
Patient Safety Organization Provider Services Agreement

This Patient Safety Organization Services Agreement (“**Agreement**”), is entered into effective _____, 20__ (the “**Effective Date**”), by and between Clarity PSO, a division of Clarity Group, Inc., a Delaware for-profit corporation, (“**Clarity PSO**”), and the Provider, _____ (“**Client**”), who wishes to participate in the Radiation Oncology Incident Learning System sponsored by the American Society for Radiation Oncology (“**ASTRO**”) and the American Association of Physicists in Medicine (“**AAPM**”).

RECITALS

WHEREAS, Clarity PSO is a Patient Safety Organization, as that term is defined under the Patient Safety and Quality Improvement Act of 2005 at 42 U.S.C. 299 et seq., and its implementing regulations at 42 CFR 3.10 et seq. (collectively, the “**Patient Safety Act**”) and is a listed PSO by the Secretary of Health and Human Services of the U.S. Government, Agency for Healthcare Research and Quality;

WHEREAS, Client (inclusive of the Department of Radiation Oncology and the staff who conduct, coordinate and plan the work and care delivery within the Department) is a healthcare provider as defined in 42 CFR Part 3, Subpart A, Section 3.20, that desires to participate in the Radiation Oncology Incident Learning System, sponsored by the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM), by collecting and voluntarily reporting information via the Radiation Oncology Incident Reporting Tool to a Patient Safety Organization on a privileged and confidential basis, as provided for under the Patient Safety Act, for analysis of patient safety events for the purpose of improving patient safety and the quality of healthcare services;

NOW THEREFORE, in consideration of the mutual covenants and obligations set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Clarity PSO and Client (each, a “**Party**” and collectively, the “**Parties**”) agree as follows:

AGREEMENT

1. DEFINITIONS

All capitalized terms shall have the meaning set forth in the Patient Safety Act, currently in effect and as may be amended from time to time, unless otherwise defined in this Agreement.

2. SERVICES

Subject to the terms and conditions of this Agreement, commencing on the Effective Date, and continuing until the effective date of termination of this Agreement, Clarity PSO shall provide Patient Safety Evaluation System services and Patient Safety Activities (hereinafter, the “**Services**” as described in the Scope of Services on **Exhibit A**, attached hereto or as may be amended over the term of the Agreement.

2.1 Performance. Clarity PSO shall provide the Services hereunder: (a) in accordance with all applicable federal and state laws and regulations; (b) on a non-discriminatory basis; and (c) in a commercially reasonable manner, in accordance with generally accepted industry standards for PSO services. Clarity PSO may utilize subcontractors to carry out Clarity's obligations under this Agreement.

2.2 Site. Except as otherwise provided in this Agreement, the Services will be performed at the Clarity PSO premises or at such other locations as Clarity PSO deems appropriate.

3. OBLIGATIONS OF CLARITY PSO

3.1 Confidentiality. Clarity PSO will receive information from Client that is included within the definition of a Patient Safety Evaluation System, as defined in Section 921(6) of the Patient Safety Act, or Patient Safety Work Product, as defined in Section 921(7) of the Patient Safety Act, or create information or analysis for Client within the meaning of Patient Safety Activities, as defined in Section 921(5) of the Patient Safety Act (collectively, "Confidential Information"). Confidential Information shall not include non-identifiable patient safety work product or non-individually identifiable health information prepared by Clarity PSO. Clarity PSO shall maintain the confidentiality and security of Confidential Information in accordance with the requirements of the Patient Safety Act and the HIPAA Privacy and Security Rules; Exhibit B describes Clarity PSO's data security processes in place. The Parties agree that the terms of the Business Associate Agreement attached as Exhibit C to this Agreement will govern Clarity PSO's receipt, use, and disclosure of data provided to Clarity PSO pursuant to this Agreement. Client understands that for educational and administrative purposes Clarity will share with ASTRO the names of participating facilities, as well as de-identified aggregate data. Clarity PSO agrees that it will inform its employees and agents, including contractors and subcontractors, engaged in handling such Confidential Information of the confidential character of such Confidential Information and of the existence of applicable laws, including the HIPAA Confidentiality Regulations, as defined in Section 921(1) of the Patient Safety Act and the privilege and confidentiality provisions of Section 922 of the Patient Safety Act. Clarity PSO will ensure that agents performing services on its behalf agree to the same restrictions and conditions that apply to Clarity PSO with respect to such information, and agrees to implement reasonable and appropriate safeguards to protect the data.

3.2 Improper Disclosures. Clarity PSO shall notify Client in a timely manner after discovery of any Disclosure of Client's Patient Safety Work Product by Clarity PSO that is not permitted by this Agreement. Such improper Disclosure shall be grounds for termination of the Agreement under Section 6.2.

