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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT PURSUANT TO  
SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): **December 16, 2015**

**21<sup>st</sup> CENTURY ONCOLOGY  
HOLDINGS, INC.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**333-170812**

(Commission File Number)

**26-1747745**

(I.R.S. Employer Identification No.)

**2270 Colonial Boulevard  
Fort Myers, Florida**

(Address of Principal Executive Offices)

**33907**

(Zip Code)

**(239) 931-7275**

(Registrant's Telephone Number, including Area Code)

**N/A**

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 1.01 Entry into a Material Definitive Agreement.**

**A. Settlement Agreement**

On December 16, 2015, 21st Century Oncology, LLC (“21C”), a subsidiary of 21st Century Oncology Holdings, Inc. (the “Company”), entered into a settlement agreement (the “Settlement Agreement”), with, among others, the United States of America and Mariela Barnes. Pursuant to the Settlement Agreement, the Company agreed to pay \$19.75 million to the federal government and \$528,000 in attorneys’ fees and costs related to the *qui tam* action brought by Ms. Barnes with respect to the previously disclosed dispute related to the fluorescence in situ hybridization (FISH) diagnostic test. The Company is required to pay both amounts on or prior to the tenth business day following the date of the Settlement Agreement.

Subject to certain conditions, the federal government agreed to release 21C from any civil or administrative monetary claim the federal government has with respect to the conduct covered by the Settlement Agreement under the False Claims Act and certain other statutes and legal theories, and Ms. Barnes agreed to release 21C from any claims she has on behalf of the federal government under the False Claims Act.

The Settlement Agreement avoids the uncertainty and expense of protracted litigation and does not constitute an admission of liability by 21C.

**B. Corporate Integrity Agreement**

In connection with the Settlement Agreement, on December 16, 2015, 21C entered into a Corporate Integrity Agreement (the “Corporate Integrity Agreement”) with the Office of Inspector General of the Department of Health and Human Services. The Corporate Integrity Agreement requires 21C to, among other things, appoint a Chief Compliance Officer; maintain its existing compliance program and Compliance Committee; provide management certifications; provide certain compliance training and education; engage an independent review organization; continue screening employees to ensure they are not barred from participating in federal health care programs; and implement a risk assessment and internal review process. 21C’s failure to comply with its obligations under the Corporate Integrity Agreement could result in monetary penalties or 21C being excluded from participating in federal health care programs. The Corporate Integrity Agreement has a term of five years, commencing on the date of the agreement.

The foregoing descriptions of the Settlement Agreement and the Corporate Integrity Agreement are qualified by the full terms of those agreements, which are attached as Exhibits 10.1 and 10.2 hereto, respectively, and incorporated herein by reference.

**Item 8.01 Other Events**

On December 17, 2015, the Company issued a press release announcing the entry into the Settlement Agreement. A copy of the press release is filed and attached hereto as Exhibit 99.1 and incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
10.1	Settlement Agreement, dated December 16, 2015, entered into by, among others, 21 <sup>st</sup> Century Oncology, LLC, the United States of America and Ms. Barnes.
10.2	Corporate Integrity Agreement, dated December 16, 2015, entered into by 21 <sup>st</sup> Century Oncology, LLC and the Office of Inspector General of the Department of Health and Human Services.
99.1	Press Release issued by the Company on December 17, 2015.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**21<sup>st</sup> CENTURY ONCOLOGY HOLDINGS, INC.**

Date: December 22, 2015

By: /s/ LeAnne M. Stewart  
Name: LeAnne M. Stewart  
Title: Chief Financial Officer

## EXHIBIT INDEX

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99.1	Press Release issued by the Company on December 17, 2015.

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS), the Defense Health Agency (DHA), acting on behalf of the TRICARE Program; 21<sup>st</sup> Century Oncology, LLC (“21C”) and Mariela Barnes (“Relator”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. 21C is a privately held corporation with its corporate headquarters located in Fort Myers, Florida. 21C provides integrated cancer care services in Florida.

B. On March 25, 2013, Mariela Barnes filed a *qui tam* action in the United States District Court for the Middle District of Florida captioned *United States, State of Florida, ex rel. Mariela Barnes, v. Dr. David Spellberg, 21<sup>st</sup> Century Oncology and Naples Urology Associates*, Civil Action No. 2:13-cv-228-FtM-99DNF (M.D. Fla.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action). The relator alleges that the defendants submitted claims to Medicare and Medicaid for (1) fluorescent in situ hybridization (FISH) tests that were not medically necessary and (2) evaluation and management services that were upcoded.

C. The United States contends that 21C submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (“Medicare”) and the TRICARE Program, 10 U.S.C. §§ 1071-1110b (“TRICARE”).

