

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PROVIDENCE HEALTH & SERVICES-WASHINGTON**

I. PREAMBLE

Providence Health & Services-Washington (Providence) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Providence is entering into a Settlement Agreement with the United States.

Prior to the Effective Date as defined below, Providence represents that it established compliance, quality assurance, and performance improvement programs that include the following elements: a Compliance Officer, Regional Compliance Directors and Hospital Compliance Leads, a Compliance Committee, written compliance standards and policies, a Risk Assessment and Internal Review Process, a Disclosure Program that includes a process for anonymous disclosure and emphasizes non-retaliation and non-retribution, a screening process and policy regarding ineligible persons, a process for identifying and addressing Overpayments, a Chief Quality Officer, regional quality officers, a Quality Division, a Quality Operations Committee, and Patient Safety, Quality Assessment, Performance Improvement, and Patient Safety programs (collectively “Compliance, Quality and Patient Safety Program”). Providence may modify its Compliance, Quality and Patient Safety Program as appropriate. However, at a minimum, Providence shall ensure that during the term of this CIA, it shall maintain a Compliance, Quality and Patient Safety Program in accordance with the obligations set forth in the CIA.

II. TERM AND SCOPE OF THE CIA

A. The Effective Date of this CIA shall be the date on which the final signatory of the CIA executes this CIA. The term of this CIA shall be five years from the Effective Date. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. This CIA applies to any hospital in which Providence has an ownership or control interest, as defined in 42 U.S.C. § 1320a -3(a)(3), and any hospital that Providence manages or operates (“Providence Hospital(s)”).

C. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Providence’s final Annual Report; or (2) any additional materials submitted by Providence pursuant to OIG’s request, whichever is later.

D. For purposes of this CIA, the term “Covered Persons” includes:

1. all owners, officers, directors of Providence, and any employees of Providence who have oversight of Providence Hospitals;
2. all owners, officers, directors, and employees of Providence Hospitals;
3. All contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Providence Hospitals excluding vendors whose sole connection with Providence Hospitals is selling or otherwise providing medical supplies or equipment to Providence Hospitals; and
4. All physicians and other non-physician practitioners who are members of Providence Hospitals’ active medical staffs.

III. COMPLIANCE PROGRAM REQUIREMENTS

Providence shall establish and maintain a compliance program that includes the following elements:

A. Compliance Management and Oversight

1. *Compliance Officer.* Within 90 days after the Effective Date, Providence shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer must have sufficient compliance and quality assurance experience to effectively oversee the implementation of the requirements of this CIA. The Compliance Officer shall be an employee and a member of senior management of Providence, shall report directly to the Chief Executive Officer of Providence, and shall not be or be subordinate to the General Counsel, Chief Financial Officer, or Chief Operating Officer, or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Providence. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters in person to the Board of Directors of Providence (Board), or the Board CIA Committee, and shall be authorized to report on such matters to the Board or Board CIA Committee at any time. Written documentation of the Compliance Officer's reports to the Board or Board CIA Committee shall be made available to OIG upon request; and
- c. Monitoring the day-to-day compliance activities engaged in by Providence and any reporting requirements created under this CIA, and ensuring that Providence is appropriately identifying and correcting quality of care problems.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Providence shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the requirements in this CIA, within five business days after such a change.

2. *Regional Compliance Directors and Hospital Compliance Leads.* Providence shall appoint and maintain during the term of the CIA individuals to serve as Regional Compliance Directors as well as Hospital Compliance Leads. The Regional Compliance Directors shall be responsible for implementing policies, procedures, and practices designed to ensure compliance with requirements set forth in this CIA and with Federal health care program requirements for the applicable regional office, and shall monitor the day-to-day compliance activities of the applicable regional office. Each Hospital Compliance Lead shall be responsible for implementing policies, procedures, and practices designed to ensure compliance with requirements set forth in this CIA and with Federal health care program requirements for the applicable hospital, and shall monitor the day-to-day compliance activities of the applicable hospital. The Regional Compliance Directors shall be members of the Compliance Department and shall be independent from Providence's Legal Department. The Hospital Compliance Leads shall report to the assigned Regional Compliance Directors for ethics and compliance purposes, and shall be independent from Providence's Legal Department.

Providence shall report to OIG, in writing, any changes in the identity of the Regional Compliance Directors or Hospital Compliance Leads, or any actions or changes that would affect the Regional Compliance Directors' or Hospital Compliance Leads' ability to perform the duties necessary to meet the requirements in this CIA, within five business days after such a change.

3. *Chief Quality Officer.* Within 90 days of the Effective Date, Providence will appoint a Covered Person to serve as its Chief Quality Officer. Providence shall maintain, during the term of the CIA, a Covered Person to serve as its Chief Quality Officer. The Chief Quality Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with professionally recognized standards of care and patient safety. The Chief Quality Officer shall be a member of senior management of

Providence, shall report directly to the Chief Executive Officer of Providence, shall make periodic (at least quarterly) reports regarding quality assurance matters directly to the Board or Board CIA Committee and shall be authorized to report on such matters to the Board or Board CIA Committee, at any time. The Chief Quality Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Chief Quality Officer shall be responsible for monitoring the day to day quality of care and patient safety activities engaged in by Providence.

