

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ECLINICALWORKS, LLC**

**I. PREAMBLE**

eClinicalWorks, LLC (eCW) 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), and with the requirements of the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program (the ONC Health IT Certification Program requirements). Contemporaneously with this CIA, eCW is entering into a Settlement Agreement with the United States.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by eCW under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA, unless otherwise specified. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) eCW’s final annual report; or (2) any and all additional materials requested by OIG during the period of the compliance obligations, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “EHR Software” refers to software and related services or

solutions (and any updates thereto) being developed, developed or marketed by eCW at any time before or during the term of this CIA that are or could be subject to the ONC Health IT Certification Program requirements, or that affect the performance of any such software, services, and solutions.

2. "Covered Persons" includes:
  - a. all owners, officers, directors, and employees of eCW; and
  - b. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions (as defined below in Section II.C.4) on behalf of ECW, excluding (1) providers of health care goods or services who provide support to eCW users with regard to the interface between their systems and eCW, and (2) ONC-certified providers of software content or functionality who are not under eCW's control.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

3. "Relevant Covered Persons" includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in any of the Covered Functions.

4. "Covered Functions" means:
  - a. the design, development, marketing, implementation, and/or support of the EHR Software;
  - b. the testing, certification, and/or maintenance of certification (including surveillance and direct review)

of the EHR Software under the ONC Health IT Certification Program;

- c. the sale, marketing, licensing, contracting, and/or distribution of the EHR Software;
- d. the preparation or submission of any attestation, application, report, or other communication relating to the EHR Software to ONC, an ONC-ACB, an ONC-Authorized Testing Lab (ONC-ATL), or any other person or entity authorized to administer requirements of the ONC Health IT Certification Program;
- e. handling, assessing, and/or responding to eCW customer complaints and alerts, including any potential and identified Patient Safety Issues (as defined below) related to the EHR Software;
- f. tracking and/or taking corrective actions in response to potential and identified Certification Issues (as defined below) and other issues with the EHR Software;
- g. performing audit or review functions; or
- h. performing any other function that relates to or is covered by this CIA, including, without limitation, activities related to quality assurance, setting policies or procedures, reporting and review functions, making staffing decisions, and/or making Payments to Health Care Providers (as defined by Section III.M.2.b. and c.).

5. "Arrangements" shall mean every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between eCW and any actual or potential source of health care business or referrals to eCW or any actual or potential recipient of health care business or referrals from eCW. The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program,

including payment programs involving the use of health information technology, and the term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom eCW refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom eCW purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program, including payment programs involving the use of health information technology.

6. “Focus Arrangements” means every Arrangement that is between eCW and any actual source of health care business or referrals to eCW and involves, directly or indirectly, the offer, payment, or provision of anything of value.

7. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of eCW’s Arrangements.

8. “Software Standards and Practices” refer to professionally recognized software development, quality assurance, and risk management standards and practices appropriate to the nature and purposes of EHR systems (including supporting clinical decision-making and the provision of medical care to patients), which are to be identified in accordance with Section III.E.6 of this CIA.

9. “Software Quality Oversight Organization” has the meaning given in Section III.E of this CIA.

10. “Software Agreement” means an agreement pursuant to which eCW grants a customer or user rights to access and use the EHR Software, including without limitation agreements entered into by eCW and titled “Software License Support and Subscription Agreement For Electronic Medical Records and Practice Management.”

11. “Existing Customer” has the meaning given in Section III.D of this CIA.

12. “Customer Notification” has the meaning given in Section III.D of this CIA.
13. “Data Transfer Option” has the meaning given in Section III.D of this CIA.
14. “Upgrade Option” has the meaning given in Section III.D of this CIA.
15. “ONC-ACB” means an organization or consortium of organizations that has applied to and has been authorized by ONC to perform the certification of Complete EHRs, EHR Modules, and other types of health IT under the ONC Health IT Certification Program.
16. “Patient Safety Issue” means a defect, deficiency, design flaw, usability problem, or other condition with respect to the EHR Software that reasonably presents a material risk of harm to patients.
17. “Certification Issue” means, for any aspects of the EHR Software that are certified under the ONC Health IT Certification Program, any concern, event, incident or other issue that reasonably calls into question the EHR Software’s conformity with any requirement of such Program.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

eCW shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee and Management Compliance Obligations**

1. *Compliance Officer.* Within 90 days after the Effective Date, eCW shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer must have sufficient 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 eCW, shall report directly to the Chief Executive Officer of eCW, shall make periodic (at least quarterly) reports regarding compliance matters directly to eCW’s owner/members, and shall be authorized to report on such matters to eCW’s owner/members at any time. Written documentation of the Compliance

Officer's reports to eCW's owner/members shall be made available to OIG upon request. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer, or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for eCW. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices to ensure:
  - i. adherence to the Software Standards and Practices identified in accordance with Section III.E.6 of this CIA;
  - ii. timely and effective identification, notification, reporting, and remediation of any software defects, usability problems, deficiencies, or other issues that may present a risk to patient safety or that may be inconsistent with any applicable requirement of the ONC Health IT Certification Program;
  - iii. performance of the Obligations to Existing and Future Customers described in Section III.D of this CIA;
  - iv. compliance with the Anti-Kickback Statute, Federal health care program requirements, including the requirements of payment programs involving the use of health information technology, and the regulations and other guidance related to these programs, and the Health IT Certification Program requirements;
  - v. compliance with all other requirements set forth in this CIA.
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the owner/members of eCW, and shall be authorized to report on such matters to the owner/members at any time. Written documentation of the Compliance Officer's reports to the owner/members shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by eCW, including ensuring that eCW is adhering to Software Standards and Practices; timely and effectively identifying and addressing Patient Safety and Certification Issues; performing the Obligations to Existing and Future Customers;

complying with the Anti-Kickback Statute, Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and the Health IT Certification Program requirements; complying with any reporting obligations created under this CIA; and complying with all other requirements set forth in this CIA.

Any non-compliance-related 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.

eCW shall report to OIG, in writing, any change 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 obligations in this CIA, within five days of such a change.

2. *Compliance and Quality Assurance Committee.* Within 120 days of the Effective Date, eCW shall appoint a Compliance and Quality Assurance Committee (hereinafter "Compliance Committee").

- a. *General Responsibilities.* The purpose of this committee shall be to support the Compliance Officer in fulfilling his/her responsibilities (including developing and implementing policies, practices, and procedures, making periodic reports, and monitoring day-to-day compliance activities). The Compliance Committee shall, at a minimum, include the Compliance Officer and representatives from among senior personnel responsible for (i) patient safety activities (including without limitation adhering to Software Standards and Practices and identifying and addressing Patient Safety Issues); (ii) design and development of the EHR Software; (iii) testing and certification of the EHR Software and identifying and addressing Certification Issues; (iv) implementation of the EHR Software; (v) other customer/user support in connection with the EHR Software; (vi) contracting and/or licensing of the EHR Software; (vii) sales, marketing, and/or distribution of the EHR Software; and (viii) any other areas of responsibility necessary to

thoroughly implement the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee.

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, senior management of eCW shall report to the Compliance Committee on the company's software development, quality assurance, and risk management activities, including any Patient Safety Issues or Certification Issues, and corrective actions planned and/or implemented in response to any such concerns. The minutes of the Compliance Committee meetings shall be made available to the OIG upon request.

eCW shall report to OIG, in writing, any changes in the composition of the Compliance Committee, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days of the change.

