to the Contracting Officer during the term of the contract in accordance with paragraph (D) below. The QIO shall have programs in place to identify, evaluate and mitigate all actual, apparent and potential conflicts of interest that preclude, or would appear to preclude, the QIO from rendering impartial assistance or advice on work performed for this contract.

C. Conflict of interest identification

1. Definitions: As used in this subpart, the following definitions apply:

   (a) Financial relationship means--

      (1) A direct or indirect ownership or investment interest (including an option or non-vested interest) in any entity that exists through equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

      (2) A compensation arrangement with an entity.

(b) Organizational conflict of interest -- has the meaning given at FAR 2.101, as follows:

Organizational conflict of interest means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage.

(c) Provider of services -- any institution or entity that directly provides or supplies health care services or supplies for which payment may be made in whole or in part under Title XVIII of the Act.

(d) Payor organization -- any organization other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a QIO contract.

(e) Health plan -- any organization that furnishes or arranges under agreement or contracts with health care providers for the furnishing of items or services to enrollees in exchange for a premium or a fee.

For purposes of this contract, the activities and relationships described include those of the QIO itself and other business entities affiliated to it, and those of officers, directors, managers, and subcontractors.

2. Identification of conflict:

(a) The Contracting Officer shall deem that a QIO has an organizational conflict of interest, or the potential for the conflict exists, if a direct or indirect financial relationship exists with an entity that is-

(1) A Provider of services located inside of the area for which the QIO is required to perform services under the terms of this contract;

(2) A Payor organization that has a contract with the Federal government to perform services as a Medicare Carrier, Medicare Intermediary or Medicare Administrative Contractor inside of the area for which the QIO is required to perform services under the terms of this contract; and

(3) A Health plan located in the area for which the QIO is required to perform services under the terms of the contract.

(b) A financial relationship may exist either--

(1) Through the QIO's parent companies, subsidiaries, affiliates, subcontractors, or current clients; or

(2) From the activities and relationships of the officers, directors, or managers of the QIO. An officer, director, or manager has an indirect financial relationship if an ownership or investment interest is held in the name of another but provides benefits to the officer, director, or manager.

Examples of indirect financial relationships are, but are not limited to, holdings in the name of a spouse or dependent child of the officer, director, or manager and holdings of other relatives who reside with the officer, director, or manager.

(c) It shall not be deemed to be a conflict of interest as described in H.11.c.2.(a):

(1) For the QIO to have a financial relationship with a provider of services, payor organization or health plan which is located outside of the area for which the QIO is required to perform services under the terms of this contract. If the provider of services or health plan is owned or operated by a health care facility, payor organization or health plan that provides services within the area for which the QIO is required to perform services under the terms of this contract, any financial relationship with such provider of services, payor organization or health plan shall be deemed to constitute a conflict of interest unless excepted under paragraph 2 below.

(2) If the total contract value of all contracts or other arrangement between the QIO and a single entity described in H.11.c.2.(a)(1-3) do not exceed 5% of the total cost of the core QIO contract (including the costs of the Themes, but not the direct costs, the indirect costs, the fee or the value of other contracts with CMS) attributable to such area and; if the total of all such contracts or other arrangements between the QIO and all entities described in H.11.c.2.(a)(1-3) does not exceed 20% of the total cost of the core QIO contract (Value of the core Themes--C.6.1, C.6.2, and C.6.3)

attributable to such area. The calculation of the 5% and 20% amounts shall be based on the total estimated contract costs for Tasks 1 -3 over the three (3) year contract period. Other than submission of a plan as described in H.11.d.1.(b), no prior approval shall be required for contracts that do not exceed the thresholds of this subpart;

(3) For the QIO to have a financial relationship with any local or state government or any Federal government agency;

(4) For any of the QIO's employees to serve on a Board of Directors of the entity described in H.11.c.2.(a)(1-3), provided that such employee serves in an ex officio, non-voting, and uncompensated capacity, and that such employee does not have any other fiduciary duties or responsibilities to the any entity described in H.11.c.2.(a)(1-3).

