



CancerLinQ™ Data Governance Policies

I. Introduction

The American Society of Clinical Oncology (“ASCO”) and ASCO’s wholly owned subsidiary, CancerLinQ LLC, are committed to conquering cancer through appropriate, secure, and ethical usage of health information entrusted to CancerLinQ. ASCO believes that 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 that is 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 applications, such as updating and developing quality benchmarks and clinical guidelines, Research, hypothesis generation, and provision of reports.

II. Glossary of Terms Used

Ancillary Data: Data that is collected by CancerLinQ from a source other than a Subscriber (for example, claims data, death indices, and environmental data).

Collected Data: The PHI and Provider Data that are collected by CancerLinQ from Subscribers in order to provide Health Care Operations services.

Consumer: An individual or entity that enters into an agreement with CancerLinQ to receive one or more reports.

Consumer-User: A User whose log-in credentials are assigned based on the individual’s association with a particular Consumer.

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).

Firewall: Administrative, technical, and physical safeguards that restrict access to and distribution of data.

Fully-Identifiable PHI: PHI that contains any one or more direct identifiers such that the PHI does not constitute a Limited Data Set or De-Identified Data.

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.

Health Information: Any information, including genetic information, whether oral or recorded in any form or medium, that: (1) is created or received by a Health Care Provider, Health Plan, Public Health Authority, Employer, life insurer, school, university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an Individual; the provision of health care to an Individual; or the past, present, or future payment for the provision of health care to an Individual.

HIPAA: Collectively, the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations as amended from time to time.

Individually Identifiable Health Information: Information that is a subset of Health Information, including demographic information collected from an Individual, and: (1) is created or received by a Health Care Provider, Health Plan, Employer, or Health Care Clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an Individual; the provision of Health Care to an Individual; or the past, present, or future Payment for the provision of Health Care to an Individual; and: (i) that identifies the Individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the Individual.

Limited Data Set: Refers to Protected Health Information that does not contain any of the following direct identifiers of the Individual who is the subject of the PHI, or of relatives, employers or household members of the individual: names; postal address information, other than town or city, State, and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

Market Report: A CancerLinQ report that is intended for a commercial entity, which contains only information created from de-identified CancerLinQ data without the use and disclosure of PHI or Provider Data.

Protected Health Information (PHI): The subset of Individually Identifiable Health Information that is: (i) transmitted by Electronic Media; (ii) maintained in Electronic Media; or (iii) transmitted or maintained in any other form or medium. Protected Health Information excludes Individually Identifiable Health Information: (i) in education

records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g; (ii) in records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); (iii) in employment records held by a Covered Entity in its role as Employer; and (iv) regarding a person who has been deceased for more than 50 years.

Provider Data: Data that relates to either a Subscriber or an individual Subscriber-User, such as practice management data or quality measure scores.

Public Health Activities: Those activities described in 45 C.F.R. § 164.512(b).

Quality Development: Activities that relate to general efforts to improve quality of care, including but not limited to, trend analysis, hypothesis generation, and the development or refinement of quality benchmarks or clinical care guidelines.

Quality Report: A report provided to Subscribers by CancerLinQ in connection with the Health Care Operations quality assessment and improvement services for which Subscriber has engaged CancerLinQ, including any customized reports and dashboards.

Practice Management Report: A report provided to Subscribers by CancerLinQ that aids with decisions, actions and resource allocation to enable the provision of professional services to meet the objectives of the organization.

Public Health Report: A report provided to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions.

Redacted Data: Refers to the De-Identified Data and Limited Data Set data, collectively, in CancerLinQ.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Report: A document or dashboard that provides information and analyses gleaned from CancerLinQ. CancerLinQ will have a family of reports, to include Quality Reports, Practice Management Reports, Public Health Reports, Market Reports, and others.

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

Subscriber-User: A User whose log-in credentials are assigned based on the individual's association with a particular Subscriber.