- b. *Quality Assurance Program.* The Compliance Committee shall ensure that, within 150 days of the Effective Date, eCW establishes and implements a program for performing internal quality audits and reviews (hereinafter "Quality Assurance Program") to allow the Compliance Committee, through the Quality Assurance Program, to oversee:
  - i. whether eCW is adhering to and/or in the process of timely implementing the Software Standards and Practices, as defined by the SQOO;
  - ii. whether eCW is proactively monitoring sources of information about potential software defects, usability problems, deficiencies, and other issues that may present Patient Safety Issues or Certification Issues;

- iii. whether eCW is reviewing, tracking, and completing root cause analyses of such potential and identified issues;
- iv. whether eCW is promptly notifying customers and users of Patient Safety Issues and Certification Issues, including whether appropriate urgency is being given to Patient Safety Issues;
- v. whether eCW is, where applicable, reporting Patient Safety Issues and Certification Issues to the Compliance Officer, Compliance Committee, SQOO (see Section III.E), any ONC-ACBs with certification or surveillance responsibilities for the EHR Software, and OIG;
- vi. whether eCW is maintaining on its customer portal, in a clear and conspicuous manner, a current and comprehensive list of all Patient Safety Issues and Certification Issues that specifies, in addition to any other pertinent information: (1) the nature of the issue; (2) the date the issue was classified as such by eCW; (3) the actions eCW is taking to address the issue, and (4) where applicable, the actions that customers and users should take to mitigate risks to patient safety until the issue is fully remedied;
- vii. whether eCW's action plans for responding to identified issues are adequate to fully address and remedy the issue and associated risks to patient safety, and are implemented and enforced in a timely and effective manner;
- viii. whether eCW is effectively coordinating quality assurance activities across its business divisions, teams, and other internal units;
- ix. whether eCW is taking all other reasonable actions to timely and effectively identify and address Patient Safety Issues and Certification Issues with the EHR Software, including remedying identified issues and mitigating any associated risks to patient safety;

- x. whether eCW is taking all reasonable actions to achieve the quality improvement goals, indicators, and performance metrics identified by the Compliance Committee under Section III.A.2.c of this CIA;
  - xi. whether eCW and the EHR Software conforms to applicable ONC Health IT Certification Program requirements;
  - xii. whether eCW is taking the necessary actions in good faith to perform its Obligations to Existing and Future Customers; and
  - xiii. whether eCW is complying with the relevant law, including federal and state statutes, regulations, and directives, applicable to EHR Software.
- c. *Software Quality Assurance Dashboard.* The Compliance Committee shall create and implement a “Software Quality Assurance Dashboard” (Dashboard). Quality indicator data shall be collected and reported on the Dashboard. Within 150 days after the Effective Date, the Compliance Committee shall: (1) identify and establish the overall quality improvement goals for eCW; (2) identify and establish the quality indicators related to those goals that eCW will monitor through the Dashboard; and (3) establish performance metrics for each quality indicator. The Compliance Committee shall measure, analyze, and track the performance metrics for the quality indicators on a quarterly basis, monitoring progress towards the quality improvement and remediation goals. At least semi-annually, the Compliance Committee shall review the quality indicators to determine if revisions are appropriate and shall make any necessary revisions based on such review.

3. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain eCW employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable eCW department

has adhered to Software Standards and Practices; timely and effectively identified and addressed Patient Safety Issues and Certification Issues; performed the Obligations to Existing and Future Customers; and complied in full with the Anti-Kickback Statute, applicable laws and regulations, Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, the ONC Health IT Certification Program requirements, eCW's own Policies and Procedures, and all reporting obligations and other requirements created under this CIA. These Certifying Employees shall include, at a minimum, the following: the President and Chief Executive Officer, the Controller, the Chief Operations Officer, the Chief Medical Officer, the Compliance Officer, the Director of Human Resources, the senior executive responsible for software development, and the Team Leads for the EHR Usability, Patient Safety, and Certification Teams. 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 that the [insert name of department] of eCW:

- complies with all applicable laws and regulations, including, to the extent applicable, Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and ONC Health IT Certification Program requirements;
- complies with all obligations and reporting requirements of the Corporate Integrity Agreement; and
- complies with eCW's policies, practices, and procedures.

I have taken reasonable steps to promote such compliance, adherence, and performance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of eCW is in compliance with all applicable laws and regulations; applicable Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and ONC Health IT Certification Program requirements; obligations and reporting requirements of the Corporate Integrity Agreement; eCW policies, practices, and

procedures; and all other applicable requirements and obligations. 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 or she is unable to provide the certification outlined above.

B. Written Standards

1. *Code of Conduct.* Within 120 days after the Effective Date, eCW shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. eCW shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. eCW’s commitment to fully comply with all Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and ONC Health IT Certification Program requirements;; and to perform eCW's obligations under the CIA;
- b. eCW’s expectation that all of its Covered Persons comply with all Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, the ONC Health IT Certification Program requirements, and eCW’s own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA); and perform eCW's other obligations under the CIA;
- c. the requirement that all of eCW’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by eCW, suspected violations of any Federal health care

program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, ONC Health IT Certification Program requirements, or eCW Policies and Procedures; and any failure to perform eCW's obligations under the CIA;

- d. the requirement that all of eCW's Covered Persons shall immediately report to the Compliance Officer, or other appropriate individual designated by eCW, any potential or identified software defects, usability problems, deficiencies, or other issues with the EHR Software that may present Patient Safety Issues or Certification Issues;
- e. the possible consequences to both eCW and Covered Persons of failure to comply with Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, the ONC Health IT Certification Program requirements, and eCW's own Policies and Procedures and the failure to report such noncompliance; and
- f. the right of all individuals to use the Disclosure Program described in Section III.I of this CIA, and eCW's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 150 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by eCW's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 150 days after the Effective Date, whichever is later.

eCW shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures.* Within 120 days after the Effective Date, eCW shall develop and implement written Policies and Procedures regarding the operation of eCW's compliance program, including the compliance program requirements outlined in this CIA and eCW's commitment to fully comply with all Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and ONC Health IT Certification Program requirements; to adhere to Software Standards and Practices; to timely and effectively identify and address Patient Safety Issues and Certification Issues with the EHR Software; to perform in good faith the Obligations to Existing and Future Customers; and to comply with eCW's other obligations under the CIA. Throughout the term of this CIA, eCW shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

At a minimum, the Policies and Procedures shall address:

- a. the compliance program requirements outlined in this CIA;
- b. Federal health care program requirements regarding payment programs involving the use of health information technology, including the regulations and other guidance related to these programs;
- c. promotion of a patient safety and compliance culture with procedures for taking immediate corrective actions if a Patient Safety Issue is identified or discovered, with immediate access to senior management to provide the necessary resources to correct the problem;
- d. notifying eCW customers, users, ONC-ACBs with certification or surveillance responsibilities for the EHR Software, and OIG of Patient Safety Issues and

Certification Issues, along with a detailed description of how eCW will be correcting the problem and instructions as to any actions the customers and users should take to mitigate the risk while it is being corrected;

- e. addressing and remediating customer and user complaints and/or alerts, including expected timeframes for complaints and/or alerts to be fully addressed with customers and users according to the severity level of the issue, with rapid timeframes followed for Patient Safety Issues;
- f. ensuring that eCW's customers and users of the EHR Software are made aware of and are encouraged to use all appropriate avenues to report Patient Safety Issues and Certification Issues, including through regular education by eCW and communications from eCW;
- g. maintaining on eCW's customer portal a current and comprehensive list of all Patient Safety Issues and Certification Issues that specifies the nature of the issue and actions customers and users should take to mitigate any patient safety risks while the issue is resolved; and ensuring that items on this list are not removed without the review and approval of the SQOO (see Section III.E);
- h. developing and implementing software modifications to address Patient Safety Issues, including but not limited to the proper use of version control systems and communication procedures for informing eCW customers and users regarding upgrades and changes to the EHR Software;
- i. identifying and consistently applying and adhering to all applicable aspects of the ONC Safety Assurance Factors for EHR Resilience (SAFER) guides, including with respect to eCW's processes for software development, implementation, maintenance, and

customer support;

- j. implementing and consistently adhering to Software Standards and Practices identified pursuant to Section III.E of this CIA;
- k. staffing, including, but not limited to:
  - i. an EHR Usability Team comprised of appropriate employees, customers, and/or outside advisors/consultants, including at least one doctor of medicine (M.D.) or doctor of osteopathy (D.O.), one registered nurse (R.N.), and one pharmacist, who have experience using multiple EHR systems for patient care in clinical settings. This team shall work with eCW's development team on screen and workflow design and shall internally consult on user feedback regarding the usability of the EHR Software;
  - ii. an EHR Patient Safety Team consisting of sufficient staff, including licensed clinicians (including at least one physician and one pharmacist) with experience in clinical system safety and EHR implementation experience. This team shall work with eCW's development team on the development of eCW's EHR Software and shall also review and internally consult on all Patient Safety Issues and related communications. In identifying potential Patient Safety Issues, the EHR Patient Safety Team shall consider input from, among other possible sources, the Compliance and Quality Assurance Committee, the Software Quality Oversight Organization, any ONC-ACB, ONC, the EHR Usability Team, the EHR Certification Compliance Team and any Independent Consultative Expert (ICE) reports.

