

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

I. PREAMBLE

Greenway Health, LLC, (Greenway) 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 (ONC Health IT Certification Program requirements). Contemporaneously with this CIA, Greenway 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 Greenway 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) Greenway’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. “Prime Suite” refers to all versions of the electronic health record product(s) and related services or solutions (and any updates thereto) marketed by Greenway under the name or brand Prime Suite and marketed as “ONC Certified Health IT” under the ONC Health IT Certification Program.

2. “Health IT Software” refers to all software and related services or solutions (and any updates thereto), including Prime Suite, being developed, developed or marketed by Greenway 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.

3. “Covered Persons” includes:

- a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired ownership interest through public trading), officers, directors, and employees of Greenway; and
- b. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions (as defined below in Section II.C.5); provided, however, that the employees of any contractor or subcontractor that performs any of the Covered Functions on behalf of Greenway shall not be considered Covered Persons if the contractor or subcontractor provides an annual certification that, with respect to its employees who perform Covered Functions on behalf of Greenway, such contractor or subcontractor:

- (1) has a policy of not employing any person who is excluded from participation in any Federal health care program to perform any duties related directly or indirectly to the performance of any of the Covered Functions defined in Section II.C.5 of this CIA, including the preparation or submission of requests for payment submitted by users of the Health IT Software to Federal health care programs, including payment programs involving the use of health information technology;

- (2) screens its prospective and current employees against the Exclusion List; and

- (3) provides training to its employees, as appropriate based on the Covered Functions for which they are responsible, on the following:

(i) the personal obligations of each individual involved in developing, testing, certifying, implementing, and supporting Health IT Software, as defined in Section II.C.2 of this CIA, to ensure that it meets Software Standards and Practices and the ONC Health IT Certification Program Requirements;

(ii) examples of software defects, usability problems, deficiencies, and other issues with Health IT Software and the procedures in place to address them;

(iii) the 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;

(iv) the personal obligations of each individual involved in the sale, marketing, licensing, contracting, and/or distribution of Health IT Software to perform the Obligations to Existing and Future Customers in Section III.D of this CIA and to comply with the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

If applicable, a copy of this certification shall be included in each Annual Report Required by Section V of this CIA, below.

4. “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.

5. “Covered Functions” means the following services provided for Greenway or on Greenway’s behalf:

a. the design, development, marketing, implementation, and/or support of Health IT Software;

- b. the testing, certification, and/or maintenance of certification (including surveillance and direct review) of Health IT Software, including PrimeSuite, under the ONC Health IT Certification Program, excluding when provided by an ONC-ACB;
- c. the sale, marketing, licensing, contracting, and/or distribution of Health IT Software;
- d. the preparation or submission of any attestation, application, report, or other communication relating to Health IT Software to ONC, an ONC-ACB (as defined in Section II.C.13), 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. the preparation or submission of any attestation, report or other data for submission to the Centers for Medicare & Medicaid Services (CMS) (including the preparation, delivery, and submission of data that Greenway provides to its customers to submit to CMS);
- f. handling, assessing, and/or responding to Greenway customer complaints and alerts, including any potential and identified Patient Safety Issues (as defined below) related to Health IT Software;
- g. tracking and/or taking corrective actions in response to potential and identified Certification Issues (as defined below) and other issues with Health IT Software;
- h. performing audit or review functions of the Health IT Software; or
- i. 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.L).

6. “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 Greenway and any actual or potential source of health care business or referrals to Greenway or any actual or potential recipient of health care business or referrals from Greenway.

7. 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.

8. The term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom Greenway refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Greenway 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.

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

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

11. “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 Health IT systems (including supporting clinical decision-making, health care, and the provision of medical care to patients) as described in Section III.A.2.b of this CIA, below.

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

13. “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, Health IT Module, and other types of health IT under the ONC Health IT Certification Program.

14. “Patient Safety Issue” means a defect, deficiency, design flaw, usability problem, or other condition with respect to Health IT Software that reasonably presents a material risk of harm to patients.

15. “Certification Issue” means, for any aspects of Health IT Software that are certified under the ONC Health IT Certification Program, any concern, event, incident or other issue that reasonably calls into question the Health IT Software’s conformity with any requirement of the ONC Health IT Certification Program.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee, Board of Managers, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Greenway shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Greenway, shall report directly to the Chief Executive Officer of Greenway, 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 Greenway. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices to ensure:
 - i. adherence to professionally recognized Software Standards and Practices, including those recommended by the Independent Review Organization described in Section III.F of this CIA. 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 Health IT systems (including supporting clinical decision-making, health care, and the provision of medical care to patients). Such standards and practices may include without limitation:

- (1) relevant standards, checklists, self-assessment tools, and other practices identified in the ONC SAFER guides to optimize the safety and safe use of Health IT 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;
- (2) relevant standards and practices developed or identified through health IT safety initiatives, such as the ECRI Institute's Partnership for Health IT Patient Safety;
- (3) relevant software development standards developed or identified through Standards Development Organizations (SDO) such as the ISO 35.080 Software standards;
- (4) a formal quality management system developed either by the Federal government or a recognized 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
- (5) any other appropriate and relevant

professionally-recognized standards identified by an independent third party software consultant and/or the IRO.

- 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, and/or Federal health care programs, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to these programs;
 - 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 data security, integrity, and privacy obligations, including those described under the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and
 - vi. compliance with all other requirements set forth in this CIA.
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Managers (Board) of Greenway and its ultimate parent company, Lightning Holdings, LLC, and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and

- c. monitoring the day-to-day compliance activities engaged in by Greenway, including ensuring that Greenway is adhering to Software Standards and Practices; timely and effectively identifying and addressing Patient Safety Issues 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 ONC 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.

Greenway 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 Committee.* Within 90 days of the Effective Date, Greenway shall appoint a Compliance Committee.