Any non-quality assurance job responsibilities of the Chief Quality Officer shall be limited and must not interfere with the Chief Quality Officer's ability to perform the activity outlined in this CIA. The Chief Quality Officer shall have sufficient clinical quality assurance experience to perform the responsibilities described in this paragraph.

Providence shall report to OIG, in writing, any change in the identity of the Chief Quality Officer, or any actions or changes that would affect the Chief Quality Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five business days after such a change.

4. *Clinical Quality Department.* Providence shall maintain a Clinical Quality Department comprised of the Chief Quality Officer, and other clinical quality staff. The Chief Quality Officer will have responsibility for the Clinical Quality Department. The Clinical Quality Department is responsible for monitoring: 1) clinical quality at Providence, 2) the Quality of Care and Patient Safety Program, 3) physician credentialing, privileging, and peer review programs, 4) evidence-based medicine programs, 5) standards of clinical excellence, 6) utilization management and review, and 7) other quality performance standards.

5. *Quality of Care and Patient Safety Program.* The Clinical Quality Department shall ensure that, within 90 days after the Effective Date, Providence establishes and implements a program for performing internal quality audits and reviews (hereinafter "Quality of Care and Patient Safety Program"). The Quality of Care and Patient Safety Program shall make findings as to:

- a. Whether the patients at Providence are receiving the quality of care consistent with professionally recognized standards of care and any other applicable Federal and State statutes, regulations, and directives;
- b. whether Providence is effectively reviewing quality of

care and patient safety related complaints and/or incidents and completing root cause analyses; and

- c. whether Providence's action plans in response to identified quality of care and patient safety problems are appropriate, timely, implemented, and enforced.

6. *Compliance Committee.* Within 90 days after the Effective Date, Providence shall appoint a Compliance Committee.

- a. *General Responsibilities.* The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., representatives from among senior personnel responsible for clinical operations and quality of care, human resources, operations, including the corporate Medical Director). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her/their responsibilities (e.g., developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care; monitoring the day-to-day compliance activities engaged in by Providence; monitoring any reporting requirements created under this CIA; and ensuring that Providence is appropriately identifying and correcting quality of care problems).

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, Providence Chief Quality Officer or their designee shall report to the Compliance Committee on the adequacy of care being provided by Providence. The minutes of the Compliance Committee meetings shall be made available to the OIG upon request.

Providence shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the requirements in this CIA, within 15 business days after such a change.

7. *Board Oversight.* The Board or Board CIA Committee, shall be responsible for the review and oversight of matters related to compliance with the requirements of this CIA, Federal health care program requirements, and professionally recognized standards of care. The Board or Board CIA Committee must include independent (i.e., non-employee and non-executive) members. The Board or Board CIA Committee shall be readily available to the Compliance Officer to respond to any issues or questions that might arise.

The Board or Board CIA Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Providence's Compliance Program, including, but not limited to, the performance of the Compliance Officer and the Compliance Committee;
- b. reviewing and overseeing Providence's Quality Program, including but not limited to the performance of the Chief Quality Officer and the Clinical Quality Department;
- c. ensuring that Providence adopts and implements policies, procedures, and practices designed to ensure compliance with:
 - i. the requirements set forth in this CIA and Federal health care program requirements
 - ii. professionally recognized standards of care and patient safety;
 - iii. credentialing, privileging, and peer review requirements.

- d. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board or Board CIA Committee summarizing its review and oversight of Providence's compliance with the requirements of this CIA, Federal health care program requirements, professionally recognized standards of care and patient safety, and credentialing, privileging, and peer review requirements.

At a minimum, the resolution shall include the following language:

“The Board [or Board CIA Committee] has made a reasonable inquiry into the operations of Providence's Compliance Program, including the performance of the Compliance Officer, Regional Compliance Directors , the Compliance Committee, the Chief Quality Officer, and the Quality of Care and Patient Safety Program. The Board [or Board CIA Committee] has also provided oversight on professionally recognized standards of care, patient safety, credentialing, privileging, and peer review issues. Based on its inquiry and review, the Board [or Board CIA Committee] has concluded that, to the best of its knowledge, Providence has implemented effective Compliance, Quality of Care, and Patient Safety Programs to meet the requirements of the CIA, Federal health care program requirements, and professionally recognized standards of care and patient safety.”

If the Board or Board CIA Committee is unable to provide such a conclusion in the resolution, the Board or Board CIA Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement effective Compliance, Quality of Care, and Patient Safety Program at Providence.

Providence shall report to OIG, in writing, any changes in the composition of the Board or Board CIA Committee, or any actions or changes that would affect the Board or Board CIA Committee's ability to perform the duties necessary to meet the requirements in this CIA, within 15 business days after such a change.

8. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Providence employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Providence department is in compliance with applicable Federal health care program requirements, with the requirements of this CIA, and with professionally recognized standards of healthcare and patient safety. These Certifying Employees shall include, at a minimum, the following: Providence's Chief Executive Officer, Chief Medical Officers, and Chief Nursing Officers. For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, requirements of the Corporate Integrity Agreement, and Providence policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Providence is in compliance with all applicable Federal health care program requirements, the requirements of the Corporate Integrity Agreement, and all professionally recognized standards of care and patient safety. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he/she/they is/are unable to provide the certification outlined above.

Within 90 days after the Effective Date, Providence shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

Within 90 days after the Effective Date, Providence shall develop and implement Policies and Procedures regarding the operation of Providence's Compliance Program, Clinical Quality Department, and Quality of Care and Patient Safety Program, including the compliance program requirements outlined

in this CIA and Providence's compliance with Federal health care program requirements and professionally recognized standards of care and patient safety. Throughout the term of this CIA, Provider shall enforce its Policies and Procedures and shall make compliance with them an element of evaluating the performance of all employees.

1. *Clinical Quality Standards.* Providence's Policies and Procedures shall also be designed to promote the delivery of patient care items or services at Providence that meet professionally recognized standards of care and patient safety, and that are reasonable and appropriate to the needs of Federal health care program beneficiaries. These Policies and Procedures shall include the following:

- a. ensuring the appropriate documentation of medical records;
- b. measuring, analyzing, and tracking quality indicators, including adverse patient events, and other aspects of performance that relate to processes of care, hospital services, and operations, and to identify opportunities for improvement and changes that will lead to improvement;
- c. setting priorities for performance improvement activities that: (1) focus on high risk, high-volume, or problem-prone areas; (2) consider the incidence, prevalence, and severity of problems in those areas; and (3) affect health outcomes, patient safety, and quality of care;
- d. tracking medical errors and adverse patient events, analyzing their causes, and implementing preventive actions and mechanism that include feedback and learning throughout Providence;
- e. conducting quality assessment and performance improvement projects, including periodic clinical quality audits;

- f. periodically reporting quality assessment and performance improvement data to the Quality of Care and Patient Safety Program;
- g. collecting, verifying, and assessing current licensure, education, relevant training, experience, ability, and current competence to perform requested privileges;
- h. monitoring practitioners with current privileges by the review of clinical practice patterns, ongoing case review, proctoring, and discussion with other individuals involved in the care of patients;
- i. implementing and monitoring medical staff peer review; and
- j. implementing effective responses when clinical quality problems are discovered.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

Within 90 days after the Effective Date, Providence shall develop a written plan (Training Plan) that outlines the steps that Providence will take to ensure that all Covered Persons receive the following training.

- 1. *Covered Persons Training.* Covered Persons shall receive:
 - a. at least annual training regarding Providence's CIA requirements and Compliance Program, and
 - b. adequate on-going training regarding:
 - i. policies, procedures, and other requirements applicable to the documentation of medical records;

- ii. the policies implemented pursuant to Section III.B of this CIA, as appropriate for the job category of each Covered Person;
- iii. policies, procedures, and other requirements relating to clinical quality, including but not limited to comprehensive clinical audits, physician credentialing, privileging, and peer review programs, evidence based medicine programs, standards of clinical excellence, utilization management and review, and clinical quality measures;
- iv. the personal obligation of each individual to ensure that care is appropriate and meets professionally recognized standards of care; and
- v. the reporting requirements and legal sanctions for violations of the Federal health care program requirements.

The Training Plan shall also include training to address quality of care problems identified by the Compliance Committee and Quality of Care and Patient Safety Program. In determining what training should be performed, the Compliance Officer, Chief Quality Officer, and Compliance Committee shall review the complaints received, and the findings, reports, and recommendations of the Quality Review Organization required under Section III.D of this CIA.

Training required in this section shall be competency-based. Specifically, the training must be developed and provided in such a way as to focus on Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Covered Person has learned as a result of the training.

2. *Board Training.* In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board or Board CIA Committee, shall receive training regarding the corporate governance responsibilities of board members, and the responsibilities of board

members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board or Board CIA Committee, and should include a discussion of the OIG's guidance on board member responsibilities.

New members of the Board or Board CIA Committee shall receive the Board training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* Providence shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. Review Procedures

Within 90 days after the Effective Date, Providence shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in Section III.D.1. The applicable requirements relating to the IRO(s) are outlined in Appendix A to this CIA. Within 90 days of the Effective Date, Providence shall also retain an entity, selected by OIG after consultation with Providence, (hereinafter "Quality Review Organization" or "QRO"), to perform the review listed in Section III.D.2. The applicable requirements relating to the QRO are outlined in Appendix C to this CIA.

1. *Claims Review.* The IRO shall review Providence's coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA.

2. *Clinical Quality Systems Review.* The QRO shall assess the effectiveness, reliability, and thoroughness of Providence's quality of care and patient safety, credentialing, privileging, and peer review processes, as outlined in Appendix D to this CIA.