- iii. an EHR Certification Compliance Team consisting of appropriate employees and/or outside advisors/consultants with knowledge of ONC Health IT Certification Program requirements. This team shall work with eCW's development team on the development of eCW's EHR system and shall also review and internally consult on all Certification Issues and related communications. In identifying potential Certification Issues, the EHR Certification Compliance Team shall consider input from, among other possible sources, the Compliance and Quality Assurance Committee, the Software Quality Oversight Organization, any ONC-ACB, ONC, the EHR Usability Team, and the EHR Patient Safety Team.
  
- l. ensuring that eCW complies with its Obligations to Existing and Future Customers;
  
- m. ensuring that all contracts and agreements entered into for the provision of the EHR Software and any associated services do not prohibit or restrict the right of eCW's customers to disclose to any person or entity information relating to the performance of the EHR Software, including for patient safety, public health, and quality improvement purposes, as set forth in Section III.D of this CIA;
  
- n. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute), and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute; and
  
- o. the requirements set forth in Section III.F (Compliance with the Anti-Kickback Statute).

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. The Policies and Procedures shall be available to OIG upon request.

At least annually (and more frequently, if appropriate), eCW shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

### C. Training and Education

1. *Training Plan.* Within 120 days after the Effective Date, eCW shall develop a written plan (Training Plan) that outlines the steps eCW will take to ensure that: (a) all Covered Persons receive adequate training regarding eCW's CIA requirements and Compliance Program, including the Code of Conduct; and (b) all Relevant Covered Persons receive adequate training regarding, as appropriate based on the Covered Functions for which they are responsible: (i) policies, procedures, and other requirements applicable to the quality assurance of the EHR Software; (ii) the Policies and Procedures implemented pursuant to Section III.B.2 of this CIA, as appropriate for the job category of each Relevant Covered Person; (iii) the coordinated approach across eCW's business divisions, teams, and other internal units on quality management of the EHR Software; (iv) the personal obligations of each individual involved in developing, testing, certifying, implementing, and supporting the EHR Software to ensure that it meets Software Standards and Practices and the ONC Health IT Certification Program requirements; (v) examples of software defects, usability problems, deficiencies, and other issues with the EHR Software and the procedures in place to address them; (vi) reporting requirements and legal sanctions for violations of the Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and the ONC Health IT Certification Program requirements; and (vii) the personal obligations of each individual involved in the sale, marketing, licensing, contracting, and/or distribution of the EHR Software to perform the Obligations to Existing and Future Customers. The Training Plan shall also include training to address the lessons learned from any quality issues with the EHR Software. In determining what training should be performed, eCW shall review the customer

and user complaints received, satisfaction surveys, any state or federal reviews, including those performed by ONC and its agents or other such private agencies, any Independent Consultative Expert (ICE) reports, any internal reviews, and the findings, reports, and recommendations of the SQOO required under Section III.E of this CIA.

In addition, the Training Plan shall outline the steps eCW will take to ensure that all Arrangements Covered Persons receive at least annual training regarding: (i) Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute; (ii) eCW's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.F of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of eCW's Arrangements to know the applicable legal requirements and eCW's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute; and (v) examples of violations of the Anti-Kickback Statute.

The Training Plan shall include information regarding the training topics, the identification of Covered Persons, Relevant Covered Persons, and Arrangements Covered Persons required to attend each training session, the length of the training sessions(s), the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of eCW's Training Plan, OIG will notify eCW of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, eCW may implement its Training Plan. eCW shall furnish training to its Covered Persons, Relevant Covered Persons, and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

3. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

4. *Update of Training Plan.* eCW shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs, ONC Health IT Certification Program requirements, and Software Standards and Practices, any issues discovered during internal audits or the Arrangements Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to eCW's Training Plan, OIG will notify eCW of any comments or objections to the revised Training Plan. Absent notification from OIG that the revised Training Plan is unacceptable, eCW may implement the revised Training Plan.

D. Obligations to Existing and Future Customers

1. *Provision of Upgrade Option to Existing Customers.* eCW shall as soon as practicable after the Effective Date make available to each of eCW's current customers and users of the EHR Software ("Existing Customers") the latest versions of the EHR Software used by the Existing Customer and the latest updates to any drug database supported by the EHR Software used by the Existing Customer, including where relevant the Existing Customer's preferred drug database from among the supported options (collectively "the Upgrade Option").
  - a. The Upgrade Option shall be provided at no additional charge to the Existing Customer (including, without limitation, any eCW-mandated fees for implementation, installation, or training services). eCW may charge for training and/or implementation services which are not mandated by eCW for implementation of the Upgrade Option but which nonetheless may be requested by an Existing Customer in connection with an update or upgrade.
    - i. Consistent with the above, eCW may charge Existing Customers reasonable and customary fees for training or implementation that are unrelated to the

exercise of the Update Option and the implementation of upgraded EHR Software and drug database updates.

- b. As part of the Upgrade Option, throughout the term of the Existing Customer's Software Agreement, eCW shall provide each Existing Customer:
    - i. release notes, documentation, webinars, tools, and other customary implementation support; and
    - ii. such further updates, upgrades, software defect fixes, and patches to the EHR Software and the supported drug database as necessary to ensure that the EHR Software conforms with the ONC Health IT Certification Program requirements, adheres to the Software Standards and Practices, and complies with any other applicable federal and state statutes, regulations and directives.
  - c. The exercise of the Upgrade Option by an Existing Customer does not preclude the Existing Customer from also exercising the Data Transfer Option.
  - d. Notwithstanding the foregoing, eCW may decline to provide updates or upgrades that do not relate to patient safety issues to any self-hosted Existing Customer who is three months or more in arrears on their licensing or maintenance fees.
2. *Data Transfer Option for Existing Customers.* Consistent with requirements and limitations in this section, eCW shall timely transfer the Existing Customer's data without penalties or service charges (including, without limitation, any break fee or termination fee) other than contractual amounts still owed in connection with goods or services already provided ("the Data Transfer Option"). eCW shall not be required to reimburse Existing Customers for any costs an Existing Customer may incur on its own as a result of a decision to exercise the Data Transfer Option.

- a. An Existing Customer must exercise the Data Transfer Option within one year of the Initial Customer Notification (described in Section III.D.3 below).
- b. Upon an Existing Customer's exercise of the Data Transfer Option, eCW shall transfer all data held by eCW on behalf of the Existing Customer (including protected health information, and all other data and information provided by the Existing Customer or which eCW develops or receives on behalf of the Existing Customer, or has access to in connection with the Software Agreement) to the Existing Customer or its designee in a commercially reasonable, structured format that allows for the customer's data to be migrated to and useable by the customer's subsequent EHR system and vendor, and provide timely good faith instructions on how this data is to be accessed by the customer or by the customer's subsequent EHR vendor.
  - i. For eCW Cloud customers, the following data transfer format shall be considered to meet the requirements of this section:
    - a. All structured EHR data (including free text notes associated with a patient's chart) provided in an unencrypted server database backup on a hard drive;
    - b. All scanned documents, unencrypted, in file folders on a hard drive;
    - c. Providing the Customer with the ability to export all patient data in C-CDA format until the time eCW delivers to the Customer a hard drive containing the data described above.
  - ii. For self-hosted customers who have control over their own information, eCW shall also remove any encryption or other limitations in order to enable

the Existing Customer to fully access and transfer all required information.

Customers requiring a hard drive from eCW to effectuate the Data Transfer Option will be responsible for the cost of the hard drive at the then standard rate.