- a. *General Responsibilities.* This Compliance Committee shall 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 Health IT Software; (iii) testing and certification of Health IT Software and identifying and addressing Certification Issues; (iv)

implementation of Health IT Software; (v) other customer support in connection with the Health IT Software; (vi) contracting and/or licensing of Health IT Software; (vii) sales, marketing, and/or distribution of Health IT Software; (viii) legal; and (ix) 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 Greenway 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, corrective actions planned (with a projected time table for implementation) and/or implemented in response to any such concerns, and the resolution status of any such concerns. The report on the resolution status shall include (a) a report on whether the corrective action was implemented as planned and/or whether there was any deviation from the planned corrective action and/or new finding(s); (b) the time it took to implement the corrective action; and (c) whether the concern is considered closed. The minutes of the Compliance Committee meetings shall be made available to the OIG upon request.

Greenway 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, Greenway 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 Greenway's adherence to the Software Standards and Practices, the Policies and Procedures, and the requirements

of this CIA including:

- i. whether Greenway is adhering to and/or in the process of timely implementing Software Standards and Practices;
- ii. whether Greenway 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 Greenway is reviewing, tracking, and completing root cause analyses of such potential and identified Patient Safety Issues and Certification Issues;
- iv. whether Greenway is promptly notifying customers and users, if applicable, of Patient Safety Issues and Certification Issues, including whether appropriate urgency is being given to Patient Safety Issues;
- v. whether Greenway is, where applicable, reporting Patient Safety Issues and Certification Issues to the Compliance Officer, Compliance Committee, IRO (see Section III.F), any ONC-ACBs with certification or surveillance responsibilities for Health IT Software, and OIG;
- vi. whether Greenway 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 Greenway; (3) the actions Greenway 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 Greenway’s action plans for responding to identified Patient Safety and Certification Issues are adequate to fully address and remedy the issue and any associated risks to patient safety, and are implemented and enforced in a timely and effective manner;
- viii. whether Greenway is effectively coordinating quality assurance activities across its business divisions, teams, and other internal units;
- ix. whether Greenway is taking all other reasonable actions to timely and effectively identify and address Patient Safety Issues and Certification Issues with Health IT Software, including remediating identified issues and mitigating any associated risks to patient safety;
- x. whether Greenway and Health IT Software conforms to applicable ONC Health IT Certification Program requirements and 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;
- xi. whether Greenway is taking the necessary actions in good faith to perform its Obligations to Existing and Future Customers (as described in Section III.D below); and
- xii. whether Greenway is complying with the relevant law, including federal and state statutes, regulations, and ONC and CMS directives, applicable to Health IT Software.

3. *Board Compliance Obligations.* The Board of Greenway shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, the ONC Health IT Certification Program requirements, and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

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

- a. meeting at least quarterly to review and oversee Greenway's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of Greenway's compliance with Federal health care program requirements, the ONC Health IT Certification Program requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Greenway's Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Greenway has implemented an effective Compliance Program to meet Federal health care program requirements, the ONC Health IT Certification Program requirements, and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Greenway.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Greenway employees (Certifying

Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Greenway department has adhered to the 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, Greenway'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, the Chief Executive Officer, the Chief Financial Officer, the Chief Operations Officer, the Chief Medical Officer, the Compliance Officer, the Chief Technology Officer, the Chief Revenue Officer, the senior executive over human resources, software development and product management, and the lead individual responsible for Patient Safety Issues and Certification Issues. 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 Greenway: (1) 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; (2) complies with all obligations and reporting requirements of the Corporate Integrity Agreement; and (3) complies with Greenway's Policies 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 Greenway 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; Greenway's Policies 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 90 days after the Effective Date, Greenway shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Greenway 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. Greenway'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 Greenway's obligations under the CIA;
- b. Greenway'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 Greenway's Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA); and perform Greenway's other obligations under the CIA;
- c. the requirement that all of Greenway's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Greenway, 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 Greenway Policies

and Procedures; and any failure to perform Greenway's obligations under the CIA;

- d. the requirement that all of Greenway's Covered Persons shall immediately report to the Compliance Officer, or other appropriate individual designated by Greenway, any potential or identified software defects, usability problems, deficiencies, or other issues with Health IT Software that may present Patient Safety Issues or Certification Issues;
- e. the possible consequences to both Greenway 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 Greenway's 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.H of this CIA, and Greenway's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

At least annually (and more frequently, if appropriate), Greenway shall assess and update, as necessary, the Code of Conduct. Any new or revised Code of Conduct shall be made available to all Covered Persons.

The Code of Conduct shall be made available to OIG upon request.

2. *Policies and Procedures.* Within 120 days after the Effective Date, Greenway shall develop and implement written Policies and Procedures, as set forth below. Throughout the term of this CIA, Greenway 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. the ONC Health IT Certification Program requirements and the 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 Greenway customers, users, ONC-ACBs with certification or surveillance responsibilities for Health IT Software, ONC itself, and OIG of Patient Safety Issues and Certification Issues, along with a detailed description of how Greenway will be correcting the problem, instructions as to any actions the customers and users should take to mitigate the risk while it is being corrected, and informing all of the above when the problem is corrected;
- e. addressing and remedying 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, within the timeframes followed for Patient Safety Issues as identified herein for Reportable Events under Section III.K of this CIA, below;
- f. ensuring that Greenway's customers and users of Health IT 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 Greenway and communications from Greenway;
- g. maintaining on Greenway'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 the items on the list are not removed until fully resolved and reported on the customer portal as fully resolved and only after IRO review and approval of such removal;

- h. developing and implementing software modifications to address Patient Safety Issues and communication procedures for informing Greenway customers and users regarding upgrades and changes to Health IT 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 Greenway's processes for software development, implementation, maintenance, and customer support;
- j. implementing and consistently adhering to Software Standards and Practices;
- k. ensuring that Greenway complies with its Obligations to Existing and Future Customers;
- l. ensuring that all contracts and agreements entered into for the provision of Health IT Software and any associated services do not prohibit or restrict the right of Greenway's customers to disclose to any person or entity information relating to the performance of Health IT Software, including for patient safety, public health, and quality improvement purposes, as set forth in Section III.D of this CIA;
- m. 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;
- n. the requirements set forth in Section III.E (Compliance with the Anti-Kickback Statute);
- o. compliance with data security, integrity, and privacy obligations, including those described under HIPAA; and

- p. compliance with all other requirements set forth in this CIA.