3. *Retention of Records.* The IRO, QRO, and Providence shall retain and make available to OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports (those exchanged between the IRO and QRO and Providence) related to the reviews.

E. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Providence shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Providence's participation in the Federal health care programs, including but not limited to the risks associated with standards of care and the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require Providence to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Providence shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

Within 90 days after the Effective Date, Providence shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Providence's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Providence shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Providence's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated

by Providence. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he/she/they has/have obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Providence shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practice places patients at risk of harm, then Providence will ensure that the practice ceases immediately and that appropriate action is taken.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record all disclosures, whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs, in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* Providence shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Providence shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, or medical staff credentialing process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Providence shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. Providence shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Providence’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Providence understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Providence may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Providence meets the requirements of Section III.G.

3. *Removal Requirement.* If Providence has actual notice that a Covered Person has become an Ineligible Person, Providence shall remove such Covered Person from responsibility for, or involvement with, Providence’s business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person’s compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part,

directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Providence has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Providence shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Providence shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Providence conducted or brought by a governmental entity or its agents involving an allegation that Providence has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Providence also shall provide written notice to OIG within 30 days after the resolution of the matter, and a description of the findings and/or results of the investigation or proceeding, if any.

In addition, within 15 days after notification, Providence shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., Joint Commission) relating to quality of care issues.

I. Overpayments

1. *Definition of Overpayment.* An "Overpayment" means any funds that Providence receives or retains under any Federal health care program to which Providence, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Providence shall develop and implement written policies and

procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with, or having as a member of the active medical staff, a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Providence.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Providence determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Providence shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a and III.J.1.b.* For Reportable Events under Section III.J.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of individuals and

entities believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Providence to identify and quantify any Overpayments; and
- e. a description of Providence's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Providence shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable CMS guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship or medical staff membership;
- c. a description of the Exclusion List screening that Providence completed before and/or during the Ineligible Person's employment, contract, or medical staff membership, and any flaw or breakdown in the screening process that led to the hiring or contracting with or credentialing the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and

- e. a description of any corrective action implemented to prevent future employment or contracting with, or credentialing, an Ineligible Person.

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include:

- a. a complete description of the Reportable Event;
- b. a description of Providence's action taken to ensure that the Reportable Event does not adversely impact patient care;
- c. any further steps Providence plans to take to address the Reportable Event;
- d. if the Reportable Event involves the filing of a bankruptcy petition, documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated; and
- e. if the Reportable Event involves the appointment of a receiver, documentation regarding the receivership, including, but not limited to, the identification and contact information of the receiver.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Providence to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Providence identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Providence is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Providence proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items

or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Providence shall give notice of such sale or purchase to OIG at least 30 days prior to the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Providence wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Providence must notify OIG in writing of the proposed sale or purchase and include the following information at least 30 days in advance: a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 120 days after the Effective Date, Providence shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, the Regional Compliance Directors required by Section III.A.2, and the Chief Quality Officer as required by Section III.A.3, and a summary of other noncompliance job responsibilities those individuals may have;
2. a description of the Clinical Quality Department required by Section III.A.4;
3. a description of the Quality of Care and Patient Safety Program required by Section III.A.5;

4. the names and positions of the members of the Compliance Committee required by Section III.A.6;
5. the names of the Board or Board CIA Committee members who are responsible for satisfying the Board compliance requirements described in Section III.A.7;
6. the names and positions of the Certifying Employees required by Section III.A.8 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.8;
7. a list of all Policies and Procedures required by Section III.B;
8. the Training Plan required by Section III.C and a description of the Board training required by Section III.C.3 (including a summary of the topics covered, the length of the training, and when the training was provided);
9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Providence that includes a summary of all current and prior engagements between Providence and the IRO.
10. a description of the risk assessment and internal review process required by Section III.E;
11. a description of the Disclosure Program required by Section III.F;
12. a description of the Ineligible Persons screening and removal process required by Section III.G;
13. copy of Providence's policies and procedures regarding the identification, quantification, and repayment of Overpayments required by Section III.I;
14. a description of Providence's corporate structure, including identification of any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business;

15. a listing of all Providence Hospital locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and

16. the certifications required by Section V.C.