D. The United States contends that it has certain civil claims against 21C arising from the submission of claims to Medicare and TRICARE for FISH tests (CPT Code 88120)

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ordered by Dr. Meir A. Daller, Dr. David Spellberg, Dr. Robert A. Scappa and Dr. Steven H. Paletsky from January 1, 2009 through June 12, 2014 that were not medically necessary. That conduct is referred to below as the "Covered Conduct."

E. This Settlement Agreement is neither an admission of liability by 21C nor a concession by the United States that its claims are not well founded. 21C expressly denies the allegations of the United States and the Relator set forth herein and in the Civil Action.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. 21C shall pay to the United States \$19,750,000.00 (Settlement Amount) no later than 10 business days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Middle District of Florida.

2. Conditioned upon the United States receiving the Settlement Amount from 21C and as soon as feasible after receipt, the United States shall pay \$3,200,000.00 to Relator by electronic funds transfer.

3. 21C shall pay to counsel for the Relator within ten (10) days of the Effective Date of this Agreement the sum of \$527,877.65 for Relator's attorneys' fees and costs ("Attorney's Fee Payment"), pursuant to written instructions provided by counsel for the Relator.

4. Subject to the exceptions in Paragraph 8 (concerning excluded claims) below, and conditioned upon 21C's full payment of the Settlement Amount, the United States releases 21C

and all of its predecessors, successors, and members, together with its current or former direct or indirect parent corporations, direct or indirect subsidiaries, direct or indirect brother or sister corporations, divisions, affiliates and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 8 below, and conditioned upon 21C's full payment of the Settlement Amount and the Attorney's Fee Payment, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, hereby fully, finally and irrevocably releases, waives and discharges 21C and all of its predecessors, successors, and members, together with its current or former direct or indirect parent corporations, direct or indirect subsidiaries, direct or indirect brother or sister corporations, divisions, affiliates and assigns, and its current and former officers, agents and employees from any claims (including civil monetary claims) the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. In consideration of the obligations of 21C in this Agreement and the Corporate Integrity Agreement (CIA), entered into between OIG-HHS and 21C, and conditioned upon 21C's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against 21C under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 8 (concerning excluded claims),

below. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude 21C from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

7. In consideration of the obligations of 21C set forth in this Agreement, and conditioned upon 21C's full payment of the Settlement Amount, DHA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against 21C under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in this Paragraph and in Paragraph 8 (concerning excluded claims), below. DHA expressly reserves authority to exclude 21C from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii) (mandatory exclusion), based upon the Covered Conduct. Nothing in this Paragraph precludes DHA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 8, below.

8. Notwithstanding the releases given in paragraphs 4, 5, 6 and 7 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- i. Any liability of individuals.

9. Relator and her heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon Relator's receipt of the payment described in Paragraph 2, Relator and her heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

10. Conditioned upon Relator's receipt of the payment described in Paragraph 2 and the Attorney's Fee Payment, Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, releases 21C and all of its predecessors, successors, and members, together with its current or former direct or indirect parent corporations, direct or indirect subsidiaries, direct or indirect brother or sister corporations, divisions, affiliates and assigns, and its current and former officers, agents, and employees, from any liability to Relator arising from or relating to the claims Relator asserted or could have asserted in the Civil Action, any claims for retaliation pursuant to 31 U.S.C. § 3730(h), or any claims under 31 U.S.C. § 3730(d) for expenses or

attorney's fees and costs ("Relator's Release"). Relator's Release shall in no way affect, and specifically excluded from the Relator's Release are, the claims currently pending in the matter captioned; *Mariela Barnes v. Naples Urology Associates, LLC and 21<sup>st</sup> Century Oncology, LLC*, No. 2:14-cv-604, U.S.D.C. M.D. Fla.

11. 21C waives and shall not assert any defenses 21C may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

12. 21C fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that 21C has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

13. 21C fully and finally releases the Relator and her heirs, successors, attorneys, agents and assigns from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that 21C has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relator's investigation and prosecution thereof on behalf of the United States ("21C's Release"). 21C's Release shall in no way affect, and specifically excluded from 21C's Release are, any claims that 21C has asserted, could have asserted, or may assert in the future related to the matter captioned: *Mariela Barnes v.*

14. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (*e.g.*, Medicare Administrative Contractor, fiscal intermediary, carrier), TRICARE or any state payer, related to the Covered Conduct; and 21C agrees not to resubmit to any Medicare contractor, TRICARE or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

15. 21C agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of 21C, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) 21C's investigation, defense, and corrective actions undertaken in response to the United States' audit (s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement;

- (5) the payment 21C makes to the United States pursuant to this Agreement and any payments that 21C may make to Relator, including costs and attorneys fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 17.a.(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to 21C.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers by 21C, and 21C shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by 21C or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: 21C further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information

reports, or payment requests already submitted by 21C or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. 21C agrees that the United States, at a minimum, shall be entitled to recoup from 21C any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by 21C or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on 21C or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine 21C's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

16. 21C agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, 21C shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use reasonable efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals and to the extent that 21C still maintains reasonable access to such individuals. 21C further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and

records in its possession, custody, or control relating solely to any investigation of the Covered Conduct that it has undertaken) or that has been performed by another on its behalf.

17. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 18 (waiver for beneficiaries paragraph), below.

18. 21C agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

19. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

20. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

21. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

22. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Middle District of Florida. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

23. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

24. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

25. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

26. This Agreement is binding on 21C's successors, transferees, heirs, and assigns.

27. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

28. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

29. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 12/16/15

BY: /s/ Kyle Cohen  
KYLE COHEN  
Assistant United States Attorney  
United States Attorney's Office for the Middle District of  
Florida

THE UNITED STATES OF AMERICA

DATED: 12/14/15

BY: /s/ Arthur S. Di Dio  
ARTHUR S. DI DIO  
Trial Attorney  
Commercial Litigation Branch  
Civil Division  
United States Department of Justice

THE UNITED STATES OF AMERICA

DATED: 12/16/15

BY: /s/ Robert K. Deconti  
ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

THE UNITED STATES OF AMERICA

DATED: 12/8/15

BY: /s/ Paul J. Hutter, Deputy G.C.  
for PAUL J. HUTTER  
General Counsel  
Defense Health Agency  
United States Department of Defense

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21<sup>ST</sup> CENTURY ONCOLOGY, LLC - DEFENDANT

DATED: 12/16/15

BY: /s/ Daniel E. Dosoretz, M.D.  
DANIEL E. DOSORETZ, M.D.  
Chief Executive Officer, 21<sup>st</sup> Century Oncology, LLC

DATED: 12/15/2015

BY: /s/ Amy Garrigues  
AMY GARRIGUES  
K & L Gates LLP  
Counsel for 21C

MARIELA BARNES - RELATOR

DATED: 12-2-15

BY: /s/ Mariela Barnes  
MARIELA BARNES

DATED: 12/3/15

BY: /s/ Michael M. Mustokoff  
MICHAEL M. MUSTOKOFF  
Duane Morris LLP  
Counsel for Mariela Barnes

DATED: 12-2-15

BY: /s/ Benjamin H. Yormak  
BENJAMIN H. YORMAK  
Yormak Employment & Disability Law  
Counsel for Mariela Barnes

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
21<sup>ST</sup> CENTURY ONCOLOGY, LLC**

**I. PREAMBLE**

21<sup>st</sup> Century Oncology, LLC (21st Century) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, 21st Century is entering into a Settlement Agreement with the United States.

21<sup>st</sup> Century represents that, prior to this CIA, 21<sup>st</sup> Century voluntarily established a Compliance Program which provides for a Corporate Compliance and Privacy Officer, a Compliance Committee, a compliance training and education program, a confidential disclosure reporting hotline, auditing and monitoring activities, and various policies and procedures aimed at ensuring that 21<sup>st</sup> Century's participation in the federal health care programs conforms to all Federal and state laws and Federal health care program requirements. 21<sup>st</sup> Century shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. 21<sup>st</sup> Century may modify its Compliance Program, as appropriate, but at a minimum, 21<sup>st</sup> Century shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

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

A. The period of the compliance obligations assumed by 21st Century 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. 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) 21st Century's final annual report; or (2) any additional materials submitted by 21st Century pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:

a. all owners, officers, directors, and employees of 21st Century; and

b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of 21st Century, excluding vendors whose sole connection with 21st Century is selling or otherwise providing medical supplies or equipment to 21st Century.

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

2. "Relevant Covered Persons" includes Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

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

21st Century shall continue to maintain a Compliance Program that includes the following elements:

#### A. **Chief Compliance Officer and Committee**

1. *Chief Compliance Officer.* Within 90 days after the Effective Date, 21st Century shall appoint a Chief Compliance Officer and shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be an employee and a member of senior management of 21st Century, shall report directly to

the Chief Executive Officer of 21st Century, and 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 21st Century. The Chief Compliance Officer shall be responsible for, without limitation:

- a. Maintaining, developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of 21st Century, and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Chief Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by 21st Century as well as for any reporting obligations created under this CIA.

