

**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:)
) Chapter 11
)
21st CENTURY ONCOLOGY HOLDINGS, INC., *et al.*,¹) Case No. 17-22770 (RDD)
)
Debtors.) (Jointly Administered)
)

**ORDER (A) APPROVING THE RESOLUTION
AGREEMENT BETWEEN DEBTOR 21ST CENTURY ONCOLOGY, INC. AND THE
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE
OFFICE FOR CIVIL RIGHTS AND (B) GRANTING RELATED RELIEF**

Upon the motion (the “Motion”)² of the above-captioned debtors and debtors in possession (collectively, the “Debtors”) for entry of an order (this “Order”): (a) approving the Resolution Agreement, by and among Debtor 21st Century Oncology, Inc. (“21C”) and the U.S. Department of Health and Human Services, Office for Civil Rights (the “OCR”), attached hereto as **Exhibit 1** (the “Resolution Agreement”), and (b) granting related relief, all as more fully set forth in the Motion; and the Court having found that it has jurisdiction over this matter pursuant to 28 U.S.C. §§ 157(a)-(b) and 1334(b) and the *Amended Standing Order of Reference from the United States District Court for the Southern District of New York*, dated January 31, 2012, and that this Court may enter a final order consistent with Article III of the United States Constitution; and the Court having found that venue of the Motion in this district is proper pursuant to 28 U.S.C. §§ 1408 and 1409; and this Court having found that the Debtors’ notice of the Motion and the opportunity for a hearing on the Motion were appropriate under the

¹ Each of the Debtors in the above-captioned jointly administered chapter 11 cases and their respective tax identification numbers are set forth in the *Order Directing Joint Administration of Chapter 11 Cases* [Docket No. 30]. The location of 21st Century Oncology Holdings Inc.’s corporate headquarters and the Debtors’ service address is: 2270 Colonial Boulevard, Fort Myers, Florida 33907.

² Capitalized terms used but not otherwise defined herein have the meanings ascribed to them in the Motion.

circumstances and no other notice need be provided; and there being no objections to the requested relief; and upon all of the proceedings had before this Court, including the record of the hearing held by the Court on the Motion on December 11, 2017 (the "Hearing"); and, after due deliberation, the Court having determined that the settlement set forth in the Resolution Agreement is fair and reasonable and in the best interests of the Debtors and their estates and that the legal and factual bases set forth in the Motion and at the Hearing establish just cause for the relief granted herein, it is HEREBY ORDERED THAT:

1. The Motion is granted as set forth herein.
2. Pursuant to Bankruptcy Rule 9019, the Debtors are authorized to enter into and perform under the Resolution Agreement, perform, execute, and deliver all documents, and take all actions, necessary to immediately continue and fully implement the Resolution Agreement in accordance with the terms, conditions, agreements, and releases set forth or provided for therein, all of which are approved.
3. The Debtors' insurer under that certain Beazley Breach Response, Policy No. W140E2150301 (the "Insurer"), is authorized to take all actions necessary to effectuate the relief granted hereunder, including the immediate payment to the OCR of the Resolution Amount and the payment of fees incurred by the Debtors in connection with regulatory defense issues.
4. The automatic stay under section 362(a) of the Bankruptcy Code is hereby modified pursuant to section 363(d)(1) of the Bankruptcy Code solely to the extent necessary to implement and effectuate the Resolution Agreement and enable the Insurer to remit payment of the Resolution Amount to the OCR.
5. The notice requirements under Bankruptcy Rule 6004(a) are hereby waived.

6. Notwithstanding Bankruptcy Rule 6004(h), the terms and conditions of this Order are immediately effective and enforceable upon its entry, for cause.

7. The Debtors and the Insurer are authorized to take all actions necessary to effectuate the relief granted pursuant to this Order in accordance with the Motion.

8. This Order shall bind the Debtors, their estates and any successors or assigns, including without limitation any trustee, liquidating trustee or other estate representative.

9. This Court retains exclusive jurisdiction with respect to all matters arising from or related to the implementation, interpretation, and enforcement of this Order.