B. Annual Reports. Providence shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer, Regional Compliance Directors, Chief Quality Officer, and a current list of the Compliance Committee members, a current list of the Board or Board CIA Committee members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Clinical Quality Department, Quality of Care and Patient Safety Program, Board or Board CIA Committee, and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.8;

3. the dates of each report made by the Compliance Officer and Chief Quality Officer to the Board or Board CIA Committee (written documentation of such reports shall be made available to OIG upon request);

4. a summary of activities and findings under Providence's Clinical Quality Department and a summary of any corrective action taken in response to any problems identified through its Quality of Care and Patient Safety Program as required by Section III.A.5;

5. a summary of the Compliance Committee’s measurement, analysis, and tracking of the performance, Providence’s progress towards its quality improvement goals, and activities, assessments, recommendations, and findings related to quality and patient safety and Providence’s response to those findings;
6. the Board or Board CIA Committee resolution required by Section III.A.7 and a description of the documents and other materials reviewed by the Board or Board CIA Committee, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
7. a list of any new or revised Policies and Procedures developed during the Reporting Period;
8. a description of any changes to Providence’s Training Plan developed pursuant to Section III.C and summary of any Board training provided during the Reporting Period;
9. a complete copy of all reports prepared pursuant to Section III.D and Providence’s response to the reports, along with corrective action plan(s) related to any issues raised by the reports, including Providence’s determination of whether the CMS overpayment rule requires the repayment of an extrapolated Overpayment (as defined in Appendix B);
10. a certification from the IRO regarding its professional independence and objectivity with respect to Providence, including a summary of all current and prior engagements between Providence and the IRO;
11. Providence’s response and action plan(s) related to any written recommendations of the QRO pursuant to Section III.D;
12. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons for such changes;
13. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal

audit reports, and corrective action plans shall be made available to OIG upon request;

14. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs and the delivery of patient care, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

16. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

17. a description of any changes to the Overpayment policies and procedures required by Section III.I, including the reasons for such changes;

18. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

19. a description of all changes to the most recently provided list of Providence Hospital locations as required by Section V.A.15;

20. a description of any changes to Providence's corporate structure, including any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business; and

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, Providence shall include the certifications of Certifying Employees as required by Section III.A.8;

2. *Compliance Officer, Chief Quality Officer, and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer, Chief Quality Officer, and Chief Executive Officer that:

- a. to the best of his/her/their knowledge, except as otherwise described in the report, Providence has implemented and is in compliance with all of the requirements of this CIA;
- b. he/she/they has/have reviewed the report and has/have made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he/she/they understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information. Providence shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Providence shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies
Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Providence:

Sharon Cockrum
Executive Director, Compliance
Providence Health & Services - Washington
1801 Lind Avenue SW
Renton, Washington 98057
Telephone: 360.726.9907
Email Address: Sharon.cockrum@providence.org

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Providence may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or to copy Providence's books, records, and other documents and supporting materials and conduct on-site reviews of any of

Providence's locations for the purpose of verifying and evaluating: (a) Providence's compliance with the terms of this CIA; and (b) Providence's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Providence to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Providence's owners, employees, contractors, and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Providence shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Providence's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Providence present.

VIII. DOCUMENT AND RECORD RETENTION

Providence shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Providence prior to any release by OIG of information submitted by Providence pursuant to its requirements under this CIA and identified upon submission by Providence as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Providence shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Specific Performance. The parties agree that, if OIG determines that Providence is failing to comply with a provision of this CIA, OIG may seek specific performance of that provision. OIG shall provide Providence with prompt written notification of such determination. (This notification shall be referred to as the "Noncompliance Notice.") Within 30 days after the date of the

Noncompliance Notice, Providence shall either: (1) come into compliance; or (2) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the provisions set for in Section X.F of this CIA.

B. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.F;

7. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.G;

8. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.H;

9. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.I;

10. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section III.J;

11. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section IV;

12. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section V;

13. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section VII;

14. A Stipulated Penalty of up to \$2,500 for each day Providence fails to comply with Section VIII; or

15. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of Providence under this CIA.

C. Timely Written Requests for Extensions. Providence may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. If OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Providence fails to meet the revised deadline set by OIG. If OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Providence receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five

business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

D. Payment of Stipulated Penalties

1. *Demand Letter.* If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Providence of: (a) Providence's failure to comply; and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Providence shall either: (a) pay the applicable Stipulated Penalties or (b) request a hearing before an ALJ to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.F.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

E. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.D;
- b. failure to comply with Section III.A.1;
- c. failure to comply with Section III.D;
- d. failure to comply with Section III.J;
- e. failure to comply with Section V;
- f. a failure to respond to a Noncompliance Notice in accordance with Section X.A;

- g. a failure to respond to a Demand Letter in accordance with Section X.D;
- h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Providence to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties pursuant to the deadlines listed in Section X.F.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Providence constitutes an independent basis for Providence's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that Providence has materially breached this CIA, OIG shall notify Providence of: (a) Providence's material breach; and (b) OIG's intent to exclude Providence. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.") The exclusion may be directed at one or more of Providence's facilities or corporate entities, depending upon the facts of the breach.