Treatment: The provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management

of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

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

III. General Policies

- A. CancerLinQ leadership, workforce, advisors, and volunteers will follow ethical guiding principles of stewardship, protection, and transparency and accountability when making decisions regarding CancerLinQ.
- B. CancerLinQ will comply with laws and regulations applicable to CancerLinQ and ASCO.
- C. CancerLinQ has adopted and will comply with ASCO's approved HIPAA Privacy and Security Policies and any other policies regarding the collection, use, disclosure, and stewardship of CancerLinQ Collected Data.

IV. Data Governance Oversight

- A. All ASCO and CancerLinQ workforce (including Data Governance Office workforce and CancerLinQ informatics workforce involved in data quality and security monitoring) will be required to participate in training appropriate to their role, including HIPAA and Human Subjects Protection training and training on CancerLinQ policies and procedures.
- B. The CancerLinQ Data Governance Oversight Committee and its subcommittees, operating under a charter approved by the ASCO Board of Directors and CancerLinQ Board of Governors, will oversee the development of policies and procedures regarding the security, quality, integrity, accessibility, and public benefit of Collected Data and Ancillary Data.

V. Data Collection

- A. CancerLinQ's collection of data is driven by the Health Care Operations activities that CancerLinQ is designed to support.
- B. The scope of Collected Data may include, but is not limited to, information such as provider and patient demographics; appointments; billing; visit/encounter details; medical history and physical examination; family and social history; consult reports; surgery reports; pathology and laboratory data; and medication administration and prescription history.
- C. In the future, CancerLinQ may also collect Ancillary Data. Ancillary Data may not be used to re-identify Redacted Data and its use and disclosure will otherwise be subject to CancerLinQ policies.

- D. CancerLinQ will not accept biofluids or biological specimens.
- E. CancerLinQ will only accept data from Subscribers that the Subscriber collects or creates in connection with Treatment, Payment, or Health Care Operations.
- F. In accordance with ASCO's HIPAA Privacy Policies, CancerLinQ will request and collect the minimum necessary information from Subscribers. With respect to the ongoing provision of Health Care Operations and Treatment services to Subscribers, CancerLinQ has determined that the minimum necessary information is the complete electronic health record. In addition, at the time a Subscriber enrolls in CancerLinQ, CancerLinQ will collect a certain amount of historic data from the Subscriber that is necessary to enable CancerLinQ to provide Health Care Operations services to the Subscriber.
- G. Subscribers are not required to obtain patient consent to disclose many types of Collected Data to CancerLinQ; however individual Subscribers may elect to obtain some form of patient consent. Further, in certain circumstances Subscribers may be required to obtain patient consent prior to disclosing particularly sensitive types of collected data to CancerLinQ. If a Subscriber is required or chooses to obtain patient consent, it is the Subscriber's responsibility to obtain valid consent and provide such accurate consent information to CancerLinQ prior to disclosing Collected Data.
- H. Subscribers are required to disclose to their patients that they are participating in CancerLinQ. CancerLinQ will provide educational materials to Subscribers to aid in proper disclosure about CancerLinQ participation.

VI. Data Use and Disclosure – Health Information

- A. Collected Data will be disclosed when required by law, consistent with CancerLinQ's contractual and regulatory obligations.
- B. Collected Data will be longitudinal in nature through the use of a master patient index that permits the linking of new information.
- C. Subject to the permitted uses under the participation agreement, the Business Associate Agreement, to applicable law, and to the data governance policies, CancerLinQ has sole discretion to determine what information is provided in response to data or analytics requests, subject to the requirements and limitations in applicable laws.

Fully-Identifiable Collected Data

- D. Collected Data that constitutes Fully-Identifiable PHI will only be used for Treatment and Health Care Operations, including quality improvement and care coordination, as well as creating Redacted Data sets. It will not be used for Research, Quality Development, or generation of Market Reports.