Dated: February 11, 2017
White Plains, New York

/s/Robert D. Drain
THE HONORABLE ROBERT D. DRAIN
UNITED STATES BANKRUPTCY JUDGE

EXHIBIT 1

Form of Resolution Agreement

**UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK**

In re:)
) Chapter 11
)
21st CENTURY ONCOLOGY HOLDINGS, INC., *et al.*,¹) Case No. 17-22770 (RDD)
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) Debtors.) (Jointly Administered)
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**ORDER (A) APPROVING THE RESOLUTION
AGREEMENT BETWEEN DEBTOR 21ST CENTURY ONCOLOGY, INC. AND THE
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, THE
OFFICE FOR CIVIL RIGHTS AND (B) GRANTING RELATED RELIEF**

Upon the motion (the “Motion”)² of the above-captioned debtors and debtors in possession (collectively, the “Debtors”) for entry of an order (this “Order”): (a) approving the Resolution Agreement, by and among Debtor 21st Century Oncology, Inc. (“21C”) and the U.S. Department of Health and Human Services, Office for Civil Rights (the “OCR”), attached hereto as **Exhibit 1** (the “Resolution Agreement”), and (b) granting related relief, all as more fully set forth in the Motion; and the Court having found that it has jurisdiction over this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the *Amended Standing Order of Reference from the United States District Court for the Southern District of New York*, dated January 31, 2012; and that this Court may enter a final order consistent with Article III of the United States Constitution; and the Court having found that venue of this proceeding and the Motion in this district is proper pursuant to 28 U.S.C. §§ 1408 and 1409; and this Court having found that the Debtors’ notice of the Motion and opportunity for a hearing on the Motion were appropriate under the

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² Capitalized terms used but not otherwise defined herein have the meanings ascribed to them in the Motion.

circumstances and no other notice need be provided; and this Court having reviewed the Motion and having heard the statements in support of the relief requested therein at a hearing, if any, before this Court (the "Hearing"); and this Court having determined that the legal and factual bases set forth in the Motion and at the Hearing establish just cause for the relief granted herein; and upon all of the proceedings had before this Court; and after due deliberation and sufficient cause appearing therefor, it is HEREBY ORDERED THAT:

1. The Motion is granted as set forth herein.
2. Pursuant to Bankruptcy Rule 9019, the Debtors are authorized to enter into and perform under the Resolution Agreement, perform, execute, and deliver all documents, and take all actions, necessary to immediately continue and fully implement the Resolution Agreement in accordance with the terms, conditions, agreements, and releases set forth or provided for therein, all of which are approved.
3. The Debtors' insurer under that certain Beazley Breach Response, Policy No. W140E2150301 (the "Insurer"), is authorized to take all actions necessary to effectuate the relief granted here under, including the immediate payment to the OCR of the Resolution Amount and the payment of fees incurred by the Debtors in connection with regulatory defense issues.
4. The automatic stay under section 362 of the Bankruptcy Code is hereby modified solely to the extent necessary to implement and effectuate the Resolution Agreement and enable the Insurer to remit payment of the Resolution Amount to the OCR.
5. The notice requirements under Bankruptcy Rule 6004(a) are hereby waived.

6. Notwithstanding Bankruptcy Rule 6004(h), the terms and conditions of this Order are immediately effective and enforceable upon its entry.

7. The Debtors and the Insurer are authorized to take all actions necessary to effectuate the relief granted pursuant to this Order in accordance with the Motion.

8. This Order shall bind the Debtors, their estates and any successors or assigns, including without limitation any trustee, liquidating trustee or other estate representative.

9. This Court retains exclusive jurisdiction with respect to all matters arising from or related to the implementation, interpretation, and enforcement of this Order.

White Plains, New York
Dated: _____, 2017

THE HONORABLE ROBERT D. DRAIN
UNITED STATES BANKRUPTCY JUDGE

EXHIBIT 1

Form of Resolution Agreement

RESOLUTION AGREEMENT

I. Recitals

1. **Parties.** The Parties to this Resolution Agreement (Agreement) are
 - A. The United States Department of Health and Human Services, Office for Civil Rights (“HHS”), which enforces the Federal standards that govern the privacy of individually identifiable health information (45 C.F.R. Part 160 and Subparts A and E of Part 164, the “Privacy Rule”), the Federal standards that govern the security of electronic individually identifiable health information (45 C.F.R. Part 160 and Subparts A and C of Part 164, the “Security Rule”), and the Federal standards for notification in the case of breach of unsecured protected health information (45 C.F.R. Part 160 and Subparts A and D of 45 C.F.R. Part 164, the “Breach Notification Rule”). HHS has the authority to conduct compliance reviews and investigations of complaints alleging violations of the Privacy, Security, and Breach Notification Rules (the “HIPAA Rules”) by covered entities and business associates, and covered entities and business associates must cooperate with HHS compliance reviews and investigations. *See* 45 C.F.R. §§ 160.306(c), 160.308, and 160.310(b).
 - B. 21st Century Oncology, Inc. (“21CO”) is a covered entity, as defined at 45 C.F.R. § 160.103, and therefore is required to comply with the HIPAA Rules. 21CO headquarters are located in Fort Myers, Florida, and it operates and manages 179 treatment centers, including 143 centers located in 17 states.