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

21st Century shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Regional Compliance Officers.* 21<sup>st</sup> Century has appointed Regional Compliance Officers for each region (as defined by 21st Century) and shall maintain Regional Compliance Officers for the term of the CIA. The Regional Compliance Officers shall be responsible for maintaining and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements for the applicable regions, and shall monitor the day-to-day compliance activities for the applicable regions. The Regional Compliance Officers shall report to the Chief Compliance Officer and shall be members of the Compliance Committee. The Regional Compliance

Officers shall make periodic (at least quarterly) written reports regarding compliance matters directly to the Chief Compliance Officer, and shall be authorized to report on such matters directly to the Compliance Committee, the Chief Compliance Officer, and the Board of Directors at any time. The Regional Compliance Officers shall make periodic (at least monthly) visits to 21st Century practices in order to fulfill the obligation of this Section.

21st Century shall report to OIG, in writing, any changes in the identity or position description of the Regional Compliance Officers, or any actions or changes that would affect the Regional Compliance Officers' ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

3. *Compliance Committee.* 21<sup>st</sup> Century has an existing Compliance Committee. 21<sup>st</sup> Century shall maintain the Compliance Committee for the term of the CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Chief Compliance Officer shall continue to chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of 21st Century's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

21st Century shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or 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 after such a change.

4. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of 21st Century (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care 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 21st Century's compliance program, including but not limited to the performance of the Chief Compliance Officer and Compliance Committee;
- b. submitting to the 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 21st Century's compliance with Federal health care program requirements and the obligations of this CIA.
- d. for the first Reporting Period of the CIA, the Board shall continue to retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of 21st Century's Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to 21st Century's compliance program. During the first Reporting Period, the Board shall review the Compliance Program Review Report as part of its review and oversight of 21st Century's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in the first Annual Report submitted by 21st Century. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to the OIG upon request.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of 21st Century’s Compliance Program including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, 21st Century has implemented and maintained an effective Compliance Program to meet Federal health care 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 21st Century.

21st Century 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.

5. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain 21<sup>st</sup> Century employees (Certifying Employees, are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable 21<sup>st</sup> department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Medical Officer, Regional Compliance Officers, and Senior Vice Presidents for Operations. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and 21st Century policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of 21st Century is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate

Integrity Agreement. 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.

Within 90 days after the Effective Date, 21st Century shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

1. *Code of Conduct.* 21<sup>st</sup> Century has developed, implemented, and distributed a written Code of Conduct to all Covered Persons, and shall maintain this Code of Conduct for the duration of the CIA. To the extent not already accomplished, within 90 days after the Effective Date, 21st Century shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. 21st Century’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. 21st Century’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with 21st Century’s policies and procedures;
- c. the requirement that all of 21st Century’s Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by 21st Century, suspected violations of any Federal health care program requirements or of 21st Century’s own Policies and Procedures; and

- d. the right of all individuals to use the Disclosure Program described in Section III.E, and 21st Century's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

21st Century shall continue to review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures.* 21<sup>st</sup> Century has developed, implemented, and distributed written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and 21st Century's compliance with Federal health care program requirements (Policies and Procedures). 21<sup>st</sup> Century shall maintain these Policies and Procedures for the duration of the CIA, which shall address, at a minimum:

- a. ensuring proper and accurate submission of all claims to Federal health care programs; and
- b. the Federal health care program billing, coding and claims submission statutes, regulations, program requirements, and directives relating to medical necessity determinations.

Throughout the term of this CIA, 21st Century shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

Within 90 days after the Effective Date, 21st Century will ensure that the Policies and Procedures continue to be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

21st Century shall continue, at least annually (and more frequently, if appropriate), assessing and updating, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, a description of the revisions shall be communicated to all affected Covered Persons and any revised or new Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *Training Plan.* Within 90 days after the Effective Date, 21st Century shall develop a written plan (Training Plan) that outlines the steps 21st Century will take to ensure that: (a) all Covered Persons receive adequate training regarding 21st Century's CIA requirements and Compliance Program, including the Code of Conduct and (b) all Relevant Covered Persons receive adequate training regarding: (i) the Federal health care program requirements regarding the accurate coding and submission of claims; (ii) policies, procedures, and other requirements applicable to the documentation of medical records; (iii) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (iv) applicable reimbursement statutes, regulations, and program requirements and directives; (v) the legal sanctions for violations of the Federal health care program requirements; and (vi) examples of proper and improper claims submission practices.

The Training Plan shall include information regarding the training topics, the categories of Covered Persons and Relevant Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of 21st Century's Training Plan, OIG will notify 21st Century of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, 21st Century may implement its Training Plan. 21st Century shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 90 days after the Effective Date, 21st Century shall provide at least two hours of training to each member of the Board of Directors. This training shall address the 21st Century's CIA requirements and Compliance Program (including the Code of Conduct), 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 of Directors 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. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials.

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

5. *Update of Training Plan.* 21st Century shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to 21st Century's Training Plan, OIG will notify 21st Century of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, 21st Century may implement the revised Training Plan.