3. *Response to Notice.* Providence shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter.* If OIG determines that exclusion is warranted, OIG shall notify Providence in writing of its determination to exclude Providence. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.F, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect. The effect of the exclusion shall be that no Federal health care program payment may be made for items or services furnished, ordered, or

prescribed by Providence, including administrative and management services, except as stated in regulations found at 42 C.F.R. § 1001.1901(c). Reinstatement to program participation is not automatic. At the end of the period of exclusion, Providence may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

F. Dispute Resolution

1. *Review Rights.* Upon OIG's issuing a Noncompliance Notice, Demand Letter, or Exclusion Letter to Providence, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Providence shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand specific performance, payment of Stipulated Penalties, or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005.2: (a) the request for a hearing involving specific performance or Stipulated Penalties shall be made within 15 business days after the date of Noncompliance Notice or the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at

<http://www.hhs.gov/dab/division/civil/procedures/divisionprocedures.html>.

2. *Specific Performance Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for specific performance of CIA requirements shall be whether Providence is full compliance with the requirements of this CIA for which OIG seeks specific performance. Providence shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Providence was not in compliance with this CIA and orders Providence to come into compliance, Providence must take the actions OIG deems necessary to come into compliance within 20 days after the ALJ issues such a decision, unless Providence properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is timely and properly appealed to the DAB and the DAB upholds the determination of OIG, Providence must take the

actions OIG deems necessary to come into compliance within 20 days after the DAB issues its decision.

3. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Providence was in full and timely compliance with the requirements of this CIA for which OIG demands payment; and (b) the period of noncompliance. Providence shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Providence has breached this CIA and orders Providence to pay Stipulated Penalties, Providence must (a) come into compliance with the requirement(s) of the CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Providence properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Providence must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

4. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Providence was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Providence shall waive its right to any notice by OIG of the exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Providence, Providence shall be reinstated effective on the date of the exclusion.

5. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Providence agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Providence and OIG agree as follows:

- A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- C. OIG may agree to a suspension of Providence's requirements under this CIA based on a certification by Providence that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If Providence is relieved of its CIA requirements, Providence shall be required to notify OIG in writing at least 30 days in advance if Providence plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.
- D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Providence's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.
- E. The undersigned Providence signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.
- F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF PROVIDENCE HEALTH & SERVICES-WASHINGTON

/Gregory D. Hoffman/

March 15, 2022

GREGORY HOFFMAN
President and Chief Executive Officer
Providence Health & Services - Washington

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa M. Re/

3/17/22

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Felicia Heimer/

3/17/22

FELICIA E. HEIMER
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement

1. Providence shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Providence in response to a request by OIG, whichever is later, OIG will notify Providence if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Providence may continue to engage the IRO.

2. If Providence engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Providence shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Providence at the request of OIG, whichever is later, OIG will notify Providence if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Providence may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Medicare and state Medicaid program requirements applicable to the claims being reviewed;

2. assign individuals to design and select the Claims Review sample who are

knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Claims Review;

3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation;

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Providence Responsibilities

Providence shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *Providence and IRO.* If Providence terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Providence must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Providence must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Providence in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Providence shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Providence regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Providence in writing that Providence shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Providence must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Providence to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review. The Claims Review shall be conducted at two Providence Hospitals locations or 10% of Providence Hospitals, , whichever is greater, for each Reporting Period.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money Providence has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. Paid Claim: A claim submitted by Providence and for which Providence has received reimbursement from the Medicare program or a state Medicaid program.

B. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify Providence and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG also may select the Providence Hospitals that will be subject to the Claims Review in each Reporting Period. In order to facilitate OIG's selection, at least 90 days prior to the end of the Reporting Period, Providence shall furnish to OIG the following information for each Providence Hospital for the prior calendar year: (1) Federal health care program revenues, (2) Federal health care program patient census, and (2) Federal health care program payor mix.

Providence, or its IRO on behalf of Providence, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed and the Providence Hospitals to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by Providence or its IRO, (2) information furnished to OIG regarding the results of Providence's internal risk assessment and internal auditing, or (3) other information obtained by OIG. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

1. *Claims Review Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample) at each Providence Hospital location selected for review. The Paid Claims shall be reviewed based on the supporting documentation available at Providence's office or under Providence's control and applicable Medicare and state Medicaid program requirements to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim.

2. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and Providence shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from Providence after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall

include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Providence cannot produce documentation shall be considered an error and the total reimbursement received by Providence for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

3. *Repayment of Identified Overpayments.* Providence shall repay within 60 days any Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance (the "CMS overpayment rule"). If Providence determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Providence shall repay that amount at the mean point estimate as calculated by the IRO. Providence shall make available to OIG all documentation that reflects the refund of any Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from Providence to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by that payor.

C. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*
 - a. Claims Review Population. A description of the Population subject to the Claims Review.
 - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
 - d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by Section A.3.a., above.
2. *Statistical Sampling Documentation.*
 - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
 - b. A description or identification of the statistical sampling software package used by the IRO.

3. *Claims Review Findings.*

a. Narrative Results.

- i. A description of Providence's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A description of controls in place at Providence to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented.
- iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by Providence differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Providence.
- ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to Providence.
- iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not

medically necessary and resulted in an Overpayment to Providence.