HHS and 21CO shall together be referred to herein as the “Parties.”

2. **Factual Background and Covered Conduct.**

On November 13, and December 13, 2015, the Federal Bureau of Investigation (FBI) notified 21CO that patient information was illegally obtained by an unauthorized third party and produced 21CO certain patient data obtained by the FBI. As part of its internal investigation, 21CO hired a third party forensic auditing firm in November 2015. 21CO determined that the attacker may have accessed 21CO’s network SQL database as early as October 3, 2015, through Remote Desktop Protocol from an Exchange Server within 21CO’s network. 21CO determined that it is possible that 2,213,597 individuals may have been affected by the impermissible access to their names, social security numbers, physicians’ names, diagnoses, treatment and insurance information.

HHS OCR’s subsequent investigation indicated that the following conduct occurred (“Covered Conduct”).

- A. 21CO impermissibly disclosed certain PHI of 2,213,597 of its patients. *See* 45 C.F.R. § 164.502(a);
- B. 21CO failed to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of the

electronic protected health information (ePHI) held by 21CO. See 45 C.F.R. § 164.308(a)(1)(ii)(A);

- C. 21CO failed to implement certain security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 C.F.R. § 164.306(A). See 45 C.F.R. § 164.308(a)(1)(ii)(B);
 - D. 21CO failed to implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports. See 45 C.F.R. § 164.308(a)(1)(ii)(D);
 - E. 21CO disclosed protected health information to a third party vendors, acting as its business associates, without obtaining satisfactory assurances in the form of a written business associate agreement. See 45 C.F.R. §§ 164.502(e) and 164.308(b)(3).
3. **No Admission.** This Agreement is not an admission of liability by 21CO.
4. **No Concession.** This Agreement is not a concession by HHS that 21CO is not in violation of the HIPAA Rules and that 21CO is not liable for civil money penalties.
5. **Intention of Parties to Effect Resolution.** This Agreement is intended to resolve HHS Transaction Number: 16-233022 and any violations of the HIPAA Rules related to the Covered Conduct specified in Section I, Paragraph 2 of this Agreement. In consideration of the Parties' interest in avoiding the uncertainty, burden, and expense of further investigation and formal proceedings, the Parties agree to resolve this matter according to the Terms and Conditions below.

II. Terms and Conditions

6. **Payment.** 21CO agrees to pay to HHS the amount of **\$2,300,000** ("Resolution Amount") as settlement for potential civil money penalties for any violations related to the Covered Conduct identified in paragraph 2 of section I prior to May 25, 2017 ("the Bankruptcy Petition date"), as determined by 11 U.S.C. § 362(a). 21CO agrees to pay the Resolution Amount on the Effective Date of this Agreement, as defined in section II, paragraph 14, by automated clearing house transaction pursuant to written instructions to be provided by HHS.
7. **Corrective Action Plan.** 21CO has entered into and agrees to comply with the Corrective Action Plan ("CAP"), attached as Appendix A, which is incorporated into this Agreement by reference. If 21CO breaches the CAP, and fails to cure the breach as set forth in the CAP, then 21CO will be in breach of this Agreement and HHS will not be subject to the Release set forth in paragraph 9 of section II of this Agreement.
8. **Release by HHS.** In consideration of Payment in paragraph 6 of Section II of this Agreement, HHS releases 21CO from any actions it may have against 21CO under the HIPAA Rules for the Covered Conduct identified in paragraph 2 of section I prior to or

on May 25, 2017, the Bankruptcy Petition date. HHS does not release 21CO from, nor waive any rights, obligations, or causes of action other than those specifically referred to in paragraph 2 of section 1. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.