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), Greenway 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. *Covered Persons Training.* Within 120 days after the Effective Date, Greenway shall develop a written plan (Training Plan) that outlines the steps Greenway will take to ensure that: (a) all Covered Persons receive adequate training regarding Greenway'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 Health IT 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 Greenway's business divisions, teams, and other internal units on quality management of Health IT Software; (iv) the personal obligations of each individual involved in developing, testing, certifying, implementing, and supporting Health IT 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 Health IT 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 Health IT Software to perform the Obligations to Existing and Future Customers. The Training Plan shall also include training to address the lessons learned from any Patient Safety Issues and Certification Issues with Health IT Software. In determining what training should be provided,

Greenway shall consider at least the following: 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 internal reviews, and the findings, reports, and recommendations of the IRO or ONC-ACB.

In addition, the Training Plan shall outline the steps Greenway 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) Greenway'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 Greenway's Arrangements to know the applicable legal requirements and Greenway'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 approximate schedule for training, and the format of the training. Greenway may modify the Training Plan annually to ensure it reflects the then-current needs of the Company and shall furnish such training to its Covered Persons, Relevant Covered Persons, and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 90 days after the Effective Date, each member of the Board shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

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

3. *Training Records.* Greenway shall make available to OIG, upon request, training materials and records verifying that Covered Persons, Relevant Covered Persons, Arrangements Covered Persons, and Board members have timely received the training required under this section.

D. Obligations to Existing and Future Customers

1. *Provision of Upgrade Option and Migration Option to Existing Prime Suite Customers.* Greenway shall as soon as practicable after the Effective Date make available to each of Greenway's customers with a signed and current Software Agreement for the use of Prime Suite ("Existing Prime Suite Customers") the latest versions of Prime Suite in the same Greenway-hosted or self-hosted model and the latest updates to all databases, including any drug database, needed to operate the latest version of the ONC certified Prime Suite (the "Upgrade Option"). Greenway shall also offer to each of Greenway's Existing Prime Suite Customers the opportunity to migrate all data from Prime Suite to another Health IT Software product developed by Greenway (the "Migration Option").

a. The Upgrade Option and the Migration Option shall be provided at no additional charge to the Existing Prime Suite Customer (including, without limitation, any fees for implementation, onsite installation, or training services).

i. Consistent with the above, Greenway may charge Existing Prime Suite Customers reasonable and customary fees for training or implementation that are unrelated to (1) the exercise of the Upgrade Option or Migration Option and (2) the implementation of upgraded Health IT Software and all database updates, including any drug database updates, needed to operate the latest version of the Health IT Software.

b. As part of the Upgrade Option and the Migration Option, throughout the then-current term of the Existing Prime Suite Customer's Software Agreement, and unless otherwise agreed and documented in writing between Greenway and the Existing Prime Suite Customer, Greenway shall provide to each Existing Prime Suite Customer:

i. release notes, documentation, webinars, tools, and other customary implementation support; and

ii. such further updates, upgrades, software defect fixes, and patches to Prime Suite or the applicable migrated to Health IT Software and

all supported databases as necessary to ensure that Prime Suite or the applicable migrated to Health IT Software conforms with the ONC Health IT Certification Program requirements, 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, adheres to 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 Prime Suite Customer does not preclude, limit, or in any way alter the right of the Existing Prime Suite Customer from also exercising the Migration Option and/or the Data Transfer Option.

d. The exercise of the Migration Option by an Existing Prime Suite Customer does not preclude, limit, or in any way alter the right of the Existing Prime Suite Customer from also exercising the Data Transfer Option.

2. *Data Transfer Option for Existing Prime Suite Customers.* Upon written request by an Existing Prime Suite Customer, Greenway shall timely transfer, within 30 days of Greenway's receipt of the written request or such later date as mutually agreed upon between Greenway and the customer, any Existing Prime Suite Customer's data without penalties, service charges, or any other fees (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"). Greenway shall use reasonable commercial efforts to timely transfer within 30 days of the customer's written request or such later date as mutually agreed upon between Greenway and the customer all Existing Prime Suite Customer's data. Greenway shall comply at all times with data portability requirements and prohibitions and limitations on data blocking in connection with Health IT Software.

a. An Existing Prime Suite Customer must exercise the Data Transfer Option by providing written notification to Greenway within one year of the Customer Notification (described in Section III.D.3 below), with the execution by Greenway of the transfer within thirty days of Greenway's receipt of the written notification or such later date as mutually agreed upon between Greenway and the customer.

b. Upon an Existing Prime Suite Customer's exercise of the Data

Transfer Option, Greenway shall transfer all data held by Greenway on behalf of the Existing Prime Suite Customer (including protected health information, and all other data and information provided by the Existing Prime Suite Customer or which Greenway develops or receives on behalf of the Existing Prime Suite Customer, or has access to in connection with the Software Agreement) to the Existing Prime Suite Customer or its designee in a commercially reasonable, structured format that allows for the Existing Prime Suite Customer's data to be migrated to and useable by the Existing Prime Suite Customer's subsequent Health IT system and vendor, and provide timely good faith instructions on how this data is to be accessed by the Existing Prime Suite Customer and/or by the Existing Prime Suite Customer's subsequent Health IT vendor.

i. The following data transfer format shall be considered to meet the requirements of this section:

a) All structured Health IT data (including free text notes associated with a patient's chart) provided in an unencrypted Microsoft SQL server database backup on a hard drive, with the exception of large note types and imaging Progress Notes which will be delivered on a hard drive as a PDF in a folder indexed per patient;

b) All scanned documents, unencrypted, in file folders on a hard drive;

c) Providing the Existing Prime Suite Customer with the ability to export all patient data in C-CDA format until the time Greenway delivers to the Existing Prime Suite Customer a hard drive containing the data described above.

ii. For self-hosted Existing Prime Suite Customers who have control over their own information, Greenway shall also remove any encryption or other limitations in order to enable the Existing Prime Suite Customer to fully access and transfer all required information.

Existing Prime Suite Customers requiring a hard drive from Greenway to effectuate the Data Transfer will be responsible for the cost of the hard drive at the then standard rate.