6. *Computer-based Training.* 21st Century may provide the training required under this CIA through appropriate computer-based training approaches. If 21st Century chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, 21st Century shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. 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 21st Century shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and 21st Century) related to the reviews.

2. *Claims Review.* The IRO shall review 21st Century's claims to the Medicare and TRICARE programs and the reimbursement received (Claims Review), pursuant to the applicable coverage, billing, coding, and medical necessity requirements, regulations, and/or guidance to determine whether the items and services provided were medically necessary, and the claims were correctly coded, submitted, and reimbursed. The IRO shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (Validation Review). 21st Century shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of a Claims Review submitted as part of 21st Century's final Annual Report shall be initiated no later than one year after 21st Century's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify 21st Century in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. 21st Century shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review and/or propose alternatives to the proposed Validation Review. The final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to 21st Century a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Risk Assessment and Internal Review Process

21<sup>st</sup> Century has developed and implemented a risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Medicare and TRICARE program beneficiaries, and will continue to maintain this risk assessment and internal review process during the term of the CIA. The risk assessment and internal review process shall require compliance, legal, and 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. 21st Century shall maintain the risk assessment and internal review process for the term of the CIA.

F. Disclosure Program

21st Century has established a Disclosure Program, and will continue to maintain a Disclosure Program, that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with 21st Century's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. 21st Century 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 non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall continue to gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall continue to 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, 21st Century shall continue to conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall continue to 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 continue to 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.

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or non-procurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or suspended.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

2. *Screening Requirements.* To the extent not already accomplished, within 90 days, 21st Century shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. 21st Century 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. 21st Century shall screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. 21st Century shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

Nothing in this Section III.G affects 21st Century's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. 21st Century understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that 21st Century may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether 21st Century meets the requirements of Section III.G.

3. *Removal Requirement.* If 21st Century has actual notice that a Covered Person has become an Ineligible Person, 21st Century shall remove such Covered Person from responsibility for, or involvement with, 21st Century'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 21st Century 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, 21st Century shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, 21st Century shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to 21st Century conducted or brought by a governmental entity or its agents involving an allegation that 21st Century 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. 21st Century 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 proceeding, if any.

I. Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” shall mean the amount of money 21st Century has received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* To the extent not already accomplished, within 90 days after the Effective Date, 21st Century shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Repayment of Overpayments.*

- a. If, at any time, 21st Century identifies any Overpayment, 21st Century shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take remedial steps within 90 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified within 60 days after identification, 21st Century shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies.

- b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

J. Reportable Events

involves:

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

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by 21st Century.

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

2. *Reporting of Reportable Events.* If 21st Century determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, 21st Century shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days after making a determination that a substantial Overpayment exists and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable

Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by 21st Century to identify and quantify the Overpayment; and
- d. a description of 21st Century's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, 21st Century shall provide OIG with a copy of the notification and repayment (if quantified) to the payor required in Section III.I.3.

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

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of 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;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of 21st Century's actions taken to correct the Reportable Event and prevent it from recurring; and

- e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by 21st Century to identify and quantify the Overpayment.

shall include:

- 5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Persons employment or contractual relationship;
- c. a description of the Exclusion Lists screening that 21st Century 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 Reportable Event was discovered; 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.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by 21st Century to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.I.3 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of solely the Stark Law that is disclosed to CMS pursuant to the SRDP. If 21st Century identifies a probable violation of the Stark Law and repays

the applicable Overpayment directly to the CMS contractor, then 21st Century is not required by this Section III.J to submit the Reportable Event to CMS through the SRDP.

**IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Sale of Business, Business Unit or Location

In the event that, after the Effective Date, 21st Century proposes to 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) that are subject to this CIA, 21st Century shall notify OIG of the proposed sale at least 30 days prior to the sale of its business, business unit or location. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit or Location

In the event that, after the Effective Date, 21st Century changes locations or closes a business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, 21st Century shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the business, business unit or location.

C. Purchase or Establishment of New Business, Business Unit or Location

In the event that, after the Effective Date, 21st Century purchases or establishes a new business, business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, 21st Century shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location's Medicare and TRICARE program provider number and/or supplier number(s) and the name and address of each Medicare and TRICARE program contractor to which 21st Century currently submits claims. Each such 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 the OIG.