9. **Conditional Release by HHS.** In consideration and conditioned upon 21CO's performance of its obligations under this Agreement, HHS releases 21CO from any actions it may have against 21CO under the HIPAA Rules for the Covered Conduct identified in paragraph 2 of section I after May 25, 2017, the Bankruptcy Petition date. HHS does not release 21CO from, nor waive any rights, obligations, or causes of action other than those specifically referred to in paragraph 2 of section 1. This release does not extend to actions that may be brought under section 1177 of the Social Security Act, 42 U.S.C. § 1320d-6.
10. **Agreement by Released Parties.** 21CO shall not contest the validity of its obligations to pay, nor the amount of, the Resolution Amount *or* any other obligations agreed to under this Agreement. 21CO waives all procedural rights granted under Section 1128A of the Social Security Act (42 U.S.C. § 1320a-7a); 45 C.F.R. Part 160 Subpart E; and HHS Claims Collection regulations at 45 C.F.R. Part 30, including, but not limited to, notice, hearing, and appeal with respect to the Resolution Amount.
11. **Binding on Successors.** This Agreement is binding on 21CO and its successors, heirs, transferees, and assigns.
12. **Costs.** Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
13. **No Additional Releases.** This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.
14. **Effect of Agreement.** This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.
15. **Execution of Agreement and Effective Date.** The Agreement shall become effective (*i.e.*, final and binding) upon the date of signing of this Agreement and the CAP by the last signatory ("Effective Date").
16. **Tolling of Statute of Limitations.** Pursuant to 42 U.S.C. § 1320a-7a(c)(1), a civil money penalty ("CMP") must be imposed within six (6) years from the date of the occurrence of the violation. To ensure that this six-year period does not expire during the term of this agreement, 21CO agrees that the time between the Effective Date of this Agreement (as set forth in Section II, paragraph 14) and the date the Resolution Agreement may be terminated by reason of 21CO's breach, plus one-year thereafter, will not be included in calculating the six (6) year statute of limitations applicable to the

violations which are the subject of this agreement. 21CO waives and will not plead any statute of limitations, laches, or similar defenses to any administrative action relating to the Covered Conduct identified in paragraph 2 of section I that is filed by HHS within the time period set forth above, except to the extent that such defenses would have been available had an administrative action been filed on the Effective Date of this Resolution Agreement.

17. **Disclosure.** HHS places no restriction on the publication of the Agreement. In addition, HHS may be required to disclose this Agreement and related material to any person upon request consistent with the applicable provisions of the Freedom of Information Act, 5 U.S.C. § 552, and its implementing regulations, 45 C.F.R. Part 5.
18. **Execution in Counterparts.** This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
19. **Authorizations.** The individual(s) signing this Agreement on behalf of 21CO represent and warrant that they are authorized by 21CO to execute this Agreement. The individual(s) signing this Agreement on behalf of HHS represent and warrant that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

For 21st Century Oncology

Date

[INSERT TITLE]
[INSERT ORGANIZATION NAME]

For United States Department of Health and Human Services

Timothy Noonan Date
Regional Manager, Southeast Region
Office for Civil Rights

Appendix A
CORRECTIVE ACTION PLAN
BETWEEN THE
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
21st CENTURY ONCOLOGY

I. Preamble

21st Century Oncology (“21CO”) hereby enters into this Corrective Action Plan (“CAP”) with the United States Department of Health and Human Services, Office for Civil Rights (“HHS”). Contemporaneously with this CAP, 21CO is entering into a Resolution Agreement (“Agreement”) with HHS, and this CAP is incorporated by reference into the Agreement as Appendix A. 21CO enters into this CAP as consideration for the release set forth in section II, paragraph 9 of the Agreement.

II. Contact Persons and Submissions

A. Compliance Representative as Contact Person

21CO shall designate an individual to serve as the Compliance Representative (“CR”). The CR shall be an individual who is knowledgeable about the HIPAA Rules and about the policies and practices of 21CO with respect to ePHI. The CR shall be responsible for assuring 21CO’s compliance with this Agreement and the CAP and for arranging for the provision of such assistance as 21CO may require to comply with the Agreement and the CAP, including, but not limited to, arranging for and/or providing policies, procedures, training and internal monitoring services, and including after resolution of 21CO’s bankruptcy.

The CR, designated immediately below, shall also serve as the contact person on behalf of 21CO regarding the implementation of this CAP and for receipt and submission of notifications and reports:

Name: _____

Title: _____

Address: _____

Email: _____

Office Phone: _____

Cell Phone: _____

Fax: _____

HHS has identified the following individual as its authorized representative and contact person with whom 21CO is to report information regarding the implementation of this CAP:

Timothy Noonan, Regional Manager, Office for Civil Rights
61 Forsyth St, Suite 16T70
Atlanta, GA 30303-8909
Voice: (404) 562-7859
Fax: (404) 562-7881
Email: Timothy.Noonan@hhs.gov

21CO and HHS agree to promptly notify each other of any changes in the contact persons or the other information provided above.

B. Proof of Submissions.

Unless otherwise specified, all notifications and reports required by this CAP may be made by any means, including certified mail, overnight mail, or hand delivery, 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.