3. *Notifications to Existing Prime Suite Customers.* Greenway shall provide notifications to its Existing Prime Suite Customers that meet the following requirements

(“Customer Notifications”).

a. *Customer Notification, Timing, and Content.* Within 60 days after the Effective Date, Greenway shall cause to be sent to Existing Prime Suite Customers a Customer Notification with the following format and content:

i. The Customer Notification shall be on Greenway letterhead.

ii. The Customer Notification shall include the following heading: **“IMPORTANT INFORMATION ABOUT YOUR HEALTH IT SOFTWARE AND SERVICES. YOU HAVE NEW OPTIONS FREE OF CHARGE TO YOU.”**

iii. The Customer Notification must include the following introductory statement: “Greenway 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 Existing Prime Suite Customers.”

iv. The Customer Notification must contain the following promises and undertakings from Greenway to each Existing Prime Suite Customer, and Greenway must present such promises and undertakings, and do all other things necessary, to make the promises and undertakings legally binding and enforceable against Greenway:

(a) Each Existing Prime Suite Customer has the opportunity to receive from Greenway, at no additional charge to the Existing Prime Suite Customer (including, without limitation, any implementation fee, onsite installation fee, or training fee):

(1) an upgrade to the latest production version of similarly hosted Prime Suite in use by the Existing Prime Suite Customer;

(2) an upgrade to the latest update of all databases, including any drug database, needed to operate the latest version of the ONC certified Prime Suite currently being used by the Existing Prime Suite Customer;

(3) the opportunity to migrate all their data from

Prime Suite to another similarly hosted Health IT Software product developed by Greenway; and

(4) upon written request to Greenway made by the Existing Prime Suite Customer within one year of this notice, the opportunity to transfer all data from Prime Suite to the Existing Prime Suite Customer or its designee Health IT vendor.

(b) throughout the then-current term of the Existing Prime Suite Customer's Software Agreement, the Existing Prime Suite Customer also has the opportunity to receive from Greenway, at no additional charge to the Existing Prime Suite Customer (including, without limitation, any fees for implementation, installation, or training services) such further updates, upgrades, software defect fixes, and patches to Prime Suite and all supported databases, including any drug database, as necessary to ensure that Prime Suite conforms with the ONC Health IT Certification Program requirements, 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, adheres to Software Standards and Practices, and complies with any other applicable federal and state statutes, regulations, and directives.

b. The Customer Notification must not have the effect of extinguishing any rights accrued by the Existing Prime Suite Customer under its Software Agreement, or any other agreement between the Existing Prime Suite Customer and Greenway, up until the date of the Customer Notification, under the doctrine of merger or otherwise.

c. All written Customer Notifications must be sent by either mail or email:

i. in a manner consistent with Greenway's customary means of communicating with its customers; and/or

ii. to any other person or position of the Existing Prime Suite Customer that Greenway deals with on a regular basis regarding the Existing Prime Suite Customer's access to and use of the Health IT Software and Greenway's services.

4. *Implementation of Obligations to Existing Prime Suite Customers.*

a. Greenway shall maintain copies of all written Customer Notifications sent by Greenway to Existing Prime Suite Customers. Any or all copies of the written Customer Notifications shall be provided to OIG and/or the IRO upon request.

b. Greenway must take all actions necessary to give effect to the Customer Notification requirements of this CIA, including without limitation to ensure every Existing Prime Suite Customer has received the Customer Notifications required by the CIA.

c. Where applicable, Greenway will encourage Existing Prime Suite Customers to exercise the Upgrade Option or Migration Option, including by timely informing any Existing Prime Suite Customer that has not exercised the Upgrade Option or Migration Option of any Patient Safety Issues, if applicable, associated with the Health IT Software version they are using.

d. Within 60 days after the Effective Date and continuing throughout the term of this CIA, Greenway shall maintain a record of the names, organizations, and contact information of all Existing Prime Suite Customers. Such record shall also include information for each Existing Prime Suite Customer regarding the Customer Notification the customer has received; the date each such Customer Notification was made; whether the Existing Prime Suite Customer has exercised (a) the Upgrade Option, (b) the Migration Option, and/or (c) the Data Transfer Option; the date(s) on which the Existing Prime Suite Customer exercised such options(s), as applicable; and the current status of the software upgrade(s) and/or data transfer, as applicable.

e. Greenway shall, on request by OIG and/or the IRO, provide information and/or access to records to OIG and/or the IRO regarding the actions taken and the records maintained by Greenway 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 Prime Suite Customer's Software Agreement, and the full performance of Greenway's obligations to transfer the Existing Prime Suite Customer's data in accordance with the Data Transfer Option, if Greenway, at the Existing Prime Suite Customer's request, provides the Existing Prime Suite Customer with continued access to Greenway's Health IT Software, Greenway may charge for such access:

a. the contractual monthly fees set forth in the Existing Prime Suite Customer's Software Agreement; or

b. where the Existing Prime Suite Customer solely requests “read only” access to its cloud-based Greenway data, the fees specified by Greenway’s then-current read only access rate structure.

6. *Permitting Customers to Report and Discuss Problems.* Greenway must not restrict or prohibit, by contract or otherwise, the rights of customers, former customers, any new customers, or users of Health IT Software to discuss problems with Health IT Software or associated services in any forum whatsoever, and Greenway agrees that it will not enforce any rights it has under contracts with customers or former customers that restrict or prohibit those customers or former customers from discussing problems with Health IT Software or associated services in any forum whatsoever.

7. *New Agreements Must Protect Customer’s Rights to Report and Discuss Problems.* Greenway must ensure that all contracts and agreements entered into for the provision of Health IT Software and any associated services do not restrict or prohibit Greenway’s customers from disclosing to any person or entity information relating to the performance of Health IT 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 Health IT implementation and clinician use;
- c. reporting of Health IT-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. Compliance with the Anti-Kickback Statute

1. *Focus Arrangements Procedures.* Within 120 days after the Effective Date, Greenway 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, and guidance related to this statute (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 and the information specified in Sections III.E.1.b-f below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System);
- b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;
- c. tracking all remuneration to and from all parties to Focus Arrangements, to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;
- d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);
- e. 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);
- f. 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);
- g. establishing and implementing a written review and approval process for 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 and documenting 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;

- h. ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.E.1.g above;
- i. 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
- j. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

2. *New or Renewed Focus Arrangements.* No later than 120 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, Greenway shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that all written Focus Arrangements are signed by Greenway and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;
- b. Ensure that all Focus Arrangements have been subject to the written review and approval process described in Section III.E.1.g prior to the payment or receipt of any remunerations pursuant to the Focus Arrangement, and that Greenway maintains appropriate documentation of the review and approval of such Focus Arrangement; and
- c. Include in any 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.* Greenway 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.

F. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Greenway shall engage an entity (or entities), such as an accounting, auditing or consulting firm with expertise in health information technology, to perform the Software Review described in Section III.F.3 and, within 90 days after the Effective Date, Greenway shall engage a law or consulting firm or a lawyer to perform the Arrangements Review described in Section III.F.2. The entity (or entities) engaged to perform the Software Review and the Arrangements Review are referred to hereinafter as the “Independent Review Organization” or “IRO.” 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 Greenway shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Greenway related to the reviews).
- c. *Responsibilities and Liabilities.* Nothing in this Section III.F affects Greenway’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.

- d. *Access to Records and Personnel.* Greenway shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.F and that all records furnished to the IRO are accurate and complete.

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. *Software Review.* The IRO shall perform a Software Review and prepare a Software Review Report as outlined in Appendix C to this CIA, which is incorporated by reference.

4. *Certifications.* The IRO for the Software Review shall include in its report(s) to Greenway a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.F 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 Greenway and the IRO. The IRO for the Arrangements Review shall include in its report(s) to Greenway a certification that the IRO (a) does not currently represent or is not currently employed or engaged by Greenway other than in its capacity as the IRO under this CIA and (b) does not have a current or prior relationship to Greenway or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Section III.F.

G. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Greenway shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with the quality of Health IT Software, including any Patient Safety Issues and Certification Issues, and with Arrangements (as defined in Section II.C., above). The risk assessment and internal review process shall require 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. Greenway shall maintain the risk assessment and internal review process for the term of the CIA.

H. Disclosure Program

Within 90 days after the Effective Date, Greenway 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 Greenway's policies, conduct, practices, or procedures with respect to (1) Health IT Software, (2) 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, or (3) the ONC Health IT Certification Program, believed by the individual to be a potential violation of criminal, civil, or administrative law. Greenway 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 Greenway'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 ONC Health IT Certification Program requirements to the Compliance Officer or other appropriate individual designated by Greenway. 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, Greenway shall conduct an internal review of the allegations set forth in the disclosure and ensure that appropriate follow-up and remediation is conducted. If a Patient Safety Issue is identified as a result of any disclosure, the Compliance Officer (or designee) shall take immediate steps to mitigate any associated risk while the Patient Safety Issue is being corrected.

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.

I. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion Lists” means the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>)

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

- a. Greenway 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. Greenway shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on a quarterly basis thereafter.
- c. Greenway shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in Section III.I affects Greenway’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Greenway understands that items or services

furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Greenway may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Greenway meets the requirements of Section III.I.

3. *Removal Requirement.* If Greenway has actual notice that a Covered Person has become an Ineligible Person, Greenway shall remove such Covered Person from responsibility for, or involvement with, Greenway'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 Greenway 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, Greenway shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of Health IT Software submitted for certification under the ONC Health IT Certification Program or the accuracy of any requests for payment submitted by users of Health IT Software to any Federal health care program.

J. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, Greenway shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Greenway conducted or brought by a governmental entity or its agents involving an allegation that Greenway 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. Greenway 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.

K. 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 Health IT 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, including the requirements of payment programs involving the use of health information technology and the regulations and other guidance related to those programs, 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.I.1.a; or
- e. The filing of a bankruptcy petition by Greenway.

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

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

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

- a. If the Reportable Event resulted in a patient death, patient hospital admission, or serious injury to a patient, Greenway shall, in writing and within 48 hours of determining that the Reportable Event exists, provide notice and the information specified by Section III.K.3.c to the IRO responsible for the Software Review, OIG and, any ONC-ACB(s) with responsibility for the certification or surveillance of the Health IT Software.
- b. If the Reportable Event did not result in a patient death, patient hospital admission, or serious injury to a patient,

Greenway 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.K.3.c to the IRO responsible for the Software Review and OIG.

- c. Greenway shall provide to the IRO responsible for the Software Review, OIG, and any ONC-ACB(s) with responsibility for the certification or surveillance of the Health IT Software:
 - i. a description of the steps taken by Greenway to identify the Patient Safety Issue or instance of actual or suspected patient harm related to the Health IT 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 Greenway's actions taken to correct the Reportable Event, including providing notice to users of the Health IT Software of any software defects, usability problems, deficiencies, or other issues that may present a risk to patient safety;
 - iv. any further steps Greenway 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.K.3.b, the current status of the Reportable Event and the estimated time to resolution.

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

III.K.1.b also provide notice and the following information to the IRO responsible for the Software Review and any ONC-ACB(s) with responsibility for the certification or surveillance of the Health IT Software:

- a. a complete description of all details relevant to the Reportable Event, including the relevant facts and persons involved, the period during which the conduct occurred, and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event (including applicable Federal health care program and ONC Health IT Certification Program requirements);
- c. a description of Greenway's actions taken to correct the Reportable Event; and
- d. any further steps Greenway plans to take to address the Reportable Event and prevent it from recurring.

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

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Greenway completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.K.1.e.* For Reportable Events under Section III.K.1.e, Greenway 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.

L. Reporting of Health Care Provider Payments.

1. *Reporting of Payment Information.* Within 90 days after the end of each calendar year during the term of this CIA, Greenway shall post on its website a report of the cumulative value of the Payments (as defined below) provided to all Health Care Providers (as defined below) from Greenway during the prior applicable calendar year. Each annual report shall be easily accessible and readily searchable.

Each report posted shall include a complete list of all Health Care Providers to whom Greenway 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 Greenway for contact purposes; and (iii) the aggregate value of the Payment(s) in the preceding year to each Health Care Provider. The report for the first reporting period shall report information regarding payments made between 120 days after the Effective Date and December 31, 2019.