(5) For the QIO to enter into any other arrangements that are approved by the Contracting Officer.

(d) Notwithstanding paragraph (c), above, and unless otherwise authorized by the terms of this contract, a conflict of interest shall be considered to exist if the QIO enters into a contract or other arrangement with a provider of services or health plan located within the QIO's area of responsibility for the performance of any service, function or activity which directly relates to such provider of services' or health plan's Medicare reimbursement. Any such arrangements shall be submitted for review and approval at least 30 days prior to the planned execution date of the agreement (deliverable 83).

(e) A conflict of interest shall be considered to exist if the QIO is affiliated with a provider of services, payor organization or health plan. The QIO shall also be deemed to be affiliated with a provider or services, payor organization or health plan if more than 20 percent of the members of the governing body of the QIO are also a governing body member, officer, partner, or five percent (5%) or more owners or managing employees in such provider of services, payor organization , or health plan and where such provider of services, payor organization or health plan is located within the QIO's area of responsibility under this contract;

(f) The Contracting Officer may determine that an Offeror or QIO has an organizational conflict of interest, or the potential for a conflict exists, based upon an apparent organizational conflict of interest.

An apparent organizational conflict of interest exists if, in the judgment of the Contracting Officer, there is cause to believe that the Offeror or QIO would have a conflict of interest in performing the requirements of a contract under this subpart. No inappropriate action by the Offeror or QIO is necessary for the Contracting Officer to determine that an apparent organizational conflict of interest exists.

The QIO shall submit a report (deliverable 82) annually on February 28, listing the agreements entered into that come under the 5 percent and 20 percent thresholds. The report shall have five (5) columns, listing:

1. Name of the entity the QIO has contracted with
2. The dollar value of the agreement, grant or contract
3. The period of performance
4. A brief description of the services to be rendered, and
5. The percent of the value of the core contract that this agreement represents.

3. Offeror's or QIO's responsibility with regard to subcontractors

A QIO is responsible for determining whether an organizational conflict of interest exists in any of its proposed or actual subcontractors at any tier and is responsible for ensuring that the subcontractors have mitigated any conflict. Documentation necessary to support its determination that its subcontractors have mitigated any conflict or potential conflict shall be submitted for review and approval at least 30 days prior to the planned execution date (deliverable 85).

D. Conflict of Interest Disclosure

1. Disclosure: The QIO shall submit, at times specified in paragraph D.2 of this section, an Organizational Conflicts of Interest Certificate (deliverable 84). The Certificate must contain the following information:

   (a) A description of all business or contractual relationships, affiliations, or activities that may be viewed by a prudent business person as a conflict of interest;

   (b) A description of the methods the QIO proposes to apply to mitigate any situations listed in the Certificate that could be identified as a conflict of interest under the terms of this contract.

   (c) A description of the QIO's program to monitor its compliance with the conflict of interest requirements of this contract and its compliance methods.

(d) Corporate and organizational structure.

(e) Financial interests in other entities, including the following:

1. Percentage of ownership in any other entity.
2. Income generated from other sources.
3. A list of current or known future contracts or arrangements, regardless of size.
4. The dollar amount of the contracts or arrangements, the type of work performed, and the period of performance.

(f) An affirmation, using language provided below, signed and dated by an official authorized to bind the QIO, as well as for the CEO, CFO and COO individually::

I, (Name and Title), certify that to the best of my knowledge and belief: 1) I am an official authorized to bind the entity; 2) the information contained in the Organizational Conflict of Interest Certificate is true and accurate as of (Date) ; and 3) I understand that the Contracting Officer may consider any deception or omission in this Certificate to be grounds for non-consideration for contract award, modification or non-renewal or termination of the current contract, and/or other contract or legal action.

The QIO shall submit an affirmation certifying the information to be true and accurate as of the date the proposal is submitted. Upon award, the QIO shall submit an updated affirmation, if necessary, certifying the information to be accurate as of the date of contract award.