III. Effective Date and Term of CAP

The Effective Date for this CAP shall be calculated in accordance with paragraph 14 of the Agreement (“Effective Date”). The period of compliance (“Compliance Term”) with the obligations assumed by 21CO under this CAP shall begin on the Effective Date and end two (2) years from the Effective Date unless HHS has notified 21CO under Section VII hereof of its determination that 21CO has breached this CAP. In the event of such a notification by HHS under Section VII hereof, the Compliance Term shall not end until HHS notifies 21CO that it has determined that the breach has been cured. After the Compliance Term ends, 21CO shall still be obligated to submit the final Annual Report as required by Section V, Paragraph F, and comply with the document retention requirement in section VI.

IV. Time

Any reference to number of days refers to number of calendar days. In computing any period of time prescribed or allowed by this CAP, the day of the act, event, or default from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday, a Sunday, or a Federal holiday, in which event the period runs until the end of the next day which is not one of the aforementioned days.

V. Corrective Action Obligations

21CO agrees to the following:

A. Completion of Risk Analysis and Risk Management Plan

1. As required by 45 CFR 164.308(a)(1)(ii)(A), 21CO shall, within 120 days of the Effective Date conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of e-PHI held by 21CO and document the security measures 21CO implemented or is implementing to sufficiently reduce the identified risks and vulnerabilities to a reasonable and appropriate level.

B. Revision of Policies & Procedures

Within ninety (90) days of completion of the Risk Analysis and Risk Management Plan required in Section V, Paragraph A of this CAP:

1. 21CO shall revise its policies and procedures regarding information system activity review to require the regular review of audit logs, access reports, and security incident tracking reports pursuant to 45 C.F.R. § 164.308(a)(1)(ii)(D).
2. 21CO shall revise its policies and procedures regarding access establishment and modification and termination pursuant to 45 C.F.R. § 164.308(a)(4)(ii)(C) and 45 C.F.R. § 164.308(a)(3)(ii)(C). Such policies shall include protocols for access to 21CO's e-PHI by affiliated physicians, their practices, and their employees.
3. 21CO shall forward the revised policies and procedures required by this Section to HHS for HHS's review and approval. HHS will inform 21CO in writing, through the CR, as to whether HHS approves or disapproves of the proposed policies and procedures.

If HHS disapproves of proposed policies and procedures, HHS shall provide the CR with comments and required revisions. Upon receiving any required revisions to such policies and procedures from HHS, 21CO shall have thirty (30) calendar days in which to revise the policies and procedures accordingly and then submit the revised policies and procedures to HHS for review and approval. This process shall continue until HHS approves the policies and procedures.

C. Adoption and Distribution of Policies and Procedures

1. Within thirty (30) days of obtaining HHS's approval of the revisions to policies and procedures, 21CO shall finalize and officially adopt the policies and procedures in Section V, Paragraph B of this CAP in accordance with its applicable administrative procedures.

21CO shall distribute the approved policies and procedures to all 21CO workforce members to whom the policies apply.

2. 21CO shall distribute the approved policies and procedures to all new workforce members to whom the policies apply within fifteen (15) days of the date they become workforce members of 21CO.
3. 21CO shall review the approved policies and procedures routinely and shall promptly update the policies and procedures to reflect changes in operations at 21CO, federal law, HHS guidance, and/or any material compliance issues discovered by 21CO that warrant a change in the policies and procedures.

D. Business Associate Agreements

1. Within 120 days of the Effective Date and annually following the Effective Date, 21CO shall provide HHS with the following:
 - a. An accounting of 21CO's business associates, to include the names of business associates, a description of services provided, a description of the business associate's handling of 21CO's PHI, and the date services began; and
 - b. Copies of the business associate agreements that 21CO maintains with its business associates.

E. Monitoring

1. *Internal Monitoring.*

Within sixty (60) days of the Effective Date, 21CO shall develop, and the CR shall submit to HHS, a written description of 21CO's plan to monitor internally its compliance with this CAP ("Internal Monitoring Plan"). 21CO shall forward the proposed Internal Monitoring Plan to HHS for HHS's review and approval. HHS will inform 21CO in writing, through the CR, as to whether HHS approves or disapproves of the proposed Internal Monitoring Plan.

If HHS does not approve of the proposed Internal Monitoring Plan, HHS shall set forth in writing the reasons for its disapproval and recommendations for the necessary modifications to the proposed Internal Monitoring Plan. Within thirty (30) days of HHS's disapproval, 21CO shall submit a revised Internal Monitoring Plan to HHS, incorporating HHS's comments and requested revisions. This process shall continue until HHS approves of the proposed Internal Monitoring Plan.