3.3 Compliance. Clarity PSO represents and warrants to Client that Clarity shall provide Services as noted in Exhibit A in accordance with all applicable provisions of the Patient Safety Act currently in effect and as may be amended from time to time.

3.4 AHRQ Certification. Clarity PSO hereby represents and warrants that it is listed as a certified Patient Safety Organization by AHRQ as of the Effective Date of this Agreement. During the term of this Agreement, Clarity PSO will keep such listing in good standing. If Clarity PSO becomes delisted by AHRQ, Clarity PSO shall provide immediate notice of the delisting to Client, and this Agreement will terminate pursuant to Section 6.

4. OBLIGATIONS OF CLIENT

4.1 Patient Safety Evaluation System and Patient Safety Work Product. Client shall be responsible for establishing and implementing the Patient Safety Evaluation System in place in its organization, as defined by the Patient Safety Act currently in effect and as may be amended from time to time, and for determining what is defined as Patient Safety Work Product collected for purposes of transmission to Clarity PSO.

4.2 Permission to provide data to the Radiation Oncology Incident Learning System. In the execution of the Agreement, Client has provided permission to the Department of Radiation Oncology to submit data into the Radiation Oncology Incident Learning System.

4.3 Transfer of Patient Safety Work Product. Client shall be responsible for providing all information via the Radiation Oncology – Incident Reporting Tool made available to the Client as a web-based reporting system, including Patient Safety Work Product, as defined by the Patient Safety Act currently in effect and as may be amended from time to time, to Clarity PSO that is necessary for Clarity PSO to provide Services (the “Client Data”). Clarity Group shall not be liable for any damages resulting from errors, omissions and inadequacies in data submitted to Clarity by Client.

4.4 Authorization of Disclosures of Patient Safety Work Product. When requesting that Clarity PSO disclose Client’s identifiable Patient Safety Work Product, Client shall complete and execute an authorization for disclosure of identifiable Patient Safety Work Product.

4.5 Virus Warranty. Client covenants, represents and warrants to Clarity PSO that Client has not knowingly incorporated, and will not knowingly incorporate, into the Client Data being transmitted to Clarity PSO any viruses, worms, bombs, traps, Trojan Horses or other code designed to interrupt normal processing Services (“Malicious Codes”) and that Client has taken and will continue to take reasonable precautions to prevent malicious codes from being introduced.

5. FEES

5.1 Services Fees. Client will not incur services fees for the provision of Patient Safety Services, as set forth in Exhibit A. Additional quality and safety projects beyond the scope of the topics included in Exhibit A may be conducted for additional fees.

6. TERM

The term of this Agreement shall be for a period of two (2) years commencing on the Effective Date. Thereafter, this Agreement shall automatically renew for successive periods of one (1) year, unless earlier terminated pursuant to Section 7 below.

7. TERMINATION

7.1 Immediate Termination. This Agreement shall terminate immediately and automatically if (i) Clarity PSO is de-listed as a federally certified Patient Safety Organization by AHRQ, (ii) either Party is dissolved, or (iii) the agreement between Clarity PSO and American Society for Radiation Oncology (ASTRO), the sponsor of the Radiation Oncology Incident Learning System, is severed.

7.2 Either Party may terminate this Agreement with or without cause (i) before the expiration of the initial or any renewal term upon 30 days advance written notice to the other Party, or (ii) if either Party materially breaches this Agreement and the defaulting Party fails to cure the breach within 30 days of the termination notice.

7.3 Upon termination, Clarity PSO will return or certify destruction of all intellectual property and confidential information of Client submitted under this Agreement, including all identifiable patient safety work product and individually identifiable health information as defined in HIPAA and the HIPAA Privacy and Security Rules. However, Clarity PSO shall not be required to delete or destroy and may use any non identifiable Patient Safe Work Product incorporated into reports or educational materials, or non-identifiable health information, as defined in HIPAA and the HIPAA Privacy and Security Rules. Destruction of the information shall be carried out in accordance with applicable state law and HIPAA regulations. Pursuant to Section 924(g) of the Patient Safety Act, Clarity PSO will within 90 days of such termination (i) transfer the patient safety work product and data relating to the Client in an industry-standard accessible format to a PSO

of the Client's choice, who agrees to accept such patient safety work product, (ii) return the identifiable patient safety work product and data back to Client in an industry-standard accessible format, or (iii) if (i) or (ii) is not practical, destroy the identifiable patient safety work product and data. In addition, upon termination, the Parties shall continue to comply with all applicable provisions of the Patient Safety Act and HIPAA related to the security and confidentiality of any re-identifiable data retained by Clarity PSO.