3. *Notifications to Existing Customers.* eCW shall provide notifications to its Existing Customers that meet the following requirements (“Customer Notifications”).
  - a. *Initial Customer Notification.* Within 60 days after the Effective Date, eCW shall cause to be sent to Existing Customers a Customer Notification with the following format and content (“Initial Customer Notification”):
    - i. The Initial Customer Notification shall be on eCW letterhead.
    - ii. The Initial Customer Notification shall include the following subject line: **“IMPORTANT INFORMATION ABOUT YOUR EHR SOFTWARE AND SERVICES. YOU HAVE NEW OPTIONS FREE OF CHARGE TO YOU.”**
    - iii. The Initial Customer Notification must include the following introductory statement: “eCW recently entered into a settlement with the U.S. Department of Justice and the Office of Inspector General, U.S. Department of Health and Human Services. As part of the settlement, we offer the following to our customers.”
    - iv. The Initial Customer Notification must contain the following promises and undertakings from eCW to each Existing Customer, and eCW must present such promises and undertakings, and do all other things necessary, to make the promises and

undertakings legally binding and enforceable against eCW:

- a. Each Existing Customer has the opportunity to receive from eCW, at no additional charge to the Existing Customer (including, without limitation, any eCW-mandated implementation fee):
  - an upgrade to the latest production version of the EHR Software in use by the Existing Customer; and
  - an upgrade to the latest update of any drug database supported by the EHR Software used by the Existing Customer, including specifying that if the EHR Software supports more than one drug database, the customer shall have the right to select from among the supported drug databases.
- b. throughout the term of the Existing Customer's Software Agreement, Existing Customer also has the opportunity to receive from eCW, at no additional charge to the Existing Customer (including, without limitation, any eCW-mandated fees for implementation, installation, or training services) such further updates, upgrades, software defect fixes, and patches to the EHR Software and the supported drug database as necessary to ensure that the EHR Software conforms with the ONC Health IT Certification Program requirements, adheres to Software Standards and Practices, and complies with any other applicable federal and state statutes, regulations, and directives.
- v. Notwithstanding the foregoing, the Initial Customer Notification may reference the limitation

on eCW's obligation to provide updates or upgrades set forth in Section III.D.1.d of this CIA.

- b. *Notifications of Data Transfer Option.* If an Existing Customer requests the opportunity to transfer data to other EHR software within one year of the Initial Customer Notification, or inquires, in any manner and in any respect, about data transfer services, including the transfer, migration, and/or conversion of the Customer's data (or any part thereof), eCW will notify the Existing Customer in writing of the Data Transfer Option.
- c. The Customer Notifications must not have the effect of extinguishing any rights accrued by the Existing Customer under the Existing Customer's Software Agreement, or any other agreement between the Existing Customer and eCW, up until the date of the Customer Notification, under the doctrine of merger or otherwise.
- d. All written Customer Notifications must be sent by either mail or email:
  - i. in a manner consistent with the delivery of invoices to Existing Customers; and/or
  - ii. to any other person or position of the Existing Customer that eCW deals with on a regular basis regarding the Existing Customer's access to and use of the EHR Software and eCW's services.

4. *Implementation of Obligations to Existing Customers.*

- a. Within 65 days after the Effective Date, eCW shall provide to the SQOO copies of all written Customer Notifications sent by eCW to Existing Customers. Within 5 days after each subsequent notification to a customer, including without limitation the written Notification of Data Transfer, eCW will send copies of such Customer Notifications to the SQOO.

- b. eCW must take all actions as the SQOO reasonably requires to give effect to the Customer Notification requirements of this CIA, including without limitation to ensure every Existing Customer has received the Customer Notifications required by the CIA.
  - c. Where applicable, eCW will encourage Existing Customers to exercise the Upgrade Option, including by timely informing any Existing Customer that has not exercised the Upgrade Option of any known patient safety risks associated with the EHR Software version they are using.
  - d. Within 60 days after the Effective Date and continuing throughout the term of this CIA, eCW shall maintain a record of the names, organizations, and contact information of all Existing Customers. Such record shall also include information for each Existing Customer regarding which Customer Notifications the customer has received; the date each such Customer Notification was made; if applicable, the date the requirement to provide the Notifications of Data Transfer Option was triggered; whether the customer has exercised (a) the Upgrade Option and/or (b) the Data Transfer Option; the date(s) on which the customer exercised such options(s), as applicable; and the current status of the software upgrade(s) and/or data transfer, as applicable.
  - e. eCW shall, on request by the SQOO and/or OIG, provide information and/or access to records to the SQOO and/or OIG regarding the actions taken and the records maintained by eCW related to fulfilling the foregoing obligations.
5. *Limitation on Charges for Continued Access to Software Following Performance of Data Transfer Option.* Following the termination of the Existing Customer's Software Agreement, and the full performance of eCW's obligations to transfer the Existing Customer's data in accordance with the Data Transfer

Option, if eCW provides the Existing Customer with continued access to eCW's Software, eCW may charge for such access:

- i. the contractual monthly fees set forth in the Existing Customer's Software Agreement; or
  - ii. where the Existing Customer solely requests "read only" access to its cloud-based eCW data, the fees specified by eCW's then-current read only access rate structure.
6. *Permitting Customers to Report and Discuss Problems.* eCW must not restrict or prohibit, by contract or otherwise, the rights of Existing Customers, former customers, or any new customers or users of eCW's EHR Software to discuss problems with eCW's EHR Software or associated services in any forum whatsoever, and eCW agrees that it will not enforce any rights it has under contracts with Existing Customers or former customers that restrict or prohibit those Existing Customers or former customers from discussing problems with eCW's EHR Software or associated services in any forum whatsoever.
7. *New Agreements Must Protect Customer's Rights to Report and Discuss Problems.* eCW must ensure that all contracts and agreements entered into for the provision of the EHR Software and any associated services do not restrict or prohibit eCW's customer from disclosing to any person or entity information relating to the performance of the EHR Software, including for patient safety, public health, and quality improvement purposes, which comprise, but are not limited to:
- a. sharing comparative user experiences that may affect patient care;
  - b. developing best practices for EHR implementation and clinician use;
  - c. reporting of EHR-related adverse events, hazards, and other unsafe conditions;

- d. reporting issues related to interoperability, information blocking, and data portability;
- e. conducting research studies for peer-reviewed journals; and;
- f. participating in cyber threat sharing activities.

E. Independent Software Quality Oversight Organization

eCW shall retain an appropriately qualified Software Quality Oversight Organization (the "SQOO") approved by OIG. eCW shall seek input from OIG to ensure that eCW selects and retains an acceptable SQOO within 60 days after the Effective Date. If eCW has not retained an appropriately qualified SQOO within such timeframe, eCW shall retain an SQOO selected by OIG within 75 days after the Effective Date.

The SQOO may retain additional personnel as needed to meet the SQOO's obligations under this CIA. The SQOO may confer and correspond with eCW or OIG individually or together. The SQOO and eCW shall not negotiate or enter into a financial relationship, other than the engagement required by this section, until after the date of OIG's CIA closure letter to eCW or six months after the expiration of this CIA, whichever is later.

The SQOO is not an agent of OIG. However, the SQOO may be removed by OIG at its sole discretion. If the SQOO resigns or is removed for any other reasons prior to the termination of the CIA, eCW shall retain, within 60 days of the resignation or removal, another appropriately qualified SQOO approved by OIG, with the same functions and authorities. If an acceptable replacement SQOO is not retained within such timeframe, eCW shall retain an SQOO selected by OIG within 75 days of the resignation or removal.

The SQOO and eCW shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the SQOO and eCW) related to the reviews, assessments, and identification of Software Standards and Practices, which are all described below in this Section III.E.

1. *Scope of Review.* The SQOO shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:

- a. *Quality Control Systems.* eCW's internal quality control systems, including, but not limited to systems designed to ensure that:
- i. the EHR Software meets all applicable ONC Health IT Certification Program requirements (including certification criteria to which EHR Software is certified or will be certified);
  - ii. Patient Safety Issues, Certification Issues, and any other potential deficiencies of the EHR Software (including issues identifiable from customer reports, service requests, internal quality assurance activities, and other relevant sources) are appropriately identified and remedied;
  - iii. eCW's implementation of its selected quality management system and other quality controls for its EHR Software is sufficient to identify and address Patient Safety Issues, Certification Issues and other potential deficiencies in a timely and effective manner;
  - iv. eCW's implementation of its selected quality management system and other quality controls incorporates appropriate input from relevant sources, as appropriate, including the Compliance Committee, the SQOO, any ONC-ACB, ONC, the EHR Usability Team, the EHR Patient Safety Team, and the EHR Certification Compliance Team;
  - v. the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals, across all of eCW's business divisions, subdivisions, and departments, in a timely fashion; and