While this CAP is in effect, 21CO may wish, or be required by changes in the law, technology, or otherwise, to update, revise or prepare a new Internal Monitoring Plan. 21CO shall be permitted to do so provided that 21CO first submit any updated, revised, or new Internal Monitoring Plan to the Assessor,

the appointment of whom is provided for below, and obtain the Assessor's approval before 21CO implements the revised version of the Internal Monitoring Plan; and, further provided, that 21CO also submit any updated, revised, or new Internal Monitoring Plan to HHS for its review and comment, and obtain HHS' approval, before 21CO implements the revised Internal Monitoring Plan. Whenever the existing Internal Monitoring Plan is updated or revised and the updated or revised version has been approved by both the Assessor and HHS and has then gone into effect, the updated or revised Internal Monitoring Plan shall be deemed to have superseded the prior Internal Monitoring Plan.

2. *External Assessments*

a. Selection and Engagement of an Assessor.

Within sixty (60) days of the Effective Date, 21CO shall engage a qualified, objective, independent third-party assessor to review its compliance with this CAP ("Assessor").

Through the CR, 21CO shall notify HHS in writing of the name of the individual or entity 21CO designates to serve as the Assessor. The CR shall also simultaneously submit to HHS the proposed Assessor's curriculum vitae or a statement of the Assessor's expertise in the area of monitoring compliance with federal and/or state statutes and regulations, including privacy statutes and regulations. Any individual or entity designated by 21CO to serve as the Assessor must certify in writing at the time of his, her or its designation, and must provide reasonable written documentation to the effect that he, she or it has the requisite expertise and experience regarding the implementation of the HIPAA Rules and has the necessary resources and is otherwise able to perform the assessments and reviews described herein in a professionally independent fashion, taking into account any other business relationships or other engagements that the individual or entity may have. HHS shall be permitted to interview an individual or representatives of any entity who are designated by 21CO to serve as the Assessor.

HHS shall either approve or disapprove of the designation in writing. HHS's approval shall not be unreasonably withheld. If HHS does not approve the designation, HHS shall explain the basis of its disapproval in writing, and the process described above shall be repeated until HHS has approved a designated Assessor. Upon receiving HHS's approval, 21CO shall enter into a written contract with the Assessor for the performance of the assessments and reviews described herein.

b. Assessor's Plan. Within sixty (60) days of being approved for service by HHS, the Assessor shall submit to HHS and 21CO a written plan, describing with adequate detail, the Assessor's plan for fulfilling the

duties set forth in this subsection (“Assessor’s Plan”). HHS shall inform the CR of its approval or disapproval of the proposed Assessor’s Plan.

If HHS does not approve of the proposed Assessor’s Plan, HHS shall set forth in writing the reasons for its disapproval and recommendations for the necessary modifications to the proposed Assessor’s Plan. If the proposed Assessor’s Plan is not approved by HHS, the Assessor shall submit a revised Assessor’s Plan to HHS, incorporating HHS’s comments and requested revisions, within thirty (30) days of HHS’s issuance of its disapproval of the proposed Assessor’s Plan. This process shall continue until HHS approves of the proposed Assessor’s Plan.

The Assessor shall review the Assessor’s Plan at least annually and shall provide HHS and 21CO with a copy of any revisions to the Assessor’s Plan within ten (10) business days of the Assessor’s making such revisions. HHS shall have a reasonable opportunity to comment and make recommendations regarding any revisions or modifications at any time while the CAP is in effect. The Assessor shall make such changes to the revisions as HHS may reasonably request.

- c. Description of Assessor Reviews. The Assessor shall investigate, assess and make specific determinations about 21CO’s compliance with the requirements of this CAP (“Assessor Reviews”). Among other things, the Assessor will: perform unannounced site visits to the various 21CO facilities and departments (as determined in the Assessor’s Plan) to determine if workforce members are complying with the 21CO policies and procedures described above; conduct quarterly progress meetings with 21CO’s key management, including the CR, Privacy Officer, Security Officer and any other appropriate personnel; interview workforce members, employees of affiliated physician practices, and business associates as needed; and follow up on reports of noncompliance with the CAP, including follow-up on reports of Reportable Events, as defined by Section V, Paragraph F.
- d. Assessor Reports and Response. The Assessor shall prepare written reports based on the Assessor Reviews (“Assessor Report”). The Assessor shall provide such written reports to HHS and 21CO. The first Assessor Report shall be due sixty (60) days after the one-year anniversary of HHS’s issuance of its approval of the appointment of the Assessor, as provided above. The Assessor shall also submit reports within sixty (60) days of the second anniversary of the date of HHS’s approval of the Assessor’s appointment and within sixty (60) days of the third anniversary of the date of HHS’s approval of the Assessor’s appointment.