- iv. Total dollar amount of all Overpayments in the Claims Review Sample.
- v. Total dollar amount of Paid Claims included in the Claims Review Sample.
- vi. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.
- vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
- viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- ix. Recommendations. The IRO's report shall include any recommendations for improvements to Providence's billing and coding system or to Providence's controls for ensuring that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented, based on the findings of the Claims Review.

4. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.

APPENDIX C

QUALITY REVIEW ORGANIZATION

A. Quality Review Organization Engagement

1. Within 60 days after the Effective Date, Providence shall retain an appropriately qualified monitoring team, the QRO, selected by OIG after consultation with Providence. The QRO may retain additional personnel, including but not limited to independent consultants, if needed to help meet the QRO's obligations under this CIA. The QRO may confer and correspond with Providence or OIG individually or together. The QRO and Providence shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, until after the date of OIG's CIA closure letter to Providence or six months after the expiration of this CIA, whichever is later.

2. The QRO is not an agent of OIG. However, the QRO may be removed by OIG at its sole discretion. If the QRO resigns or is removed for any other reasons prior to the termination of the CIA, Providence shall retain, within 60 days of the resignation or removal, another QRO selected by OIG after consultation with Providence, with the same functions and authorities.

B. QRO Responsibilities. The QRO shall:

1. perform a Clinical Quality Systems Review, in accordance with the specific requirements of Appendix D;
2. apply professionally recognized standards of care and patient safety in making assessments in the Clinical Quality Systems Review;
3. respond to all OIG inquiries in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix D to the CIA.

C. QRO Qualifications. The QRO's employees shall have expertise in evaluating clinical quality management in the acute care setting, professionally-recognized standards of care and patient safety, credentialing, privileging and peer review.

APPENDIX D

CLINICAL QUALITY SYSTEMS REVIEW

The QRO shall perform a Clinical Quality Systems Review annually to cover each of the five Reporting Periods. The QRO shall perform all components of each Clinical Quality Systems Review.

A. Clinical Quality Systems Review

The QRO shall perform a Clinical Quality Systems Review to assess the effectiveness, reliability, and thoroughness of Providence's quality management infrastructure and systems throughout Providence. The QRO shall assess Providence's efforts to achieve compliance with its Clinical Quality Policies and Procedures described in Section III.B, the Medicare Conditions of Participation, and other standards designed to ensure that the delivery of patient care items or services at Providence meet professionally recognized standards of health care and patient safety, and are reasonable and appropriate to the needs of Federal health care program beneficiaries. The Clinical Quality Systems Review will be undertaken at all relevant levels of the organization. The QRO shall assess, among other things, the effectiveness, reliability, and thoroughness of the following:

1. Providence's quality management infrastructure, including but not limited to an assessment of:
 - a. The accuracy of Providence's internal reports, data, and assessments required by the Clinical Quality Policies and Procedures;
 - b. Providence's ability to analyze outcome measures and other data;
 - c. The extent to which reviews under Providence's Quality of Care and Patient Safety Program and other reviews are occurring to identify and address quality management issues at Providence;
 - d. Providence's compliance with the Clinical Quality Training requirements, Clinical Quality Policies and

Procedures, and performance standards of Section III.B of the CIA;

- e. The extent to which Providence's Clinical Quality Training program is effective, thorough, and competency-based;
- f. The extent to which Providence's communication systems are effective and results of decisions are transmitted to the proper individuals in a timely fashion;
- g. The extent to which Providence has implemented an effective Quality of Care and Patient Safety Program as required under Section III.A.5 of this CIA
- h. The extent to which Providence's credentialing and privileging process is effective and thorough;
- i. The extent to which Providence monitors practitioners with current privileges by the review of clinical practice patterns, ongoing case review, proctoring, and discussion with other individuals involved in the care of patients; and
- j. Providence's implementation and monitoring of medical staff peer review.

2. Providence's response to quality of care issues, which shall include an assessment of:

- a. Providence's ability to identify the problem;
- b. Providence's ability to determine the scope of the problem (e.g., systemic or isolated);
- c. Providence's ability to conduct a root cause analysis;
- d. Providence's ability to create a corrective action plan to respond to the problem;

- e. Providence's ability to execute the corrective action plan;
- f. Providence's ability to operate in a timely and effective manner; and
- g. Providence's ability to monitor and evaluate whether the assessment, corrective action plan, and execution of that plan were effective, reliable, thorough, and maintained.

3. Providence's proactive steps to ensure that each patient receives care in accordance with:

- a. professionally recognized standards of health care and patient safety;
- b. State and local statutes, regulations, and other directives or guidelines; and
- c. the Policies and Procedures adopted by Providence, including those implemented under Section III.B of this CIA.

B. Reportable Quality Events

1. *Definition of Reportable Quality Event.* For purposes of this CIA, a "Reportable Quality Event" means anything that involves:

- a. An incident in which items or services furnished to a patient are substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care; and
- b. Any other incident that involves or causes actual harm to a patient when such incident is required to be reported to any local, State, or Federal government agency.