(g) A QIO shall submit the following Ownership Interest information with its proposal and shall update the information by February 28th of each contract year (deliverable 88):

The name of any organization listed below in which the QIO, or the CEO, CFO or COO has an ownership interest:

1. A health care facility or association of facilities;
2. A payor organization;
3. A health plan or association of health plans;
4. A university, college or other educational institution that owns or is associated with a medical school and/or health care facility;
5. A pharmaceutical company or manufacturer;
6. A laboratory;

7. A DME supplier;
8. A provider of ambulance or medical transport services;
9. A health information technology vendor (including vendors of hardware and/or software and/or support services);
10. A corporation, partnership, joint venture or other entity comprised of, affiliated with, reimbursed by or funded by any of the above organizations; or
11. Any other entity CMS identifies for disclosure.

Separate certifications shall be submitted by the QIO, CEO, CFO and COO.

2. When disclosure is to be made

The Organizational Conflict of Interest Certificate (deliverable 81) shall be submitted—

(a) With the QIO's initial proposal, unless otherwise identified in the solicitation;

(b) When the Contracting Officer requests a revision in the Certificate;

(c) Annually on February 28; and,

(d) 45 days before any change in the information submitted in accordance with this paragraph. Only changed information needs to be submitted.

E. Conflict of Interest Resolution

1. Evaluation

The Contracting Officer evaluates organizational conflicts of interest and potential conflicts, using information, including that provided in the Organizational Conflicts of Interest Certificate, in order to promote the effective and efficient administration of the QIO Program. For each conflict identified, the Contracting Officer will evaluate the plan proposed to mitigate the conflict to determine if the mitigation plan will allow the QIO to render impartial assistance or advice to the Government.

2. Resolution

An actual or apparent conflict of interest may be resolved by the Contracting Officer by means of a determination that:

(a) The conflict has been mitigated;

(b) The conflict precludes award of a contract to the Offeror;

(c) The conflict precludes the exercise of an option to extend the term of the contract;

(d) The conflict requires that the Contracting Officer modify the contract;

(e) The conflict requires that the Contracting Officer terminate the contract; or,

(f) It is in the best interest of the Government to contract with the Offeror or QIO notwithstanding an actual or apparent conflict of interest.

3. Exception

In accordance with Section 9.503 of the FAR, the Government may waive an unresolved conflict.

F. Personnel Changes Requiring Conflict of Interest Review

Due to the nature of the QIO work within the health care industry, CMS considers changes in a QIOs Corporate Management Personnel as a condition to conduct a review of the proposed replacement individual. The review of the proposed replacement individual's resume or CV is required to determine that no organizational conflict of interest or the appearance thereof exists. Therefore, prior to engaging the services of replacement personnel for the positions of CEO, COO and, CFO the QIO shall submit an up-to-date resume or CV along with a complete list of their outside affiliations, business activities, other BOD positions, ownership interests of 5 percent or more in healthcare entities etc. to the Contracting Officer and COI Specialist for review (deliverable 86).

G. Subsidiary Start-Up

Any QIO that determines to start-up a wholly or partially owned subsidiary business shall advise CMS of its intent at least 60 days before the projected start-up date (deliverable 87). This notification shall include:

1. a description of the structure of the subsidiary,
2. the line(s) of business,
3. the physical location,
4. any support services from the parent QIO,
5. the source(s) of funding,

6. the composition of the BOD,
7. any partners in the venture, and
8. a certification that no federal funds will be used.

H.12. CMS-DIRECTED SUBCONTRACTS/SPECIAL PROJECT LEAD QIOS

A. Directed Subcontract

Each QIO is directed to enter into a subcontract or coordinate with QIOSCs and Special Project Lead QIOs for performance of the work under this contract:

CLINICAL DATA ABSTRACTION CENTER (CDAC)
STANDARD DATA PROCESSING SYSTEM (SDPS)
TELECOMMUNICATIONS (PIC-TEL) CONTRACTOR
SPECIAL PROJECT LEAD QIOS/SUPPORT QIOs (TO BE NAMED)
WESTAT

B. QIO Liability

CMS will not hold the QIO responsible for any performance problems/delays attributable to any of the above named subcontractors/Lead QIOs.