Within sixty (60) days of 21CO’s receipt of each Assessor Report, the CR shall submit to HHS and the Assessor a written response to the Assessor

Report. HHS may, but is not required to, comment on any of the reports submitted by the Assessor and/or any response from the CR.

The Assessor shall immediately report to 21CO and HHS any significant violation of the CAP which the Assessor identifies during the course of the performance of the Assessor Reviews. The CR shall prepare a written response, including, when appropriate, a plan of correction, and provide such response to HHS and the Assessor, within thirty (30) days of the issuance of the Assessor's report of the significant violation.

- e. Retention of Records. The Assessor, the CR and 21CO shall retain and make available to HHS, upon HHS's request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the Assessor and the CR or 21CO) related to Assessor Reviews.
- f. Assessor Removal/Termination. 21CO may not terminate the Assessor except for cause and may only do so with HHS's consent, which shall not be unreasonably withheld. In the event that 21CO seeks to terminate the Assessor, the CR shall provide a written statement to HHS setting out in detail the basis for the request, and HHS shall take those steps it deems appropriate in reviewing and deciding whether adequate cause actually exists for the termination of the Assessor. If HHS agrees that the current Assessor should be terminated, HHS will so inform the CR in writing and 21CO will be authorized to terminate the services of the current Assessor. If such termination does occur, 21CO must engage a replacement Assessor in accordance with this CAP within thirty (30) days of the termination of the previous Assessor, subject to HHS's approval.

If HHS concludes that cause does not exist for the removal of the original Assessor, it shall so inform the CR in writing and the original Assessor shall remain in place and be authorized to function in all respects as if 21CO had never sought to remove the Assessor.

In the event HHS determines that the Assessor does not possess the expertise, independence, or objectivity required by this CAP, or has failed to carry out its responsibilities as set forth in this CAP, HHS may, at its sole discretion, require 21CO to terminate the original Assessor and to engage a new Assessor in accordance with this CAP. Prior to requiring such action, HHS shall provide a written explanation to the CR explaining the rationale for HHS's decision. In such event, 21CO must engage a replacement Assessor in accordance with this CAP within thirty (30) days of the termination of the previous Assessor.

In the event that the Assessor resigns while the CAP is in effect, 21CO shall nominate a replacement Assessor using the same process as described herein for appointing a replacement Assessor who is removed for cause at the instigation of either 21CO or HHS.

- g. Validation Review. In the event HHS, in its discretion, determines or has reason to believe that: (a) one or more Assessor Reports fail to conform to the requirements of this CAP; or (b) one or more Assessor Reports are factually inaccurate or otherwise improper or incomplete, HHS may, in its sole discretion, conduct its own review to determine whether the Assessor Report(s) comply with the requirements of this CAP and/or are factually inaccurate, incorrect or otherwise improper (“Validation Review”).

Prior to initiating a Validation Review, HHS shall notify the CR of its intent to do so and provide a written explanation of why HHS believes such a review is necessary. To resolve any concerns raised by HHS, the CR may request a meeting with HHS to discuss the results of any Assessor Review or Assessor Report submissions or findings; present any additional or relevant information to clarify the results of the Assessor Review or Assessor Report to correct the inaccuracy; and/or propose alternatives to the proposed Validation Review. The CR shall provide any additional information as may be requested by HHS under this section in an expedited manner. HHS will attempt in good faith to resolve any concerns with the CR prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of HHS.

3. *HHS’s Authority Is Not Superseded*. The use of an assessor does not affect or limit, in any way, HHS’s authority to investigate complaints against 21CO or conduct additional compliance reviews of 21CO under any applicable statute or regulation that HHS administers.

F. Internal Reporting

1. *Procedure for Internal Reporting*. 21CO shall require all members of its workforce who have access to ePHI to report to the CR at the earliest possible time any violation of 21CO’s policies and procedures related to the HIPAA Rules of which they become aware. Within sixty (60) days of HHS’s approval of the CR’s Internal Monitoring Plan, 21CO shall develop a written procedure for such reporting (“Internal Reporting Procedure”) and shall submit the Internal Reporting Procedure to HHS for its comment and approval. The review and approval process of the Internal Reporting Procedure shall be identical to that of the Internal Monitoring Plan, as set out in this CAP.

While the CAP is in effect, 21CO may determine from time to time to revise or amend the Internal Reporting Procedure; such revisions or amendments may only take effect after the CR has presented them to HHS for review and approval and made any changes that HHS may reasonably request.