**V. IMPLEMENTATION AND ANNUAL REPORTS**

**A. Implementation Report**

Within 120 days after the Effective Date, 21st Century 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 Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names, addresses, phone numbers, and position descriptions of the Regional Compliance Officers required by Section III.A.2,
3. the names and positions of the members of the Compliance Committee required by Section III.A.3;
4. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.4;
5. the names and positions of the Certifying Employees required by Section III.A.5.
6. a copy of 21st Century's Code of Conduct required by Section III.B.1;
7. a summary of all Policies and Procedures required by Section III.B (copies of the 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 Directors 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. 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; (d) a summary and description of any and all current and prior engagements and agreements between 21st Century and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to 21st Century;
10. a description of the risk assessment and internal review process required by Section III.E;
11. a description of the Disclosure Program required by Section III.F;
12. a certification that 21st Century has implemented screening requirements described in Section III.G regarding Ineligible Persons, or a description of why 21st Century cannot provide such a certification;
13. a copy of 21st Century's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.I;
14. a list of all of 21st Century's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers, each location's Medicare and TRICARE program provider number(s) and/or supplier number(s), and the name and address of each Medicare and TRICARE program contractor to which 21st Century currently submits claims;
15. a description of 21st Century's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
16. the certifications required by Section V.C.

B. Annual Reports

21st Century shall submit to OIG annually a report with respect to the status of, and findings regarding, 21st Century's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer described in Section III.A.1; any change in the identity, or position description of the Regional Compliance Officers described in Section III.A.2; any change in the membership of the Compliance Committee described in Section III.A.3; any change in the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.4; and any change in the group of Certifying Employees described in Section III.A.5.

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

3. the Board resolution required by Section III.A.4 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;

4. a copy of the Compliance Program Review Report as required by Section III.A.4.d;

5. a summary of any significant changes or amendments to 21st Century's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

6. a copy of 21st Century's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered; the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which 21st Century ensures that all designated employees receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter, and 21st Century's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

8. a summary and description of any and all current and prior engagements and agreements between 21st Century and the IRO (if different from what

was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to 21st Century;

9. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;

10. a summary of all internal audits performed pursuant to Section III.E during the Reporting Period and any corrective action plans developed in response to those internal audits. Copies of the internal audit reports and corrective action plans shall be made available to OIG upon request;

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

12. a certification that 21st Century has completed the screening required by Section III.G regarding Ineligible Persons;

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

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

15. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare and TRICARE (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

17. a summary describing any audits conducted during the applicable Reporting Period by a Medicare or TRICARE program contractor or any government entity or contractor, involving a review of Federal health care program claims, and 21st Century's response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

18. a description of all changes to the most recently provided list of 21st Century's locations (including addresses) as required by Section V.A.13; and

19. the certifications required by Section V.C.

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

C. Certifications

1. *Certifying Employees.* In each Annual Report, 21st Century shall include the certifications of Certifying Employees as required by Section III.A.5.

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

- a. to the best of his or her knowledge, except as otherwise described in the report, 21st Century is in compliance with all of the requirements of this CIA; and
- b. 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.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, 21st Century has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or

state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

21st Century 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. 21st Century 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

21st Century:

Compliance Officer  
21<sup>st</sup> Century Oncology, LLC  
2270 Colonial Boulevard  
Fort Myers, FL 33907  
Telephone: (239) 931-7333  
Facsimile: (239) 931-7380

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, 21st Century may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

**VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative (s) may examine and/or request copies of 21st Century's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of 21st Century's locations for the purpose of verifying and evaluating: (a) 21st Century's compliance with the terms of this CIA and (b) 21st Century's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by 21st Century 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 21st Century's Covered Persons 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. 21st Century shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. 21st Century's Covered Persons may elect to be interviewed with or without a representative of 21st Century present.

**VIII. DOCUMENT AND RECORD RETENTION**

21st Century shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

**IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify 21st Century prior to any release by OIG of information submitted by 21st Century pursuant to its obligations under this CIA and identified upon submission by 21st Century as trade secrets, or information that is

commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, 21st Century shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

21st Century 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, 21st Century 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 21st Century fails to establish and implement any of the following obligations as described in Sections III and IV:

- a. a Chief Compliance Officer;
- b. Regional Compliance Officers;
- c. a Compliance Committee;
- d. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review and the preparation of a Compliance Program Review Report, as required by Section III.A.3.
- e. the management certification obligations;
- f. a written Code of Conduct;
- g. written Policies and Procedures;

- h. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Board Members;
- i. a risk assessment and internal review process as required by Section III.E;
- j. a Disclosure Program;
- k. Ineligible Persons screening and removal requirements;
- l. notification of Government investigations or legal proceedings;
- m. policies and procedures regarding the repayment of Overpayments;
- n. the repayment of Overpayments as required by Section III.I and Appendix B;
- o. reporting of Reportable Events; and
- p. disclosure of changes to business units or locations.