If the QIO becomes involved in a suit, action or proceeding pursuant to Section 1157(d) of the Act as a result of a subcontractor action, the QIO may seek relief from the related legal expenses it incurs as a result of the suit, action, or proceeding. To the extent that the QIO's costs are not reimbursed under Section 1157(d), the QIO may seek relief through the Disputes clause contained in this contract.

C. QIO/Subcontractor/Lead QIO Performance Disagreements

1. The QIO shall notify its Project Officer and the Contracting Officer of any performance disagreements between the QIO and the above directed subcontractors/Lead QIOs which cannot be resolved by the parties. Regardless of any performance disagreements, both parties are still contractually bound to continue performance of their contract/subcontract.

2. If a performance disagreement results in the QIO incurring a financial liability, the QIO may request financial relief from the Contracting Officer to the extent allowable under the prime contract with CMS.

H.13. SEVERANCE PAY/TERMINATION COSTS

Within sixty (60) days of the effective date of this contract, each QIO shall submit a copy of its severance plan to the Contracting Officer. The plan must be

approved, in writing, by the Contracting Officer prior to reimbursement of severance costs.

CMS will recognize normal severance costs in accordance with OMB Circular A-122 effective May 10, 2004. In the event that the QIO contract is terminated or not renewed for any reason, the QIO shall not be reimbursed for severance costs paid by the QIO to its employees. Requests for reimbursement of severance (other than normal severance) will be reviewed on a case-by-case basis by the Contracting Officer.

H.14. CHANGES IN CLINICAL SCIENCE

CMS acknowledges that clinical science may change during the course of this contract; and, as such, CMS reserves the right to drop, alter or add indicators. In this event, the contract will be modified accordingly. Any modifications to the contract will be handled in such a way as to hold the QIO harmless to any negative effects of a change in indicator.

H.15. QIO MANUAL CHANGES AND SDPS USER'S GUIDE

CMS maintains a unilateral right to make changes to the QIO Manual and the SDPS User's Guide. Changes to the QIO Manual and SDPS Users' Guide are not subject to contract modification unless such changes affect the SOW or result in a cost impact. If the QIO believes that changes to the Manual or the SDPS Users' Guide have resulted in a change to the SOW and/or a cost impact, the QIO shall immediately provide written notification to the Contracting Officer.

Ongoing changes to these documents will be provided to the QIO through Project Officer and SDPS User's Guide. It is the responsibility of the QIO to perform in accordance with all the incorporated Sections of the QIO Manual. All other portions of the QIO Manual, as updated, are reference material only.

Note: The 9th SOW contract, HHSAR, FAR and OMB A-122 Circular take precedence over any term or condition of the QIO Manual in the event the contents of the Manual conflict.

H.16. GENERAL MAILING REQUIREMENTS

The QIO shall submit all contract deliverables, reports, general correspondence...etc, through the process identified in Section F.2.0. Hard copy (non-electronic mail) contract products shall be submitted utilizing the most cost efficient method (e.g., regular mail, 1st class mail, etc.). The QIO shall not submit items such as ongoing monthly reports, annual subcontracting reports, etc., items such as these shall be submitted utilizing the most cost efficient means. QIOs will be required to demonstrate the cost reasonableness of utilizing

overnight mail for contract products other than those authorized under Section B.6.C. of the contract.

H.17. DEFINITION OF A QIO AS A LARGE BUSINESS

The Department of Health and Human Services (DHHS) has determined that all non-profit organizations are defined as large businesses for reporting purposes. A sample Subcontracting Plan is included as Section J, Attachment J-18.

