

Subscriber Audit and Compliance Policy

I. Introduction

CancerLinQ is committed to conquering cancer through appropriate, secure, and ethical usage of health information entrusted to the CancerLinQ system. The ability to learn from every patient will accelerate progress against cancer and will give patients and physicians more comprehensive information to make decisions about cancer prognosis and treatment.

CancerLinQ is a learning health system designed to monitor, coordinate, and improve the quality of care provided to cancer patients. Once collected for these Health Care Operations purposes, CancerLinQ data is expected to also have utility in other secondary applications, such as updating and developing quality benchmarks and clinical guidelines, hypothesis generation, research, and provision of reports.

To maintain data within the CancerLinQ system with a high level of security, accuracy and utility, Subscribers are required to comply with CancerLinQ policies and agreements. To ensure that Subscribers are in compliance with all CancerLinQ policies and agreements, an Audit Policy has been developed, with which Subscribers are required to comply.

II. Glossary of Terms Used

De-Identified Data: Refers to Health Information: (a) that has been redacted or otherwise revised to exclude all identifiers specified in 45 CFR § 164.514(b)(2) and with respect to which no actual knowledge exists that the information could be used alone or in combination with other information to identify any individual who is a subject of the information; or (b) that an appropriately qualified professional has determined does not constitute Individually Identifiable Health Information in accordance with 45 CFR § 164.514(b)(1).

Electronic Health Record (EHR): Longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Includes, but is not limited to, information about patient demographics, progress notes, diagnoses, medications, vital signs, past medical history, immunizations, laboratory data, and pathology and radiology reports.

Health Care Operations: Any one or more of the activities set forth in 45 C.F.R. § 164.501, including, but not limited to, quality assessment and improvement, outcomes evaluation, case management and care coordination, business planning and development, and business management and general administrative activities.

Licensed Marks: A trademarked image or logo that the Subscriber has obtained permission to utilize or display.

Research: A systematic investigation, including development, testing, and evaluation of a therapeutic intervention, designed to develop or contribute to generalizable knowledge. Research includes development of research projects or preparation for research.

Report: A document or dashboard that provides information and analyses gleaned from review or analysis of CancerLinQ data. CancerLinQ will offer a family of reports, to include Quality Reports, Practice Management Reports, and others.

Primary Account User: A User at each practice whose responsibility it is to manage all Users within the practice, including but not limited to, setting up new User accounts, monitoring User activity, and communicating with CancerLinQ when necessary for technical issues and questions.

Subscriber: An entity that enters into a Participation Agreement and Business Associate Agreement with CancerLinQ in order to provide data to CancerLinQ and receive Health Care Operations services from CancerLinQ.

User: An individual who is assigned log-in credentials to access services from CancerLinQ. A Subscriber account may have one or more Users associated with it.

III. General Audit and Compliance Policies

- A. This policy applies to Subscribers to CancerLinQ LLC.
- B. By using CancerLinQ, Subscribers consent to self-auditing, and agree that a representative will perform annual self-audits in line with CancerLinQ policies and procedures.
- C. Noncompliance with CancerLinQ policies and agreements may subject a Subscriber to this Compliance Policy.
- D. CancerLinQ Subscribers must comply with all applicable laws and all CancerLinQ agreements, policies, and procedures.
- E. CancerLinQ's Subscriber Audit Process consists of yearly self-audits as well as real-time usage monitoring by CancerLinQ.
- F. Although the CancerLinQ Audit Procedure primarily consists of Subscriber self-audits, CancerLinQ reserves the right to conduct on-site and/or off-site audits of Subscribers at any time and for any reason, after providing reasonable advanced written notice (30 days). CancerLinQ will provide a reason for an audit, agree with the Subscriber to a

mutually agreeable timeframe for the audit, determine the scope of the audit in advance, and work with the Subscriber to ensure that the audit does not pose undue hardship on ordinary workflows within the practice.

- G. CancerLinQ reserves the right to conduct random audits of Subscribers.
- H. When compliance issues are identified, CancerLinQ will attempt to resolve the issue with the Subscriber, which may include informal notification of the issue, a written warning, or sanctions from the CancerLinQ Compliance Committee.
- I. If a Subscriber chooses not to resolve compliance issues, or if they disagree with a decision made by the Compliance Committee, they may invoke mediation under the CancerLinQ Participation Agreement.
- J. If Subscriber noncompliance includes infractions against State or Federal law, CancerLinQ may report to governmental bodies as required.
- K. By using CancerLinQ, Subscribers acknowledge that their activity within CancerLinQ may be monitored.

IV. CancerLinQ Usage Monitoring

- A. CancerLinQ strives to proactively identify instances of Subscriber noncompliance through annual Subscriber self-audits, CancerLinQ system usage monitoring, and ongoing engagement with Subscribers.
- B. CancerLinQ administrators may monitor Subscriber usage of CancerLinQ, including but not limited to:
 - 1. Reports viewed;
 - 2. System logon events;
 - 3. Access to data within CancerLinQ;
 - 4. Patients opted out;
 - 5. User account creation; and
 - 6. User permission assignment.

V. CancerLinQ Subscriber Self-Auditing

- A. By using CancerLinQ, Subscribers consent to self-auditing, and agree that a representative will perform annual self-audits as specified by CancerLinQ policies and procedures.
- B. CancerLinQ may rely upon Subscriber self-audits to evaluate compliance with CancerLinQ policies, agreements, terms of use, applicable law, and addendums.
- C. CancerLinQ Subscribers are required to complete a self-audit form annually, on a cycle determined by the date the Primary Account User's account is activated in the system and on the calendar year thereafter. CancerLinQ Data Governance Staff will communicate this process to Subscribers and ensure that audits are submitted annually.
- D. Self-audits are to be completed by the practice's Primary Account User or their designee.
- E. For practices with multiple locations, the Primary Account User will submit a self-audit form annually for each location.

VI. CancerLinQ Audits of Subscribers

- A. Potential reasons for audits may include but are not limited to:
 - 1. Conduct that violates Subscriber Agreements;
 - 2. Conduct that violates the Business Associate Agreement;
 - 3. Conduct that violates the CancerLinQ Terms of Use
 - 4. Conduct that violates State or Federal law.
- B. By using CancerLinQ, Subscribers agree to fully cooperate in an audit.

VII. Potential Sanctions

- A. Failure to comply with CancerLinQ policies and procedures may result in sanctions, which may include but are not limited to:
 - 1. Letter from CancerLinQ counsel
 - 2. Loss of some CancerLinQ functionality
 - 3. Invocation of ASCO Member sanctions
 - 4. Temporary suspension of some or all CancerLinQ functionality or termination of CancerLinQ Services
 - 5. Legal action or regulator involvement

Application:

Applies to CancerLinQ LLC

History:

Adopted by CancerLinQ LLC Board of Governors October 13, 2015