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 21st Century fails to engage and use an IRO, as required by Section III.D, Appendix A, or Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day 21st Century fails to submit the Implementation Report or any Annual Reports 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 21st Century fails to submit any Claims Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day 21st Century fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date 21st Century fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of 21st Century as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day 21st Century fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to 21st Century stating the specific grounds for its determination that 21st Century has failed to comply fully and adequately with the CIA obligation(s) at issue and steps 21st Century shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date 21st Century receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

21st Century 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 21st Century 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 days after 21st Century 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 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 21st Century 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 21st Century of: (a) 21st Century'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, 21st Century 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 21st Century elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until 21st Century 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 21st Century 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 21st Century to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
  - 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.D, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by 21st Century constitutes an independent basis for 21st Century’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 21st Century has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify 21st Century of: (a) 21st Century’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.* 21st Century 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) 21st Century has begun to take action to cure the material breach; (ii) 21st Century is pursuing such action with due diligence; and (iii) 21st Century has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, 21st Century fails to satisfy the requirements of Section X.D.3, OIG may exclude 21st Century from participation in the Federal health care programs. OIG shall notify 21st Century in writing of its determination to exclude 21st Century. (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 21st Century’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, 21st Century 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 21st Century 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, 21st Century 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 to 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 21st Century was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. 21st Century 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 21st Century to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless 21st Century 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 21st Century was in material breach of this CIA and, if so, whether:

- a. 21st Century 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 21st Century's receipt of the Notice of Material Breach: (i) 21st Century had begun to take action to cure the material breach; (ii) 21st Century pursued such action with due diligence; and (iii) 21st Century 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 21st Century, only after a DAB decision in favor of OIG. 21st Century's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude 21st Century 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 21st Century 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. 21st Century 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 21st Century, 21st Century 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**

21st Century 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 21st Century's obligations under this CIA based on a certification by 21st Century that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If 21st Century is relieved of its CIA obligations, 21st Century shall be required to notify OIG in writing at least 30 days in advance if 21st Century plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D.       All requirements and remedies set forth in this CIA are in addition to and do not affect (1) 21st Century's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

E.       The undersigned 21st Century 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 21ST CENTURY**

/s/ Daniel E. Dosoretz, MD  
DANIEL E. DOSORETZ, MD  
Chief Executive Officer  
21st Century Oncology, LLC

12/16/15  
DATE

/s/ Amy O. Garrigues  
AMY O. GARRIGUES  
K&L Gates LLP  
Counsel for 21st Century Oncology, LLC

12/15/2015  
DATE

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

<u>/s/ Robert K. Deonti</u> ROBERT K. DECONTI Assistant Inspector General for Legal Affairs Office of Inspector General U. S. Department of Health and Human Services	<u>12/16/15</u> DATE
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<u>/s/ Felicia E. Heimer</u> FELICIA E. HEIMER Senior Counsel Office of Inspector General U. S. Department of Health and Human Services	<u>12/16/15</u> DATE
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## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. 21st Century shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by 21st Century in response to a request by OIG, whichever is later, OIG will notify 21st Century if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, 21st Century may continue to engage the IRO.

2. If 21st Century 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, 21st Century shall submit the information identified in Section V.A.8 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 21st Century at the request of OIG, whichever is later, OIG will notify 21st Century if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, 21st Century may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, claims submission and other applicable Medicare and TRICARE program requirements;

2. assign individuals who have expertise in determining the medical necessity of items and services pursuant to applicable Medicare and TRICARE requirements;

3. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

4. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements); and
5. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare and TRICARE rules and reimbursement guidelines in making assessments in the Claims Review;
3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or TRICARE policy or regulation;
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *21st Century and IRO.* If 21st Century terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, 21st Century 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. 21st Century must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify 21st Century in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. 21st Century shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by 21st Century regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify 21st Century in writing that 21st Century shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. 21st Century 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 21st Century to engage a new IRO shall be made at the sole discretion of OIG.

**APPENDIX B**  
**CLAIMS REVIEW**

A. **Claims Review.** The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

1. *Definitions.* For the purposes of the Claims Review, the following definitions shall be used:
  - a. **Overpayment:** The amount of money 21st Century has received in excess of the amount due and payable under Medicare and TRICARE program requirements, as determined by the IRO in connection with the review of claims performed under this Appendix B, including any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.
  - b. **Paid Claim:** A claim submitted by 21st Century and for which 21st Century has received reimbursement from the Medicare and TRICARE programs.
  - c. **Population:** The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
  - d. **Error Rate:** The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)  
  
The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Samples.* The IRO shall randomly select and review two samples of 100 Paid Claims (Discovery Samples). One Discovery Sample is for Paid Claims drawn from all laboratory claims, and the other Discovery Sample is for Paid Claims drawn from all service lines within which physicians participate in 21<sup>st</sup> Century's ancillary bonus pools. The Paid Claims shall be reviewed based on the supporting

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documentation available at 21st Century's office or under 21st Century's control, and the applicable coverage, billing, coding, and medical necessity requirements, regulations, and/or guidance to determine whether the items and services provided were medically necessary, and whether the claims were correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for each Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, 21st Century should, as appropriate, further analyze any errors identified in the Discovery Sample. 21st Century recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Samples or any other segment of the universe.)