H.18. HIPAA BUSINESS ASSOCIATE PROVISION

Definitions:

All terms used herein and not otherwise defined shall have the same meaning as in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA," 42 U.S.C. sec. 1320d) and the corresponding implementing regulations. Provisions governing the Contractor's duties and obligations under the Privacy Act (including data use agreements) are covered elsewhere in the contract.

"Business Associate" shall mean the Contractor.
"Covered Entity" shall mean CMS's Medicare fee-for-service program and/or Medicare's Prescription Drug Discount Care and Transitional Assistance Programs.
"Secretary" shall mean the Secretary of the Department of Health and Human Services or the Secretary's designee.

Obligations and Activities of Business Associate

(a) Business Associate agrees to not use or disclose Protected Health Information ("PHI"), as defined in 45 C.F.R. § 160.103, created or received by Business Associate from or on behalf of Covered Entity other than as permitted or required by this Contract or as required by law.

(b) Business Associate agrees to use safeguards to prevent use or disclosure of PHI created or received by Business Associate from or on behalf of Covered Entity other than as provided for by this Contract. Furthermore, Business Associate agrees to use appropriate administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the electronic protected health information ("EPHI"), as defined in 45 C.F.R. 160.103, it creates, receives, maintains or transmits on behalf of the Covered Entity to prevent use or disclosure of such EPHI.

(c) 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 in violation of the requirements of this Contract.

(d) Business Associate agrees to report to Covered Entity any use or disclosure involving PHI it receives/maintains from/on behalf of the Covered Entity that is not provided for by this Contract of which it becomes aware. Furthermore, Business Associate agrees to report to Covered Entity any security incident involving EPHI of which it becomes aware.

(e) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Contract to Business Associate with respect to such information. Furthermore, Business Associate agrees to ensure that its agents and subcontractors implement reasonable and appropriate safeguards for the PHI received from or on behalf of the Business Associate.

(f) Business Associate agrees to provide access, at the request of Covered Entity, to PHI received by Business Associate in the course of contract performance, to Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR § 164.524.

(g) Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 CFR § 164.526 upon request of Covered Entity.

(h) Business Associate agrees to make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of Covered Entity, available to Covered Entity, or to the Secretary for purposes of the Secretary determining Covered Entity's compliance with the various rules implementing the HIPAA.

(i) Business Associate agrees to document 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 in accordance with 45 CFR § 164.528.

(j) Business Associate agrees to provide to Covered Entity, or an individual identified by the Covered Entity, information collected under this Contract, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528.

Permitted Uses and Disclosures by Business Associate

Except as otherwise limited in this Contract, Business Associate may use or disclose PHI on behalf of, or to provide services to, Covered Entity for purposes of the performance of this Contract, if such use or disclosure of PHI would not violate the HIPAA Privacy or Security Rules if done by Covered Entity or the minimum necessary policies and procedures of Covered Entity.

Obligations of Covered Entity

(a) 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 PHI.

(b) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by Individual to use or disclose PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

(c) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI 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 PHI.

Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under the HIPAA Privacy or Security Rules.

Term of Provision

(a) The term of this Provision shall be effective as of the effective date of the contract, and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions in this Section.

(b) Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

(1) Provide an opportunity for Business Associate to cure the breach or end the violation consistent with the termination terms of this Contract. Covered Entity may terminate this Contract for default if the Business Associate does not cure the breach or end the violation within the time specified by Covered Entity; or

(2) Consistent with the terms of this Contract, terminate this Contract for default if Business Associate has breached a material term of this Contract and cure is not possible; or

(3) If neither termination nor cure is feasible, Covered Entity shall report the violation to the Secretary.

(c) Effect of Termination.

(1) Except as provided in paragraph (2) of this Section, upon termination of this Contract, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.

(2) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon such notice that return or destruction of PHI is infeasible, Business Associate shall extend the protections of this Contract to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

Miscellaneous

(a) A reference in this Contract to a Section in the Rules issued under HIPAA means the section as in effect or as amended.

(b) The Parties agree to take such action as is necessary to amend this Contract from time to time as is necessary for Covered Entity to comply with the requirements of the Rules issued under HIPAA.