Pursuant to the Internal Reporting Procedure, whenever 21CO or the CR learns that a member of its workforce may have violated 21CO's policies and procedures related to the HIPAA Rules, the CR, with the full cooperation of 21CO, shall promptly investigate the allegations raised and shall document each investigation in writing. If 21CO determines that a member of its workforce has failed to comply with 21CO's policies and procedures related to the HIPAA Rules, the CR shall notify both the Assessor and HHS in writing of the finding within thirty (30) days of such determination. Such violation findings shall be known as "**Reportable Events**." The CR's written report to HHS and the Assessor shall include the following information:

- a. A complete description of the Reportable Event, including the relevant facts, the persons involved, the date, time and place on which the events occurred, and the provision(s) of the implicated requirement; and
 - b. A description of the actions taken by 21CO and/or the CR to mitigate any harm and any further steps that they plan to take to address the problems that gave rise to the violation(s) and prevent them from recurring.
2. If no Reportable Events occur during any one Reporting Period, as defined in this CAP, 21CO shall so inform HHS in its Annual Report for that Reporting Period.

G. Annual Reports

1. The one-year period after HHS's last approval of the policies and procedures required by this CAP, and each subsequent one-year period during the Compliance Term as defined in this CAP, shall each be known as a "**Reporting Period**." 21CO shall submit to HHS a report with respect to the status of and findings regarding its compliance with this CAP for each Reporting Period ("Annual Report"). Each Annual Report shall include:
 - a. An attestation signed by the CR attesting that the revision or implementation of policies and procedures required under this CAP: (a) have been adopted; (b) are being implemented; and (c) have been distributed to all 21CO workforce members, workforce members of affiliated physician practices, business associates, and vendors;
 - b. An attestation signed by the CR listing all of 21CO's locations, facilities, affiliates, etc. under its system, the name under which each such location is doing business, the corresponding mailing address, phone number and fax number for each location, and attesting that each location has complied with the obligations of this CAP;

- c. A summary of Reportable Events identified during the Reporting Period and the status of any corrective or preventative action(s) taken by 21CO relating to each Reportable Event;
- d. An attestation signed by the CR stating that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content, and believes that, upon such inquiry, the information is accurate and truthful.

VI. Document Retention

21CO shall maintain for inspection and copying, and shall provide to OCR upon request, all documents and records relating to compliance with this CAP for six (6) years from the Effective Date.

VII. Requests for Extensions and Breach Provisions

21CO is expected to fully and timely comply with all provisions of its CAP obligations.

A. Timely Written Requests for Extensions

21CO may, in advance of any due date in this CAP, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CAP. A “timely written request” is defined as a request in writing received by HHS at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed. It is within HHS’s sole discretion as to whether to grant or deny the extension requested.

B. Notice of Breach and Intent to Impose Civil Monetary Penalty (CMP)

The Parties agree that a breach of this CAP by 21CO constitutes a breach of the Agreement. Upon a determination by HHS that 21CO has breached this CAP, HHS may notify 21CO of (1) 21CO’s breach; and (2) HHS’s intent to impose a CMP pursuant to 45 C.F.R. Part 160 for the Covered Conduct set forth in section I, paragraph 2 of the Agreement and any other conduct that constitutes a violation of the HIPAA Rules occurring after May 25, 2017 (the Bankruptcy Petition date).

C. Response

21CO shall have thirty (30) days from the date of receipt of the Notice of Breach and Intent to Impose CMPs from HHS to demonstrate to HHS’s satisfaction that:

1. 21CO is in compliance with the obligations of this CAP that HHS cited as the basis for the breach;
2. The alleged breach has been cured; or

3. The alleged breach cannot be cured within the 30-day period, but that (a) 21CO has begun to take action to cure the breach; (b) 21CO is pursuing such action with due diligence; and (c) 21CO has provided to HHS a reasonable timetable for curing the breach.

D. Imposition of CMP

If at the conclusion of the 30 day period, 21CO fails to meet the requirements of Section VII, Paragraph C to HHS's satisfaction, HHS may proceed with the imposition of a CMP against 21CO pursuant to 45 C.F.R. Part 160 for the Covered Conduct set forth in section I, paragraph 2 of the Agreement and any other conduct that constitutes a violation of the HIPAA Rules occurring after May 25, 2017 (the Bankruptcy Petition date). HHS shall notify 21CO in writing of its determination to proceed with the imposition of a CMP.

For 21st Century Oncology

[INSERT NAME] Date
[INSERT TITLE]
[INSERT ORGANIZATION NAME]

For United States Department of Health and Human Services

Timothy Noonan Date
Regional Manager, Southeast Region
Office for Civil Rights