8. NOTICES

Except as otherwise expressly provided herein, all notices, certifications, requests, demands, payments and other communications hereunder: (i) shall be in writing; (ii) may be delivered by certified or registered mail via the United States Postal Service, postage prepaid; by hand; by facsimile; or by any internationally recognized private courier; (iii) shall be effective (a) if mailed via certified or registered mail, on the date five (5) days after the date of mailing, or (b) if hand delivered, faxed or delivered by private courier, on the date of delivery; and (iv) shall be addressed as follows:

If to Clarity PSO:

Clarity Group, Inc
8601 W Bryn Mawr Ave, Suite 110
Chicago, IL 60631
Attn: Executive Director, Clarity PSO

If to Client:

or to such other address or addresses as may hereafter be specified by notice given by one Party to the other.

9. FORCE MAJEURE

If the performance of this Agreement by either Party is prevented, hindered, delayed or otherwise made impracticable by reason of any cause beyond a Party's reasonable control, such as acts of God, acts of any government, war, acts of terrorism or other hostility, the elements, fire, explosion, power failure, equipment failure, labor dispute, stability or availability of the Internet or the inability to obtain necessary supplies and the like (a "Force Majeure Event"), that Party shall be excused from such performance to the extent, including for the duration of time, that it is prevented, hindered or delayed by such Force Majeure Event. In the event a Party becomes aware of a Force Majeure Event that will affect its performance under this Agreement, it shall so notify the other Party as soon as reasonably practicable. The Parties shall thereafter work together to take reasonable steps to mitigate the effects of any inability to perform or degradation of performance, if practicable.

10. GOVERNING LAW

The Agreement shall be construed in accordance with the laws of Illinois.

11. AMENDMENT

This Agreement may not be modified except by mutual agreement of the Parties. No modification of this Agreement shall be valid unless in writing and duly executed by both Parties.

12. SURVIVAL

The terms and conditions contained in this Agreement that by their sense and context are intended to survive the performance hereof by either or both parties hereunder shall so survive the completion of the performance, cancellation or termination of this Agreement including, without limitation, the provisions related to Confidentiality, set forth in section 2.1 above.

13. RELATIONSHIP OF PARTIES

Nothing contained in this Agreement will be deemed to create, or be construed as creating, a joint venture or partnership between the parties. Neither Party is, by virtue of this Agreement or otherwise, authorized as an agent or legal representative of the other Party. Neither Party is granted any right or authority hereunder to assume or create any obligation or responsibility, express or implied, on behalf or in the name of the other Party, or to bind such other Party in any manner.

14. INDEMNIFICATION AND INSURANCE

Each Party will indemnify and hold the other Party harmless from any and all third party claims arising from any breach or default on the part of the indemnifying Party in the performance of the confidentiality and security obligations of this Agreement. Each Party shall further indemnify and hold the other Party harmless against all costs, reasonable, actual attorney fees, expenses, and liabilities incurred in connection with any such action or proceeding brought against the other Party by reason of any such claims. The indemnifying Party, upon notice to the other Party, shall resist and defend, at the expense of the indemnifying Party, such action or proceeding with counsel reasonably satisfactory to the other Party.

15. ASSIGNMENT

The Services to be rendered and the duties performed by Clarity PSO under this Agreement are of a unique and personal nature. Clarity PSO agrees not to assign this Agreement or any interest herein without Client's prior written consent. Any such assignment shall be null and void and without any force or effect.

16. ENTIRE AGREEMENT

This Agreement, including the attached Business Associate Agreement, constitutes the entire agreement between the Parties pertaining to the subject matter herein and expressly supersedes all prior and written and oral agreements and understanding between the Parties hereto with respect to the subject matter hereof. This Agreement may not be amended or modified unless so modified in writing by the Parties.

17. WAIVER

No waiver by a Party of any breach or default under this Agreement shall be deemed to be a waiver of any other breach or default of any kind or nature, whether or not such Party knows of such breach or default at the time it accepts such payment or performance. No failure or delay on the part of a Party to exercise any right it may have with respect to this Agreement shall prevent the exercise thereof by such Party at any time such other Party may continue to be so in default, and no such failure or delay shall operate as a waiver of any default. A failure by either Party to insist upon strict compliance with any terms of the terms of this Agreement in any instance shall not be construed as a waiver of such terms in the future.

18. SEVERABILITY

If any such provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of any Party hereto under this Agreement will not be materially or adversely affected thereby, (a) such provision will be fully severable, (b) this Agreement will be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement will remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision or by its severance here from, and (d) in lieu of such illegal, invalid or unenforceable provision, there will be added automatically as a part of this Agreement a legal, valid and enforceable provision as may be possible and reasonably acceptable to the parties herein.