(c) The respective rights and obligations of Business Associate under paragraph (c) of the Section entitled “term of Provision” shall survive the termination of this Contract.

(d) Any ambiguity in this Contract shall be resolved to permit Covered Entity to comply with the Rules implemented under HIPAA.

H.19. POST AWARD CONFERENCE

Upon award of contract, CMS may require that the QIO attend a Post Award Conference. Should CMS determine that a Post Award Conference is necessary; the Post Award Conference will be conducted as follows:

Within ten (10) business days after the award of the contract, the QIO shall meet with the Contracting Officer, the Project Officer(s) and other government technical personnel to thoroughly review the requirements of the contract document, contract administration procedures and invoicing requirements. QIO representatives attending the Conference shall consist of a company representative authorized to bind the company, the Program Director responsible for overall contract administration and all Key Personnel. The Conference may be held by telephone or at:

DHHS/CMS/OAGM, Division of Quality Contracts,
7500 Security Blvd., 2C-21-15
Baltimore, MD 21244

H.20. TRANSITION FROM INCUMBENT QIO TO SUCCESSOR QIO

A. General

During performance of this contract should termination or non-renewal of an existing QIO's contract occur, CMS may require the successor QIO to provide transition services beginning at the earliest mutually agreeable date. During this period, the incumbent QIO shall work with the new QIO, CMS staff, as well as other identified CMS Contractors to ensure continued operation of the QIO Program.

Prior to commencement of transition, CMS will request a transition plan from the incumbent QIO. The Transition Plan shall provide adequate coverage to ensure uninterrupted service to the QIO Program, be effectively and efficiently administered, and be completed within a reasonable timeframe.

The successor QIO shall cooperate fully with the incumbent QIO, as directed by the Project Officer, to ensure that all services continue without interruption.

B. Contract Phase-Out Services

At the end of this contract, if a determination is made to terminate or not renew the incumbent QIO's contract, the QIO shall provide similar transition/phase-in/

phase-out support to the successor QIO selected by CMS (refer to Federal Acquisition Regulation 52.237-3 Continuity of Services).

C. Transition Plan

At a minimum, the Transition Plan shall provide detailed methods that will be used to ensure a smooth transition from the incumbent QIO's operation to sole operation by the successor QIO. At a minimum, the Transition Plan shall provide for the following:

A milestone chart detailing the time lines and stages of transition from the effective date of contract performance until the QIO assumes sole responsibility for the QIO Program work;

An organizational chart that displays internal and external organizational relationships. The organizational chart shall identify the individuals (at all levels) who will be responsible for the transition and their respective roles; detail the lines of communication and how the QIO will interface with CMS during this phase of contract performance;

Plans to communicate and cooperate with the current incumbent QIO; Transition services will include transfer of Government-Furnished Property (GFP) (e.g., hardware, software, records/data) from the incumbent QIO to the successor QIO, or to CMS or another CMS Contractor. CMS may elect to require the transition of GFP as follows:

a. Prior to procurement of an asset, the QIO shall propose a transition charge to be evaluated and negotiated by the CMS.

b. A successor QIO to this contract, or CMS, will be afforded the opportunity to acquire QIO assets at a reasonable transition charge. Alll existing assets shall remain installed and usable by CMS through the transition of assets for their replacement by the successor QIO. In the event a decision is made not to procure the assets, the QIO has the responsibility to dispose of the assets as instructed by CMS.

H.21. SECTION 508 ACCESSIBILITY OF ELECTRONIC AND INFORMATION TECHNOLOGY (EIT) TO FEDERAL EMPLOYEES AND THE GENERAL PUBLIC WITH DISABILITIES

QIOs are informed that this contract is subject to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by the Workforce Investment Act of 1998 (P.L. 105-220).

Subsection 508(a)(1) requires that when the Federal Government procures EIT, the EIT must allow Federal employees and individuals of the public with disabilities comparable access to and use of information and data that is provided to Federal employees and individual of the public without disabilities.