2. *Definitions and Miscellaneous Provisions.*

- a. Greenway shall make each annual report of Payments available on its website during the term of the CIA. Greenway 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.L.1, "Payments" is defined to include all payments or transfer of value (whether in cash or in kind) made to Health Care Providers. The term "Payments" includes all indirect payments or other transfers of value made to a Health Care Provider through a third party

where Greenway 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 Greenway on behalf of a Health Care Provider. The term “Payments” excludes refunds of overpayments to Health Care Providers, settlement of disputes with Health Care Providers by way of payments, credits against invoices, or provision of additional services. The term “Payments” also excludes 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.L, 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 reimbursable by Federal health care programs, except for a physician or other individual who is a bona fide employee of Greenway.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Greenway 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. Greenway shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Greenway 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, Greenway 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 150 days after the Effective Date, Greenway 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 of the Board members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a description of the Quality Assurance Program required by Section III.A.2.b;
6. a copy of Greenway's Code of Conduct required by Section III.B.1;
7. 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);
8. the Training Plan required by Section III.C.1 and a description of the Board of Managers training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
9. a copy of the Customer Notification required by Section III.D.3;

10. a detailed description of the manner in which Greenway is implementing the Obligations to Existing and Future Customers described in Section III.D;

11. a description of (a) the Focus Arrangements Tracking System required by Section III.E.1.a, (b) the internal review and approval process required by Section III.E.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.E.1;

12. 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 Greenway or that it does not have a prohibited relationship with Greenway as set forth in Section III.F.4, as applicable;

13. a description of the risk assessment and internal review process required by Section III.G;

14. a description of the Disclosure Program required by Section III.H;

15. a description of the Ineligible Persons screening and removal process required by Section III.I;

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

17. a description of Greenway's corporate structure, including identification of any parent and sister companies, subsidiaries, affiliates, and their respective lines of business; and

18. the certifications required by Section V.C.2.

B. Annual Reports. Greenway shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

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

Compliance Committee members, a current list of the Board members who are responsible for satisfying the Board compliance obligations, and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

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

4. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

5. a summary of any significant changes or amendments to Greenway's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes;

6. a description of any changes to Greenway's Training Plan developed pursuant to Section III.C and summary of any Board training provided during the Reporting Period;

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

8. a detailed description of any changes to the manner in which Greenway is implementing the Obligations to Existing and Future Customers described in Section III.D;

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

10. a complete copy of all reports prepared pursuant to Section III.F and Greenway's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

11. a certification from the IRO regarding its professional independence and objectivity with respect to Greenway or that the IRO does not have a prohibited relationship with Greenway, as described in Section III.F.4, as applicable;

12. a description of any changes to the risk assessment and internal review process required by Section III.G., including the reasons for such changes;

13. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective actions plans shall be made available to OIG upon request;

14. a summary of the disclosures in the disclosure log required by Section III.H that: (a) relate to Health IT 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 of conduct 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);

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

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.J. 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;

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

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

19. a description of all changes to the most recently provided list of Greenway's locations (including addresses) as required by Section V.A.16;

20. a copy of any certifications from Greenway's contractors and/or subcontractors required by Section II.C.2.b (if applicable); and

21. 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.

C. Certifications

1. *Certifying Employees.* In each Annual Report, Greenway shall include the certifications of Certifying Employees as required by Section III.A.4.

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, Greenway is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, Greenway 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.E of the CIA;
- c. to the best of his or her knowledge, Greenway has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.E.2 of the CIA;
- 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; and

- e. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information. Greenway 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. Greenway 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

Greenway:
Susan Kohler, Chief Compliance Officer
Greenway Health, LLC
4301 W. Boy Scout Blvd., Suite 800
Tampa, FL 33637
Telephone: 813-202-5008
Email: Susan.kohler@greenwayhealth.com

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of Greenway's software code (source and production codes, as needed) books, records, other media, documents, and supporting materials and/or conduct on-site reviews of any of Greenway's locations or locations hosting Greenway products and services, for the purpose of verifying and evaluating: (a) Greenway's compliance with the terms of this CIA; and (b) Greenway'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 Greenway to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Greenway's owners, employees, contractors, and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Greenway shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Greenway's owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Greenway present.

VIII. DOCUMENT AND RECORD RETENTION

Greenway shall maintain for inspection by OIG or the IRO all of Greenway'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. Greenway shall not be required to give possession of its source code or other sensitive information to OIG or the IRO.

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 Greenway prior to the release of information submitted by Greenway pursuant to its obligations under this CIA and identified upon submission by Greenway as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Greenway shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

Greenway 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, Greenway 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 Greenway fails to establish, implement and comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations;
- d. the management certification obligations;
- e. a Quality Assurance Program;
- f. a written Code of Conduct;
- g. written Policies and Procedures;
- h. the development of a written training plan and the training and education of Covered Persons and Board Members;
- i. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;
- j. a risk assessment and internal review process;
- k. a Disclosure Program;
- l. Ineligible Persons screening and removal requirements;

- m. notification of Government investigations or legal proceedings;
- n. reporting of Reportable Events; and
- o. posting of any Payment-related information as required by Section III.L.

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 Greenway fails to engage and use an IRO, as required by Section III.F., Appendix A, Appendix B, or Appendix C.

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 Greenway 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 Greenway fails to submit any Arrangements Review Report in accordance with the requirements of Section III.F and Appendix B.

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

6. A Stipulated Penalty of \$2,500 for each day Greenway fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.F., and for each day Greenway fails to furnish accurate and complete records to the IRO, as required by Section III.F and Appendix A.

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

8. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Greenway as part of its Implementation Report, any Annual

Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

9. A Stipulated Penalty of \$2,500 per day (which shall begin to accrue on the day after the obligation became due) for each day that Greenway is late in issuing the Customer Notification to its Existing Prime Suite Customers as required by Section III.D.3 of this CIA.

10. A Stipulated Penalty of \$2,500 per day (which shall begin to accrue on the day after the obligation became due) for each day that Greenway fails to establish, implement, and comply with the Implementation of Obligations to Existing Prime Suite Customers as described in Section III.D.4 of this CIA;

11. A Stipulated Penalty of \$25,000 for each instance in which Greenway:

- a. Refuses, or seeks to impose impermissible costs or fees in respect of, the transfer of data upon an Existing Prime Suite 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 or migrating of an Existing Prime Suite Customer's Prime Suite Software upon the Existing Prime Suite Customer exercising an Upgrade Option or Migration Option, as discussed in Section III.D.1 above.
- c. Enters into a contract or agreement with a customer for the provision of Health IT Software and/or related services that contains provisions that restrict or prohibit the customer's rights to discuss and/or disclose problems with the Health IT Software or Greenway's services, in any forum whatsoever, as discussed in Section III.D.6 and 7, above.
- 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 and/or disclose problems with Health IT Software or Greenway's services, in any forum whatsoever,

as discussed in Section III.D.6 and 7, above.