2. If Providence determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any

means that there is a Reportable Quality Event, Providence shall notify the QRO, in writing, within 60 days after making the determination that the Reportable Quality Event exists.

3. For Reportable Quality Events, the report to the QRO shall include:

- a. a complete description of the Reportable Quality Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Providence's actions taken to correct the Reportable Quality Event;
- c. any further steps Providence plans to take to address the Reportable Quality Event and prevent it from recurring; and
- d. if the Reportable Quality Event has resulted in an Overpayment, a description of the steps taken by Providence to identify and quantify the Overpayment.

4. Providence shall provide all reports to the QRO of Reportable Quality Events to its Compliance Committee, Clinical Quality Department, Audit and Compliance Committee, and Quality of Care and Patient Safety Committee.

C. Access. The QRO shall have:

1. immediate access to Providence, at any time and without prior notice, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;
2. immediate access to:
 - a. internal or external surveys, assessments, or reports;
 - b. Reportable Quality Event disclosures;
 - c. documents related to any clinical quality training;

- d. Clinical Quality Policies and Procedures;
- e. staffing data;
- f. reports of abuse, neglect, or an incident that resulted in patient harm;
- g. reports of any incident involving a patient that prompts a full internal investigation;
- h. patient records;
- i. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and
- j. any other data in the format the QRO determines relevant to fulfilling the duties required under this CIA;

3. immediate access to patients and Covered Persons for interviews outside the presence of Providence supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The QRO shall give full consideration to an individual's clinical condition before interviewing a patient.

D. Clinical Quality Systems Review Report

The QRO shall prepare a report based upon each Clinical Quality Systems Review performed (Clinical Quality Systems Review Report).

1. The Clinical Quality Systems Report shall set forth, at a minimum:
- a. a summary of the QRO's activities in conducting the assessment;
 - b. the QRO's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section A of this Appendix;

- c. the QRO's recommendations to Providence as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.A of this Appendix; and
- d. an assessment of Providence's response to the QRO's prior recommendations.

E. Financial Requirements of Providence and the QRO.

1. Providence shall be responsible for all reasonable costs incurred by the QRO in connection with this engagement, including but not limited to labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).
2. Providence shall pay the QRO's bills within 30 days of receipt. Failure to pay the QRO within 30 calendar days of submission of the QRO's invoice for services previously rendered shall constitute a basis to impose stipulated penalties or exclude Providence, as provided under Section X of this CIA. While Providence must pay all of the QRO's bills within 30 days, Providence may bring any disputed QRO's costs or bills to OIG's attention.
3. The QRO shall charge a reasonable amount for its fees and expenses, and shall submit monthly invoices to Provider with a reasonable level of detail reflecting all key category costs billed.
4. The QRO shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to Providence and to OIG by the submission deadline of Providence's Annual Report. This report shall reflect, on a cumulative basis, all key category costs included on monthly invoices.

F. Additional Providence Requirements. Providence shall:

1. within 30 days after receipt of each Clinical Quality Systems Review Report, submit to OIG and the QRO a written response to each recommendation contained in those reports stating what action Providence took in response to each recommendation or why Providence has not to take action based on the recommendation;

2. provide to its Compliance Committee and Board or Board CIA Committee copies of all documents and reports provided to the QRO;
3. ensure the QRO's immediate access to facilities, Covered Persons, and documents, and assist in obtaining full cooperation by Providence's current employees, contractors, and agents;
4. provide access to current patients consistent with the rights of such individuals under state or federal law, and not impede their cooperation with the QRO;
5. not sue or otherwise bring any action against the QRO related to any findings made by the QRO or related to any exclusion or other sanction of Providence under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the QRO, whether acting alone or in collusion with others.

G. Additional QRO Obligations. The QRO shall:

1. abide by all State and Federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons and patients;
2. abide by the legal requirements of Providence to maintain the confidentiality of each patient's personal and clinical records. Nothing in this subsection, however, shall limit or affect the QRO's obligation to provide information, including information from patient clinical records, to OIG, and, when legally or professionally required, to other agencies;
3. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and simultaneously submit copies of such reports to OIG and to Providence;
4. not be bound by any other private or governmental agency's findings or conclusions, including but not limited to the Joint Commission, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the QRO's findings or conclusions. The QRO's reports

shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the QRO, or any opinions, testimony, or conclusions from the QRO as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Providence, and Providence shall similarly be restricted from using material generated by the QRO, or any opinions, testimony, or conclusions from the QRO as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude OIG or Providence from using any material generated by the QRO, or any opinions, testimony, or conclusions from the QRO in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

5. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Providence; and

6. if the QRO has concerns about systemic problems that could affect Providence's ability to render quality care to its patients, then the QRO shall:

- a. report such concerns in writing to OIG; and
- b. simultaneously provide notice and a copy of the report to Providence's Compliance Committee, Clinical Quality Department, and Quality of Care and Patient Safety Committee referred to in Section III.A of this CIA.