- vi. the training programs related to software quality are effective and thorough.
- b. *Identifying and Addressing Issues.* eCW's policies, practices, and procedures for identifying and addressing issues with the EHR Software, which shall include an assessment of:
  - i. eCW's ability to timely and effectively identify potential Patient Safety Issues, Certification Issues, and other issues;
  - ii. eCW's ability to determine the scope of identified issues, including, but not limited to, whether the issue is isolated or systemic as well as the potential nature, extent, and severity of the issue and any associated risks to patient safety;
  - iii. eCW's ability to conduct a root cause analysis of identified issues;
  - iv. eCW's ability and procedures for ensuring that customers and users are notified of identified issues and associated risks, how eCW will be correcting the issue, and instructions regarding actions that customers and users should take to mitigate the risk while it is being corrected;
  - v. eCW's ability to create action plans to timely and effectively track, respond to, and remedy identified issues, including providing prompt notice and instructions to customers and users and, where applicable, reporting identified issues to the Compliance Officer, Compliance Committee, SQOO, ONC-ACBs with certification or surveillance responsibilities for the EHR Software, and OIG;

- vi. eCW's ability to execute the action plans described above;
  - vii. eCW's ability to monitor and evaluate whether the assessment, action plan, and execution of the action plan was effective, reliable, thorough, and timely;
  - viii. eCW's ability to handle Patient Safety Issues, including the following reviews by the SQOO:
    - (1) a review of service level agreements(s) complete with differentiation of low/medium/high-alert patient safety concerns, as well as timeframes and expectations for both eCW and their customers when contact is made regarding those issues;
    - (2) a comprehensive review of customer alerts, remediation of identified Patient Safety Issues, and technical assistance process; and
  - ix. eCW's ability to effectively test the implementation of its EHR software, and full cooperation with the ONC-ACB surveillance activities, including in-the-field surveillance, in order to identify and remedy patient safety related deficiencies not found during development.
- c. *Adherence to Software Standards and Practices and compliance with other requirements.* eCW's proactive steps to ensure that eCW and its EHR software:
- i. comply with applicable ONC Health IT Certification Program requirements;
  - ii. adhere to the Software Standards and Practices identified by the SQOO under Section III.E.6 of

this CIA (provided, however, that any EHR software developed prior to the identification by the SQOO of the Software Standards and Practices but released after such identification shall not be required to go through a new development process to retroactively apply the Software Standards and Practices for software development identified in accordance with Section III.E.6.c absent a determination by the SQOO that a new development process is necessary to address potential Patient Safety Issues or potential Certification Issues);

- iii. comply with applicable laws and regulations, applicable requirements of payment programs involving the use of health information technology and other Federal health care programs that incorporate the use of certified health information technology, including but not limited to applicable Federal and State requirements for interoperability, information blocking, and data portability;
  - iv. comply with the Policies and Procedures adopted by eCW, including those implemented under Section III.B of this CIA; and
  - v. comply with the staffing requirements set forth in this CIA, including the staffing requirements for eCW's EHR Usability Team, eCW's EHR Patient Safety Team, and eCW's EHR Certification Compliance Team.
- d. *Other Quality Assurance Activities.* As required under the terms of this CIA:
- i. eCW's Quality Assurance Program required under Section III.A.2.b of this CIA; and

ii. eCW's Software Quality Assurance Dashboard required under Section III.A.2.c of this CIA.

e. *Obligations to Existing and Future Customers.* eCW's policies, practices, and procedures to ensure that:

i. Existing Customers are notified of eCW's Obligations to Existing and Future Customers and are afforded all opportunities and rights described in Section III.D of this CIA; and

ii. any contracts and agreements entered into for the provision of the EHR Software and any associated services do not restrict or prohibit the right of eCW's customers to disclose to any person or entity information relating to the performance of the EHR Software, including for patient safety, public health, and quality improvement purposes, as set forth in Section III.D of this CIA.

2. *Access.* The SQOO shall have:

a. timely access to all persons, places, documents, records, and information the SQOO considers appropriate to perform its responsibilities set forth in this CIA, including, without limitation, access to relevant software, media, and code; software development procedures, documentation, manuals, and artifacts; incident and complaint logs, reports, interviews, and resolutions; internal policies and/or procedures; internal reviews and reports; customer surveys and other communications with customers; and staffing documentation and information.

b. timely access to Covered Persons for interviews outside the presence of eCW supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the legal rights of such individuals; and

- c. to the extent permitted by OIG, access to any documents, reports, findings, or other information obtained by OIG, regardless of the source or content of the information, that in OIG's sole judgment may be germane to the SQOO's obligations under this CIA.

Notwithstanding the above, eCW may require the SQOO to execute a non-disclosure agreement and/or undertake such other precautions reasonable and necessary to protect eCW's intellectual property, provided that such non-disclosure agreement and/or precautions shall not in any way limit the disclosure of any information whatsoever to OIG.

3. *Baseline Assessment.* Within 180 days after the Effective Date, the SQOO shall:

- a. complete a Baseline Assessment of the effectiveness, reliability, scope, and thoroughness of the systems, policies, practices, procedures, and activities described in Section III.E.1;
- b. in conducting this assessment, visit eCW's facilities (selected by the SQOO) and, at a minimum, observe quality assurance meetings, observe corporate compliance meetings, observe EHR software development, testing, and implementation team meetings, assess implementation plans and workflows, interview key Covered Persons, and review relevant documents, records, data, code, and other information as necessary; and
- c. submit a written report to eCW and OIG that sets forth, at a minimum:
  - i. a summary of the SQOO's activities in conducting the assessment;
  - ii. the SQOO's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems, policies,

practices, procedures, and activities described in Section III.E.1; and

- iii. the SQOO's recommendations to eCW as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems, policies, practices, procedures, and activities described in Section III.E.1.

4. *Interval Improvements Assessments.* Every six months after the Baseline Assessment, the SQOO shall:

- a. re-assess the effectiveness, reliability, and thoroughness of the systems, policies, practices, procedures, and activities described in Section III.E.1;
- b. assess eCW's response to recommendations made in prior written assessment report(s);
- c. visit eCW's facilities (selected by the SQOO), as appropriate, to observe quality assurance meetings, observe corporate compliance meetings, observe EHR software development, testing, and implementation meetings, assess implementation plans and workflows, interview key employees, and review relevant documents, records, data, code, or other information; and
- d. submit a written report to eCW and OIG that sets forth, at a minimum:
  - i. a summary of the SQOO's activities in conducting the assessment;
  - ii. the SQOO's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems, policies, practices, procedures, and activities described in Section III.E.1;

- iii. the SQOO's recommendations to eCW as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems, policies, practices, procedures, and activities described in Section III.E.1; and
- iv. the SQOO's assessment of eCW's response to the SQOO's prior recommendations.

5. The SQOO shall perform the Interval Improvements Assessments at six month intervals after submission of the Baseline Assessment. The SQOO shall submit written reports no later than 30 days after the end of the relevant six-month period to eCW and OIG.

6. *Identification of Software Standards and Practices.* Within 90 days of being retained, the SQOO, working in consultation with eCW, shall identify the Software Standards and Practices to which eCW must adhere under this CIA and shall submit a written report to eCW and OIG setting out these Software Standards and Practices. Such standards and practices shall consist of professionally recognized software development, quality assurance, and risk management standards and practices appropriate to the nature and purposes of EHR systems (including supporting clinical decision-making and the provision of medical care to patients). Such standards and practices may include without limitation:

- a. relevant standards, checklists, self-assessment tools, and other practices identified in the ONC SAFER guides and the ICE Report(s) to optimize the safety and safe use of EHRs in the following areas: (i) High Priority Practices; (ii) Organizational Responsibilities; (iii) Contingency Planning; (iv) System Configuration; (v) System Interfaces; (vi) Patient Identification; (vii) Computerized Provider Order Entry with Decision Support; (viii) Test Results Reporting and Follow-Up; and (ix) Clinician Communication;
- b. relevant standards and practices developed or identified through health IT safety initiatives, such as the ECRI Institute's Partnership for Health IT Patient Safety;

- c. relevant software development standards developed or identified through Standards Development Organizations (SDO) such as the ISO 35.080 Software standards;
- d. a formal quality management system either developed by the Federal Government or a recognized Standards Development Organization (SDO). Examples of formal quality management systems include ISO 9001:2015 for general quality management system requirements, and ISO 25010:2011 for system and software quality models; and
- e. any other appropriate and relevant professionally-recognized standards identified by the SQOO.