12. A Stipulated Penalty of \$1,000 for each day Greenway fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Greenway stating the specific grounds for its determination that Greenway has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Greenway shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Greenway 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 1-11 of this Section.

B. Timely Written Requests for Extensions. Greenway 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 Greenway 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 Greenway 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 Greenway 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 Greenway of: (a) Greenway'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, Greenway shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Greenway elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Greenway 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.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Greenway 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 Greenway to report a Reportable Event and take corrective action as required in Section III.K;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.F, Appendix A, Appendix B, or Appendix C..

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Greenway constitutes an independent basis for Greenway'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 Greenway has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Greenway of: (a) Greenway'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.* Greenway shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate 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) Greenway has begun to take action to cure the material breach; (ii) Greenway is pursuing such action with due diligence; and (iii) Greenway has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Greenway fails to satisfy the requirements of Section X.D.3, OIG may exclude Greenway from participation in the Federal health care programs. OIG shall notify Greenway in writing of its determination to exclude Greenway. (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 Greenway’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, Greenway 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 Greenway of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Greenway 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 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 Greenway was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Greenway 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 Greenway to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Greenway 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 Greenway was in material breach of this CIA and, if so, whether:

- a. Greenway 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 Greenway's receipt of the Notice of Material Breach: (i) Greenway had begun to take action to cure the material breach; (ii) Greenway pursued such action with due diligence; and (iii) Greenway 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 Greenway, only after a DAB decision in favor of OIG. Greenway's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Greenway 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 Greenway 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. Greenway 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 Greenway, Greenway 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

Greenway 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 Greenway's obligations under this CIA based on a certification by Greenway 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 Greenway is relieved of its CIA obligations, Greenway will be required to notify OIG in writing at least 30 days in advance if Greenway 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) Greenway'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 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.

E. The undersigned Greenway 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 GREENWAY HEALTH, LLC

/Richard Atkin/
RICHARD ATKIN
Chief Executive Officer
Greenway Health, LLC

2/4/19
DATE

/Adam Schwartz/
ADAM SCHWARTZ, ESQ.
Carlton Fields
Counsel for Greenway Health, LLC

2/4/19
DATE

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

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

2/5/19
DATE

/John W. O'Brien/
JOHN W. O'BRIEN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

2/5/19
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Greenway shall engage an IRO to perform the Software Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the Software Review in a professionally independent and objective fashion, as set forth in Paragraph E.

2. Greenway shall engage an IRO to perform the Arrangements Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to Greenway as set forth in Paragraph F.

3. Within 30 days after OIG receives the information identified in Section V.A.12 of the CIA or any additional information submitted by Greenway in response to a request by OIG, whichever is later, OIG will notify Greenway if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Greenway may continue to engage the IRO.

4. If Greenway 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, Greenway shall submit the information identified in Section V.A.12 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 Greenway at the request of OIG, whichever is later, OIG will notify Greenway if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Greenway 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;

2. possess expertise in fair market valuation issues or have the ability to associate with a valuation firm to assist in conducting the transactions review component of the Arrangements Review;

3. assign individuals to conduct the Software Review who have expertise in the Medicare and state Medicaid 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 requirements; and

4. 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 and Software Review in accordance with the specific requirements of the CIA;

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

3. request clarification from the appropriate authority (e.g., Medicare contractor, ONC, and/or ONC-ACB), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation or ONC Health IT Certification requirement;

4. review Greenway's reports of Reportable Events under Section III.K.1.a and b of the CIA and coordinate with OIG on the reports that are most notable and/or concerning within 30 days of such reports being provided by Greenway to the IRO responsible for the Software Review, OIG, and ONC-ACB pursuant to Sections III.K.3.c and III.K.4;

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

6. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C (as applicable) to the CIA.

D. Greenway Responsibilities

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

E. IRO Independence and Objectivity

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

F. IRO Relationship to Greenway

The IRO engaged to perform the Arrangements Review shall not (1) currently represent or currently be employed or engaged by Greenway or (2) have a current or prior relationship to Greenway or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the Arrangements Review.

G. Assertions of Privilege

Greenway shall not assert claims that it has an attorney-client relationship with the IRO in connection with the IRO's performance of the Arrangements Review or in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement to perform the Arrangements Review. Greenway's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

H. IRO Removal/Termination

1. *Greenway and IRO.* If Greenway terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Greenway 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. Greenway 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 E or has a prohibited relationship as set forth in

paragraph F (as applicable), or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Greenway in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Greenway shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence, relationship to Greenway or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Greenway regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Greenway in writing that Greenway shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Greenway 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 Greenway 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 Greenway's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Greenway 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 Greenway's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Greenway'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. Greenway's systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

3. Greenway's systems, policies, processes, and procedures for tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;

4. Greenway's systems, policies, processes and procedures for documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Arrangements Covered Person(s) involved with the fair market value determination(s);

5. Greenway’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);

6. Greenway’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);

7. Greenway’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;

8. Greenway’s systems, policies, processes, and procedures for the internal review and approval of existing, new and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by Greenway, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

9. the Compliance Officer’s annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, Greenway’s internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. Greenway’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

11. Greenway’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.E.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 Greenway's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;
3. findings and supporting rationale regarding weaknesses in Greenway's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and
4. recommendations to improve Greenway's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-11 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 Greenway during the Reporting Period. The IRO shall assess whether Greenway has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.E.1 and III.E.2 of the CIA, with respect to the selected Focus Arrangements.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:
 - a. verifying that the Focus Arrangement is maintained in Greenway's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e, items or services actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);
 - b. 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;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with Greenway's policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with Greenway's policies and procedures;

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

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

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.E.2 of the CIA.