19. PUBLIC ANNOUNCEMENTS

Client authorizes Clarity PSO and ASTRO to publicly list Client by name as a participant in RO-ILS.

_____ YES _____ NO

Clarity PSO and ASTRO shall not otherwise make public the fact that the Parties have entered into this Agreement or use Client’s name, logo or trademarks in any advertisement or other publicity without Client’s prior written consent.

IN WITNESS WHEREOF, the Parties have executed this Patient Safety Organization Services Agreement as of the Effective Date:

CLARITY PSO

CLIENT

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Exhibit A

Scope of Services

For purposes of this Scope of Services, Client shall be known as “**RO-ILS Provider**”.

Description of PSO Services and Work Plan:

Initial contracting for PSO services and protections under the Patient Safety Act

- Privilege and confidentiality protections under the Patient Safety and Quality Improvement Act of 2005
- Educational tutorials and presentations describing the Patient Safety Act, the aims of the PSO program, and participation compliance.

Development of a Patient Safety Evaluation System

- Education on the formation of the RO-ILS Provider’s Patient Safety Evaluation System: Identifying the purpose, structure, and process for RO-ILS Provider to collect, analyze, and report quality/safety information to/from the PSO

Reporting functionality

- **Healthcare SafetyZone® Portal** as the web-based operating system to report information to the PSO via the Radiation Oncology Incident Reporting Tool; data collection and management of safety information for quality and safety purposes and for reporting to the PSO
 - Specific access link to web-based application
 - Create/maintain users
 - Training of the Healthcare SafetyZone® Portal
- Information denoted as ‘Submit to PSO’ is considered Patient Safety Work Product (“**PSWP**”)

Patient Safety Activities performed by the PSO

- Analysis of PSWP in conjunction with a Radiation Oncology Healthcare Advisory Council (“**RO-HAC**”)
- Examples of analysis of safety information may include, but are not limited to:
 - Safety events submitted into Portal and reported to PSO (MLC positioning errors, radiation overdosing, calibration errors)
 - Quarterly comparative reports of safety events: Clinical or safety event trending and analysis
 - Safety Alerts
 - Focus studies: Deep dive of specific events or event type reported
 - Development of safety alerts and/recommendations (i.e. case study regarding patient harm or near misses)
 - Safety culture development (i.e. how to improve reporting with a non-punitive, learning environment)
 - Clinical quality and safety outcomes analyses (recommendations from SME, general safety experts review, positive change analysis)
 - Policy and Procedure/Protocol/Best Practice analyses and development
 - Clinical Education development

On Demand Services:

Additional quality and safety projects beyond the scope of the aforementioned topics may be conducted for additional fees.

Exhibit B

Data Security: Processes and Review

Physical Security

High security physical controls and procedures keep Clarity software applications up and running around the clock. Clarity's hosting facility has multiple levels of protection and is secured 24X7X365 by full time on-site staff and dedicated security personnel through the use of proximity card readers, biometric sensors and video surveillance systems.

Virtual Security

Clarity maintains a completely private network at our hosting facility. Using Cisco firewalls and Windows 2017 Servers, Clarity uses the highest level of security possible. Patches are applied monthly with a two week notice. Critical patches are applied as needed.

Connectivity is made through an SSL connection that uses a 2048 bit key combined with SHA1 and RSA algorithms.

Clarity does periodic security scans/audits of all of the **Healthcare SafetyZone® Portal** servers verifying that host operating systems provide the lowest risk possible. We contract with third party vendors for these scans/audits.

Clarity uses monitoring tools on all hosts to review the health and performance and receives immediate notification on all threshold alerts as well as any outages. The hardware, operating systems and network are also monitored by our third party host 24/7.

Disaster Recovery

Our hosting facilities offer our clients the highest levels of security, protection and reliability. The data center is designed for fault-tolerance and feature fully redundant power grids with multiple feeds from separate substations. The network and cable distribution are designed with divergent routes and multiple connections for unsurpassed reliability and have 2N high-availability standard uninterrupted power supply (UPS) systems and N+1 backup diesel generators to all equipment.

Clarity maintains off-site backups and has a tested disaster recovery plan that accommodates partial and complete failure.

A copy of the disaster recovery plan can be made available upon request.

Audits

Clarity has SSAE SOC 1 Type 2 audits performed. SSAE 16 is an attestation standard put forth by the Auditing Standards Board (ASB) of the American Institute of Certified Public Accountants (AICPA) that addresses engagements undertaken by a service auditor for reporting on controls at organizations (i.e., service organizations) that provide services to user entities, for which a service organization's controls are likely to be relevant to a user entities' internal control over financial reporting (ICFR).

A copy of the audit report can be made available upon request.

Exhibit C
Business Associate Agreement

Please insert your BAA.

SAMPLE