The SQOO shall periodically (in conjunction with the Baseline Assessment and each Interval Improvements Assessment) update the Software Standards and Practices and shall submit a written report to eCW and OIG setting out the updated Software Standards and Practices.

- 7. *SQOO's recommendations and eCW's obligations.*
  - a. eCW shall implement the recommendations of the SQOO in the timeframes specified herein or such other timeframe approved by the SQOO.
  - b. In good faith, eCW shall have an opportunity to meaningfully consider, address, and attempt to resolve differences in the SQOO's recommendations and eCW's own opinions, including disagreements about the timeframe in which recommendations must be implemented. In the event that eCW and the SQOO cannot come to an agreement on the issue, the SQOO's findings and recommendations, and eCW's response, must be submitted to OIG for review. eCW shall promptly implement any determination made by OIG.
- 8. *Financial Obligations of eCW and the SQOO.*
  - a. eCW shall be responsible for all reasonable costs incurred by the SQOO in connection with this

engagement, including, but not limited to, labor costs (direct and indirect); consultant and subcontract costs; materials costs (direct and indirect); and other direct costs (travel, other miscellaneous).

- b. eCW shall pay the bills in accordance with the terms of the engagement agreement between eCW and the SQOO. Failure to pay the SQOO in conformance with this requirement may constitute a basis to impose stipulated penalties or exclude eCW, as provided under Section X of this CIA. eCW may bring any disputed SQOO's costs or bills to OIG's attention for purposes of facilitating the resolution of any dispute.
- c. The SQOO shall charge a reasonable amount for its fees and expenses, and shall submit monthly invoices to eCW with a reasonable level of detail reflecting all key categories of costs and fees billed. OIG will work in good faith with eCW on at least an annual basis to assess whether the costs and fees associated with the SQOO are reasonable in light of the benefits provided by the SQOO's work, and to take such actions as may be necessary to address any imbalance.
- d. The SQOO shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to eCW and to OIG by the submission deadline of eCW's Annual Report. This report shall reflect, on a cumulative basis, all key categories of costs and fees included on monthly invoices.

9. *Additional SQOO Obligations.* The SQOO shall:

- a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons,
- b. abide by the legal requirements of eCW to maintain the confidentiality of each patient's personal and

clinical records. Nothing in this subsection, however, shall limit or affect the SQOO's obligation to provide information, including information from patient clinical records, to OIG, and, when legally or professionally required, to other agencies;

- c. at all times act reasonably in connection with its duties under the CIA including when requesting information from eCW;
- d. if the SQOO has concerns about action plans that are not being enforced or systemic problems that could affect eCW's ability to prevent, detect, or remediate Patient Safety Issues or Certification Issues in the EHR Software to its customers and users, then the SQOO shall:
  - i. report such concerns in writing to OIG; and
  - ii. simultaneously provide notice and a copy of the report to eCW's Compliance Committee referred to in Section III.A of this CIA;
- e. where independently required to do so by applicable law, regulations, 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 eCW;
- f. 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 eCW; and
- g. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures, and forms obtained in connection with its duties under this

CIA and not comment publicly concerning its findings except to the extent authorized by OIG.

F. Compliance with the Anti-Kickback Statute

1. *Focus Arrangements Procedures.* Within 120 days after the Effective Date, eCW shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- d. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;

- e. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- f. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

2. *New or Renewed Focus Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, eCW shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by eCW and the other parties to the Focus Arrangement;
- b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete at least one hour of training regarding the Anti-Kickback Statute and examples of arrangements that potentially implicate the Anti-Kickback Statute. Additionally, eCW shall provide or make available to each party to the Focus Arrangement a copy of its Anti-Kickback Statute Policies and Procedures;
- c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* eCW shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus

Arrangements and the actual performance of the duties under the Focus Arrangements.

G. Review Procedures for the Arrangements Review by the Independent Review Organization

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, eCW shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.G. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records.* The IRO and eCW shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and eCW) related to the reviews.

c. *Responsibilities and Liabilities.* Nothing in this Section III.G affects eCW’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

2. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to eCW a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.G and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this

CIA. The IRO's certification shall include a summary of all current and prior engagements between eCW and the IRO.

#### H. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, eCW shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the quality of the EHR Software, including any Patient Safety Issues, and with Arrangements (as defined in Section II.C.5 above). This risk assessment and internal review process shall require, as appropriate, compliance, legal and other department leaders, at least annually, 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. eCW shall maintain the risk assessment and internal review process for the term of the CIA.

#### I. Disclosure Program

Within 120 days after the Effective Date, eCW 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 eCW's policies, conduct, practices, or procedures with respect to the EHR Software), a Federal health care program, including payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and/or the Health IT Certification Program believed by the individual to be a potential violation of criminal, civil, or administrative law. eCW 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 eCW's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to

these programs, and/or Health IT Certification Program requirements to the Compliance Officer or other appropriate individual designated by eCW. 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 or she has 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, eCW shall conduct an internal review of the allegations set forth in the disclosure and ensure that appropriate follow-up and remediation is conducted. If the inappropriate or improper practices places patients at risk of harm, then eCW will ensure that that practice ceases immediately and that appropriate action is taken.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure 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 status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

Disclosures in the disclosure log relating to activities or functions falling within the SQOO Scope of Review defined above shall be sent to the SQOO required under Section III.E of this CIA not less than monthly.

J. 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, debarred, suspended, or otherwise declared ineligible.

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

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

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

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

3. *Removal Requirement.* If eCW has actual notice that a Covered Person has become an Ineligible Person, eCW shall remove such Covered Person from responsibility for, or involvement with, eCW’s business operations related to the Federal health care programs 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 Federal health care programs or otherwise with

Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If eCW 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, eCW shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of the EHR Software submitted for certification under the ONC Health IT Certification Program or the accuracy of any requests for payment submitted by users of the EHR Software to any Federal health care program.

K. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, eCW shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to eCW conducted or brought by a governmental entity or its agents involving an allegation that eCW 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. eCW shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

L. Reportable Events

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

- a. a Patient Safety Issue or any identified instance of actual or suspected patient harm related to the EHR Software;
- b. a Certification Issue;
- c. a matter that a reasonable person would consider a probable violation of applicable criminal, civil, or administrative laws and regulations or any applicable Federal health care program requirements for which penalties or exclusion may be authorized;

- d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.J.1.a; or
- e. The filing of a bankruptcy petition by eCW.

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

2. *Reporting of Reportable Events.* If eCW determines (after a reasonable opportunity to conduct an appropriate review or investigation of the facts) through any means that there is a Reportable Event, eCW shall report such event in the manner and timeframe prescribed by Sections III.L.3–5 below.

3. *Reportable Events Under Section III.L.1.a.* For a Reportable Event under Section III.L.1.a:

a. If the Reportable Event resulted in a patient death, patient hospital admission, or serious injury to a patient, eCW shall, in writing and within 48 hours of determining that the Reportable Event exists, provide notice and the information specified by Section III.L.3.c to OIG, the SQOO, and any ONC-ACB(s) with responsibility for the certification or surveillance of the EHR Software.

b. If the Reportable Event did not result in a patient death, patient hospital admission, or serious injury to a patient, eCW shall, in writing and within 7 days of determining that the Reportable Event exists or of resolving the event (whichever is earlier), provide notice and the information specified by Section III.L.3.c to the SQOO and OIG.

c. eCW shall provide to the SQOO, and if required by Section III.L.3.a, to OIG and any ONC-ACB(s):

- i. a description of the steps taken by eCW to identify the Patient Safety Issue or instance of actual or suspected patient harm related to the EHR Software;
- ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and the legal, regulatory, or other requirements implicated

(including requirements of the ONC Health IT Certification Program);

- iii. a description of eCW's actions taken to correct the Reportable Event, including providing notice to users of the EHR Software of any software defects, usability problems, deficiencies, or other issues that may present a risk to patient safety;
- iv. any further steps eCW plans to take to address the Reportable Event and prevent it from recurring; and
- v. where applicable, if not resolved by the reporting deadline described in Section III.L.3.b, the current status of the Reportable Event and the estimated time to resolution.

4. *Reportable Events under Sections III.L.1.b, c, and d.* For Reportable Events under Section III.L.1.b, c, and d, eCW shall, in writing and within 30 days after making the determination that the Reportable Event exists, provide notice and the following information to OIG:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal, regulatory, or other requirements implicated (including applicable Federal health care program and ONC Health IT Certification Program requirements);
- b. a description of eCW's actions taken to correct the Reportable Event; and
- c. any further steps eCW plans to take to address the Reportable Event and prevent it from recurring.