2. For any Focus Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Focus Arrangements subject to the Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Arrangements Transactions Review Report, the OIG may require that the IRO select an additional sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the IRO, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and submit to Greenway and OIG an Additional Transactions Review Report that includes the information specified in Section D below, within 60 days of the date the OIG notifies Greenway and its IRO that an Additional Transactions Review will be required.

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

1. *Review Methodology*.

- a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.
- b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions 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 Transactions Review and Greenway 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 Greenway after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions 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 Transactions 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 Greenway 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, including findings for each item listed in Sections C.1.a-g above. In addition, as applicable, the Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials.* The names and credentials of the individuals who conducted the Arrangements Systems Review and the Arrangements Transactions Review.

APPENDIX C

SOFTWARE REVIEW

The Software Review shall consist of six components: (1) a Quality Control Systems review; (2) an Identifying and Addressing Issues review; (3) an Adherence to Software Standards and Practice and Other Requirements review; (4) a Quality Assurance Program review; (5) an Obligations to Existing and Future Customers review; and (6) a Customer Complaint and Service Request review. The IRO shall perform the Software Review for each six-month period during the term of this CIA (Biannual Software Review) and shall prepare a report for each Biannual Software Review performed. The first six-month period shall begin 180 days following the Effective Date of this CIA.

A. *Quality Control Systems.* The IRO shall perform a review of Greenway's internal quality control systems, including, but not limited to systems designed to ensure that:

1. Health IT Software meets all 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 (including certification criteria to which Health IT Software is certified or will be certified);

2. Patient Safety Issues, Certification Issues, and any other potential deficiencies of Health IT Software (including issues identifiable from customer reports, service requests, internal quality assurance activities, and other relevant sources) are appropriately identified and remedied;

3. Greenway's implementation of its selected quality management system and other quality controls for Health IT Software is sufficient to identify and address Patient Safety Issues, Certification Issues, and other potential deficiencies in a timely and effective manner; and

4. The training programs related to software quality are effective and thorough.

B. *Identifying and Addressing Issues.* The IRO shall perform a review of Greenway's policies, practices, and procedures for identifying and addressing issues with Health IT Software, which shall include an assessment of the following:

1. Greenway’s ability to timely and effectively identify potential and actual Patient Safety Issues, Certification Issues, and other issues;
2. Greenway’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;
3. Greenway’s ability to conduct a root cause analysis of identified issues;
4. Greenway’s ability and procedures for ensuring that customers and users are notified of identified issues and associated risks, how Greenway will be correcting the issue, and instructions regarding actions that customers and users should take to mitigate the risk while it is being corrected;
5. Greenway’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, ONC-ACBs with certification or surveillance responsibilities for Health IT Software, and OIG;
6. Greenway’s ability to execute the action plans described above;
7. Greenway’s ability to monitor and evaluate whether the assessment, action plan, and execution of the action plan was effective, reliable, thorough, and timely;
8. Greenway’s ability to handle Patient Safety Issues, including the following reviews:
 - (a) 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 Greenway and their customers when contact is made regarding those issues; and
 - (b) a comprehensive review of customer alerts, remediation of identified Patient Safety Issues, and technical assistance process.
9. Greenway’s ability to effectively test the implementation of Health IT Software, and full cooperation with the ONC-ACB surveillance activities,

including in-the-field surveillance, in order to identify and remedy patient safety and certification related deficiencies not found and/or known during development.

C. *Adherence to Software Standards and Practices and Other Requirements.* The IRO shall perform a review of Greenway's efforts to ensure that Health IT Software:

1. comply with applicable ONC Health IT Certification Program requirements;
2. adhere to professionally recognized Software Standards and Practices, including those recommended by third party consultants engaged by Greenway and/or the IRO;
3. 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; and
4. comply with the Policies and Procedures adopted by Greenway, including those implemented under Section III.B.2 of this CIA.

D. *Quality Assurance Program.* The IRO shall perform a review of Greenway's efforts to comply with the Quality Assurance Program required under Section III.A.2.b. of this CIA.

E. *Obligations to Existing and Future Customers.* The IRO shall perform a review of Greenway's efforts to ensure that:

1. customers are notified of Greenway's Obligations to Existing and Future Customers and are afforded all opportunities and rights described in Section III.D of this CIA; and
2. any contracts and agreements entered into for the provision of Health IT EHR Software and any associated services do not restrict or prohibit the right of Greenway's customers to disclose to any person or entity information relating to the performance of Health IT Software, including for patient safety, public health, and quality improvement purposes, as set forth in Section III.D of this CIA.

F. *Customer Complaints and Service Requests.* The Customer Complaints and Service Requests review shall consist of a review by the IRO of 50 randomly selected Customer Complaints and Service Requests made to Greenway during the relevant Biannual Review Period. The IRO shall assess whether Greenway has determined the source of the software defect, usability problem, Patient Safety Issue, Certification Issue, deficiency, or other problem; has taken timely remediation; and has ensured that all nonconformities and actual or potential Patient Safety Issues are tracked and are accurately documented on Greenway's customer portal.

G. *Software Review Report.* The IRO shall prepare a report based upon each Software Review performed. The Software Review Report shall include the following information:

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

2. a detailed description of Greenway's systems, policies, processes, and procedures relating to the items identified in Sections A thru F, above;

3. for the Customer Complaints and Service Requests review component of the Software Review described in Section F, above, the Software Review Report shall include the following information:

a. *Review Methodology.*

i. Review Protocol. A description of the process used by the IRO to identify the Customer Complaints and Service Requests subject to review in the Customer Complaints and Service Requests review;

ii. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Customer Complaints and Service Requests review;

iii. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Customer Complaints and Service Requests selected as part of the Customer Complaints and Service Requests review and Greenway shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Customer

Complaints and Service Requests. If the IRO accepts any supplemental documentation or materials from Greenway after the IRO has completed its initial review of the Customer Complaints and Service Requests (Supplemental Materials), the IRO shall identify in the Software 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 Software Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials;

4. findings and supporting rationale regarding weaknesses in Greenway's systems, processes, policies, and procedures relating to the items identified in Sections A thru F above;
5. recommendations to improve Greenway's systems, policies, processes, or procedures relating to the items identified in Sections A thru F above;
6. the IRO's assessment of Greenway's response to the IRO's prior recommendations; and
7. the names and credentials of the individuals who conducted each of the six components of the Software Review.