3. *Full Sample.* If either Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at 21st Century or under 21st Century's control and applicable billing and coding regulations and guidance to determine whether the items and services provided were medically necessary, and whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from 21st Century to the appropriate Federal health care program payor (e.g., Medicare contractor), for appropriate follow-up by that payor.

4. *Systems Review.* If either Discovery Sample identifies an Error Rate of 5% or greater, 21st Century's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of 21st Century's medical necessity review process, and billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the process by which the claims are reviewed for medical necessity, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims
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submission and billing; and procedures to identify and correct inaccurate coding and billing);

- b. for each claim in the Discovery Samples and Full Samples that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments, The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Samples or Full Samples (if applicable), and 21st Century shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Samples or Full Samples (if applicable). If the IRO accepts any supplemental documentation or materials from 21st Century after the IRO has completed its initial review of the Discovery Samples or Full Samples (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
  - b. Paid Claims without Supporting Documentation. Any Paid Claim for which 21st Century cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by 21st Century for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
  - c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).
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6. *Repayment of Identified Overpayments.* 21st Century shall repay within 30 days any Overpayment(s) identified in the Discovery Samples, regardless of the Error Rate, and (if applicable) the Full Samples, including any extrapolated Overpayments determined by the IRO in accordance with Section A.3 above, in accordance with payor refund policies. 21st Century shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*
    - a. Claims Review Population. A description of the Population subject to the Claims Review.
    - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
    - c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
    - d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
    - e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.
  2. *Statistical Sampling Documentation.*
    - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
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- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.
  - c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.
3. *Claims Review Findings.*
- a. Narrative Results.
    - i. A description of 21st Century's medical necessity review process, claims submission process, billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
    - ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of each Discovery Sample, and the results of the Full Samples (if any).
  - b. Quantitative Results.
    - i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by 21st Century (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
    - ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to 21st Century.
    - iii. Total dollar amount of all Overpayments in each Discovery Sample and Full Samples (if applicable).
    - iv. Total dollar amount of Paid Claims included in each Discovery Sample and Full Sample, and the net Overpayment associated with the Discovery Samples and the Full Samples.
    - v. Error Rate in each Discovery Sample and the Full Sample.
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- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to 21st Century's billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

- a. the strengths and weaknesses in 21st Century's billing systems and processes;
- b. the strengths and weaknesses in 21st Century's coding systems and processes;
- c. the strengths and weaknesses in 21<sup>st</sup> Century's medical necessity review systems and processes; and
- d. possible improvements to 21st Century's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

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

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FOR IMMEDIATE RELEASE

December 17, 2015

**Statement from 21<sup>st</sup> Century Oncology**

**FORT MYERS, FLA.** 21<sup>st</sup> Century Oncology, the nation's leading provider of integrated cancer care services, has entered into a settlement with the federal government to resolve a dispute related to the fluorescence in situ hybridization (FISH) diagnostic test in the interest of avoiding protracted expense and litigation. 21<sup>st</sup> Century fully cooperated with federal officials during the process and has agreed to the settlement with no admission of wrongdoing.

The FISH test is a diagnostic tool used for identifying bladder cancer, specifically with older patients and other high-risk patients. The dispute involved the medical necessity of the FISH test specifically ordered by four of the company's urologists in conjunction with other diagnostic tests, and the complex Medicare and Medicaid billing criteria required.

21<sup>st</sup> Century Oncology's primary goal is to provide top quality patient care and to that end supports the judgment of our physicians to determine what diagnostic and treatment tools should be utilized for each individual patient based on that patient's unique clinical needs. 21<sup>st</sup> Century Oncology is also committed to compliance and to that end, has further enhanced our comprehensive compliance and auditing programs to ensure transparency and the delivery of the highest quality, most clinically appropriate care to our patients, and that only those services that meet the complex Medicare and Medicaid billing criteria are submitted for reimbursement.

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*About 21<sup>st</sup> Century Oncology*

*21<sup>st</sup> Century Oncology is the largest global, physician led provider of Integrated Cancer Care services. The company offers a comprehensive range of cancer treatment services, focused on delivering academic quality, cost-effective patient care in personal and convenient settings. As of March 31, 2015, the company operated 182 treatment centers, including 147 centers located in 17 states and 35 centers located in six countries in Latin America. The company holds market-leading positions in most of its domestic local markets and abroad.*

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