5. *Reportable Events under Section III.L.1.e.* For Reportable Events under Section III.L.1.e, eCW shall notify OIG, in writing and within 30 days after making the determination that the Reportable Event exists, and the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

M. Reporting of Health Care Provider Payments.

1. *Reporting of Payment Information.* eCW shall post on its website reports of the cumulative value of the Payments (as defined below) provided to all Health Care Providers (as defined below) from eCW subsequent to the Effective Date. During the first Reporting Period, such Payments shall be posted quarterly, and each quarterly posting will reflect the cumulative Payments made since the Effective Date. The quarterly Payments will be posted within 30 days of the end of the applicable quarter. In subsequent Reporting Periods, within 90 days of the end of the calendar year falling within that Reporting Period, eCW shall post on its website a report of the cumulative value of the Payments provided to all Health Care Providers during the prior applicable calendar year. Each quarterly or annual report shall be easily accessible and readily searchable.

Each report posted pursuant to this Section III.M shall include a complete list of all Health Care Providers to whom eCW made Payments in the preceding year. Each report shall be arranged alphabetically according to the Health Care Provider's name and, if an individual, by the last name of the Health Care Provider. The Payment amounts in the reports shall be reported in the actual amount paid for all Health Care Providers on the report. For each Health Care Provider, the applicable report shall include the following information: (i) Health Care Provider's full name; (ii) city and state that the Health Care Provider has provided to eCW for contact purposes; and (iii) the aggregate value of the Payment(s) in the preceding year.

2. *Definitions and Miscellaneous Provisions.*

- a. eCW shall make each annual report of Payments available on its website during the term of the CIA. eCW shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual report of Payments.
- b. For purposes of Section III.M.1, "Payments" is defined to include all payments or transfer of value (whether in cash or in kind) made to physicians. The term "Payments" includes all indirect payments or other transfers of value made to a Health Care Provider through a third party where eCW requires, instructs,

directs, or otherwise causes the third party to provide the Payment to the Health Care Provider. The term also includes direct and indirect payments or other transfers of value provided to a third party at the request of or designated by eCW on behalf of a Health Care Provider. The term does not include the refund of overpayments made in the ordinary course of business, or payments required by court order or legal settlement. The term also does not include any amounts relating to a single Health Care Provider which total less than the de minimis exception set forth in the Physician Payments Sunshine Act.

- c. For purposes of this Section III.M, the term “Health Care Provider” is defined to include any physician, physician practice, and any other individual or entity involved in providing, directly or indirectly, health care items or services to Federal health care program beneficiaries, except for a physician or other individual who is a bona fide employee of eCW.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, eCW 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, including payment programs involving the use of health information technology, 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, including payment programs involving the use of health information technology, 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.

If, in advance of a proposed sale or a proposed purchase, eCW 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, eCW must notify

OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include 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 160 days after the Effective Date, eCW 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, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names and positions of the Certifying Employees required by Section III.A;
4. a description of the Quality Assurance Program required by Section III.A.2.b;
5. a description of the Dashboard required by Section III.A.2.c;
6. a copy of eCW's Code of Conduct required by Section III.B.1;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to OIG upon request);

9. a copy of the Customer Notification required by Section III.D.3;
10. a detailed description of the steps taken and being taken to perform the Obligations to Existing and Future Customers described in Section III.D;
11. the following information regarding each type of training required by Section III.C:
- a. a description of such training, including the targeted audience, the categories of personnel required to participate in the training, a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be made available to OIG, upon request.

12. a description of (a) the Focus Arrangements Tracking System required by Section III.F.1.a, (b) the internal review and approval process required by Section III.F.1.e; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.F.1;
13. 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 eCW;
14. a description of the risk assessment and internal review process required by Section III.H;
15. a description of the Disclosure Program required by Section III.I;

16. a description of the process by which eCW fulfills the requirements of Section III.J regarding Ineligible Persons;

17. a list of all of eCW's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;

18. a certification from the Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on eCW's website as required by Section III.M;

19. a description of eCW's corporate structure, including identification of any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business; and

20. the certifications required by Section V.C.

B. Annual Reports. eCW shall submit to OIG annually a report with respect to the status of, and findings regarding, eCW's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, and a current list of the Certifying Employees;

2. the dates of each report made by the Compliance Officer and Compliance Committee to the owner/members of eCW or their designees (written documentation of such reports shall be made available to OIG upon request);

3. a summary of activities and findings under eCW's Quality Assurance Program and a summary of any corrective action taken in response to any problems identified through its Quality Assurance Program as required by Section III.A.2.b;

4. a summary of the Compliance Committee's measurement, analysis, and tracking of the performance metrics included in eCW's Dashboard, eCW's progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes, and activities, assessments,

recommendations, and findings related to staffing and eCW's response to those findings;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG, upon request);

6. a summary of any significant changes or amendments to eCW's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

7. if applicable, a copy of any changes to the Customer Notification required by Section III.D.3;

8. a detailed description of the steps taken and being taken to perform the Obligations to Existing and Future Customers described in Section III.D;

9. a copy of eCW's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which eCW ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request;

10. eCW's response and action plan(s) related to any written recommendations of the SQOO pursuant to Section III.E;

11. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.F.1.a; (b) any changes to the internal review and approval process required by Section III.F.1.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.F.1;

12. a complete copy of all reports prepared pursuant to Section III.E and eCW's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
13. a certification from the IRO regarding its professional independence and objectivity with respect to eCW;
14. a description of any changes to the risk assessment and internal review process required by Section III.H., including the reasons for such changes;
15. a summary of the following components of the risk assessment and internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective actions plans shall be made available to OIG upon request;
16. a summary of the disclosures in the disclosure log required by Section III.I that: (a) relate to the EHR Software; (b) relate to Federal health care programs, including payment programs involving the use of health information technology and the regulations and other guidance related to these programs; (c) relate to the Health IT Certification Program; or (d) involve allegations that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute (the complete disclosure log shall be made available to OIG upon request);
17. a summary of Reportable Events (as defined in Section III.L) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
18. a certification that eCW has completed the screening required by Section III.J regarding Ineligible Persons;
19. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.K. 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;

20. a certification from the Compliance Officer that information regarding Payments has been posted on eCW's website as required by Section III.M;

21. a description of all changes to the most recently provided list of eCW's locations (including addresses) as required by Section V.A.17; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; and

22. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 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.

Within 180 days of the submission of each Annual Report, eCW shall participate in an in-person meeting with representatives of OIG to review eCW's performance under the CIA. OIG, in its discretion, may waive this meeting requirement.

### C. Certifications

1. *Certifying Employees.* In each Annual Report, eCW shall include the certifications of Certifying Employees as required by Section III.A.3.

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

- a. to the best of his or her knowledge, except as otherwise described in the report, eCW is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, eCW has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, including the Focus Arrangements Procedures required in Section III.F of the CIA;

- c. to the best of his or her knowledge, eCW has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.F.2 of the CIA; and
- d. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful.

D. Designation of Information. eCW 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. eCW 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

eCW:

Michael D. Laycob  
Compliance Officer  
eClinicalWorks, LLC  
2 Technology Drive  
Westborough, MA 01581

Telephone: 508-836-2700 x18073

Email: [Michael.Laycob@eclinicalworks.com](mailto:Michael.Laycob@eclinicalworks.com).

Unless otherwise specified, all notifications and reports required by this CIA may be made by overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, eCW may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

## **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 examine or request copies of eCW's software code (source and production codes, as needed) books, records, and other media, documents and supporting materials and/or conduct on-site reviews of any of eCW's locations or locations hosting eCW products and services, for the purpose of verifying and evaluating: (a) eCW's compliance with the terms of this CIA; and (b) eCW's compliance with applicable laws and regulations, the requirements of the Federal health care programs, including payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and the ONC Health IT Certification Program. The documentation described above shall be made available by eCW to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of eCW's employees, contractors, or agents 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. eCW shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. eCW's Covered Persons may elect to be interviewed with or without a representative of eCW present.

## **VIII. DOCUMENT AND RECORD RETENTION**

eCW shall not be required to provide OIG with copies of its source code, user guides and other sensitive intellectual property. However, eCW shall maintain for inspection all of eCW's relevant source code, all historical versions, and related media, and documents and records relating 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 eCW prior to the release of information submitted by eCW pursuant to its obligations under this CIA and identified upon submission by eCW as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, eCW shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

eCW is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, eCW and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day eCW fails to establish and effectively implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the management certification obligations;
- d. an EHR Quality Assurance Program;

- e. a Dashboard;
- f. a written Code of Conduct;
- g. written Policies and Procedures;
- h. the training of Covered Persons, Relevant Covered Persons, and Arrangements Covered Persons in the manner required by Section III.C;
- i. retention of a SQOO;
- j. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;
- k. a risk assessment and internal review process;
- l. a Disclosure Program;
- m. Ineligible Persons screening and removal requirements;
- n. notification of Government investigations or legal proceedings;
- o. reporting of Reportable Events; and
- p. posting of any Payment-related information as required by Section III.M.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day eCW fails to engage and use an IRO, as required by Section III.G., Appendix A, or Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day eCW fails to submit a complete Implementation Report, Annual Report, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day eCW fails to submit any Arrangements Review Report in accordance with the requirements of Section III.G and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day eCW fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date eCW fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of eCW as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day eCW fails to pay a SQOO, as required in Section III.E.8.

8. A Stipulated Penalty of \$2,500 for each day eCW fails to comply fully and adequately with any of its obligations with respect to the SQOO, including, but not limited to, the obligation to adequately and timely respond to any written recommendation of the SQOO as set forth in Section III.E. OIG shall provide notice to eCW stating the specific grounds for its determination that eCW has failed to comply fully and adequately with the CIA obligation(s) at issue and steps eCW shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after eCW receives this notice from OIG of the failure to comply.)

9. A Stipulated Penalty of \$2,500 per day (which shall begin to accrue on the day after the obligation became due) for:

- a. Each day that eCW is late in issuing any Customer Notification to its Existing Customers as required by Section III.D.3 of this CIA.
- b. Each day that eCW is late in providing a copy of its notifications to the SQOO as required by Section III.D.4 of this CIA.

- eCW:
10. A Stipulated Penalty of \$25,000 for each instance in which
    - a. Refuses, or seeks to impose impermissible costs or fees in respect of, the transfer of data upon an Existing Customer exercising a Data Transfer Option, as discussed in Section III.D.2 above.
    - b. Refuses, or seeks to impose impermissible costs or fees in respect of, the upgrading of an Existing Customer's EHR Software upon the Existing Customer exercising an Upgrade Option, as discussed in Section III.D.1 above.
    - c. Enters into a contract or agreement with a customer for the provision of the EHR Software and/or related services that contains provisions that restrict or prohibit the customer's rights to discuss problems with the EHR Software or eCW's services, in any forum whatsoever.
    - d. Takes action, whether by enforcing a contractual right or otherwise, and whether by formal legal process or otherwise, that has the effect of restricting or prohibiting a customer's right to discuss problems with the EHR Software or eCW's services, in any forum whatsoever (though nothing in this section is intended to require eCW to continue providing financial or other support to any particular forum).

11. A Stipulated Penalty of \$1,000 for each day eCW fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to eCW stating the specific grounds for its determination that eCW has failed to comply fully and adequately with the CIA obligation(s) at issue and steps eCW shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after eCW receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. eCW 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. Notwithstanding any other provision in this Section, 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 eCW fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, 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 eCW 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.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that eCW has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify eCW of: (a) eCW's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, eCW shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS ALJ to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event eCW elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until eCW cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.E.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that eCW has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by eCW to report a Reportable Event and take corrective action as required in Sections III.L;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to retain, pay, or use the SQOO, or failure to respond to the recommendations of the SQOO, in accordance with Section III.E; or
- e. a failure to engage and use an IRO in accordance with Section III.G, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* OIG and eCW agree that a material breach of this CIA by eCW constitutes an independent basis for eCW'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 per material breach. Upon a determination by OIG that eCW has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify eCW of: (a) eCW's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.").

3. *Opportunity to Cure.* eCW shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30-day period, but that: (i) eCW has begun to take action to cure the material breach; (ii) eCW is pursuing such action with due diligence; and (iii) eCW has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, eCW fails to satisfy the requirements of Section X.D.3, OIG may exclude eCW from participation in the Federal health care programs. OIG shall notify eCW in writing of its determination to exclude eCW. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of eCW's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, eCW may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to eCW of its Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, eCW 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 as if they applied to the specific performance, Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be

found at:

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

2. *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 eCW was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. eCW shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders eCW to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless eCW requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *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 eCW was in material breach of this CIA and, if so, whether:

- a. eCW cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following eCW's receipt of the Notice of Material Breach: (i) eCW had begun to take action to cure the material breach; (ii) eCW pursued such action with due diligence; and (iii) eCW provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for eCW, only after a DAB decision in favor of OIG. eCW's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude eCW upon the issuance of an

ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that eCW may request review of the ALJ decision by the DAB. 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. eCW shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of eCW, eCW shall be reinstated effective on the date of the original exclusion.

4. *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. Consequently, 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.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

eCW 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 eCW's obligations under this CIA based on a certification by eCW that it is no longer providing health care items or services that will be billed to any Federal health care program, including payment programs involving the use of health information technology, and that 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 eCW is relieved of its CIA obligations, eCW will be required to notify OIG in writing at least 30 days in advance if eCW plans to resume providing health care items or services that are billed to any Federal health care program, including payment programs involving the use of health information technology, 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) eCW's responsibility to follow all applicable Federal health care program requirements, including the requirements of the payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and ONC Health IT Certification Program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable requirements of the Federal health care programs, including the requirements of the payment programs involving the use of health information technology and the regulations and other guidance related to these programs, and ONC Health IT Certification Program requirements.

E. The undersigned eCW 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. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF eCLINICALWORKS, LLC**

/Girish Navani/

5/26/2017

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GIRISH NAVANI  
Chief Executive Officer  
eClinicalWorks, LLC

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DATE

/R. Joseph Burby, IV/

5/26/17

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R. JOSEPH BURBY, IV  
Bryan Cave LLP  
Counsel for eClinicalWorks, LLC

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DATE

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

/Lisa M. Re/

5/30/2017

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LISA M. RE

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DATE

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

/John W. O'Brien/

05/26/2017

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JOHN W. O'BRIEN

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DATE

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

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. eCW 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 D, below. Within 30 days after OIG receives the information identified in Section V.A.13 of the CIA or any additional information submitted by eCW in response to a request by OIG, whichever is later, OIG will notify eCW if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, eCW may continue to engage the IRO.

2. If eCW 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, eCW shall submit the information identified in Section V.A.13 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 eCW at the request of OIG, whichever is later, OIG will notify eCW if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, eCW may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations and other guidance documents related to this statute; and

2. 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 Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Arrangements 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.

E. IRO Removal/Termination

1. *eCW and IRO.* If eCW terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, eCW 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. eCW 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 that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify eCW in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. eCW 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 eCW regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify eCW in writing that eCW shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. eCW 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 eCW to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to eCW's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If eCW materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of eCW's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. eCW's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;
2. eCW's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. eCW's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
4. eCW's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
5. eCW's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority

to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

6. eCW's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by eCW, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

7. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, eCW's internal review and approval process, and other Arrangements systems, processes, policies, and procedures;

8. eCW's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

9. eCW's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.F.2 of the CIA.

**B. Arrangements Systems Review Report.** The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of eCW's systems, policies, processes, and procedures relating to the items identified in Section A.1-9 above;

3. findings and supporting rationale regarding weaknesses in eCW's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve eCW's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-9 above.

**C. Arrangements Transactions Review.** The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus

Arrangements that were entered into or renewed by eCW during the Reporting Period. The IRO shall assess whether eCW has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.F.1 and III.F.2 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in eCW's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (*i.e.*, the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.);

2. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;

3. verifying that the remuneration related to the Focus Arrangement is properly tracked;

4. verifying that the service and activity logs are properly completed and reviewed (if applicable);

5. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

6. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.F.2 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.

- a. Review Protocol. A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.

- b. Sources of Data. A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and eCW shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from eCW after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction 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 Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The IRO's findings with respect to whether eCW has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to eCW's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.