- E. Designated ASCO and CancerLinQ workforce and/or vendors contracted by ASCO or CancerLinQ to provide services in support of the development, operation or maintenance of CancerLinQ will have access to Fully-Identifiable Collected Data only as necessary to perform their specific services and responsibilities, such as data quality maintenance and security monitoring.
- F. An ASCO or CancerLinQ workforce member who has access to the Redacted Data for the purpose of engaging in Research, Quality Development, generation of Market Reports, or any other activity for which the use of Fully-Identifiable PHI is prohibited under applicable law or CancerLinQ policies, may not access, use, or disclose Fully-Identifiable Collected Data or any key to a code that links the Fully-Identifiable Collected Data and the Redacted Data.
- G. Except as provided below in Section (VI)(T), a Subscriber-User will have access to Fully-Identifiable PHI only where the Fully-Identifiable PHI relates to a patient with whom the Subscriber-User has a treatment relationship. CancerLinQ will not permit Subscribers to have direct access to Fully-Identifiable PHI that does not relate to a patient of the Subscriber's practice. Where a particular patient has received treatment from more than one Subscriber, CancerLinQ features (such as clinical decision support reports) provided to a Subscriber-User regarding the patient may be informed by PHI collected from other Subscribers; however, the Subscriber-User will not have direct access to the underlying PHI from the other Subscribers.

Redacted Data

- H. In its capacity as a Business Associate of Subscribers, CancerLinQ may create two types of Redacted Data from the Fully-Identifiable Collected Data: De-Identified Data and Limited Data Sets.
- I. The Redacted Data will enable CancerLinQ to provide Health Care Operations services and conduct Quality Development activities, using the minimum necessary PHI (or no PHI) whenever possible. The Redacted Data may also be used for Research, Public Health Activities, and other purposes as permitted by applicable law and as set forth in this Policy.
- J. A Firewall will segregate the Fully-Identifiable Collected Data and the Redacted Data and will prohibit access to Fully-Identifiable Collected Data by persons who may access the Redacted Data for the purpose of engaging in Research, Quality Development, generation of Market Reports, or any other activity for which the use of Fully-Identifiable Collected Data is prohibited under applicable law or CancerLinQ policies.
- K. Requests for external, third-party use of Redacted Data or for analyses using Redacted Data will be reviewed by the Data Governance Office, with a review process and procedures overseen by the Data Governance Oversight Committee. The Data Access Subcommittee of the Data Governance Oversight Committee or their delegates will also review data and analytics requests, as specified in policies and procedures.

- L. Subscribers and Consumers are prohibited from re-identifying Redacted Data.

Limited Data Sets

- M. Limited Data Set data may be used for Health Care Operations services, Quality Development, Research and Public Health Activities.
- N. In all cases, the minimum necessary amount of PHI within a Limited Data Set will be used and disclosed.
- O. Limited Data Set data will not be used to create Market Reports.

De-Identified Data

- P. In addition to the purposes for which Fully-Identifiable PHI and Limited Data Set data may be used and disclosed, De-Identified Data may be used to create Market Reports or other types of reports.
- Q. Market Reports will not include PHI. Market Reports will be generated using only De-Identified Data.
- R. The minimum necessary amount of De-Identified Data will be used and disclosed by CancerLinQ.

Quality Reports

- S. CancerLinQ Quality Reports may have a drill-down feature that enables a Subscriber-User to view PHI within a Quality Report to see which patient visits affected a particular quality score.
- T. As a default setting, a Subscriber-User will be permitted to drill down in a Quality Report to the Fully-Identifiable PHI of only those patients with whom the Subscriber-User has a treatment relationship. A Subscriber may also designate specific Users to be permitted to drill down to Fully-Identifiable PHI of any patient of the Subscriber if the User requires access to such PHI for the Subscriber's Health Care Operations.

VII. Data Use and Disclosure - Provider Data

- A. CancerLinQ will contain Provider Data (for example, quality improvement reports that describe provider performance compared to a clinical guideline or aggregate measure). Provider Data may describe professional or practice characteristics of an individual Subscriber-User or characteristics of a Subscriber through the aggregate reporting of the Users in a Subscriber practice.
- B. Any type of Provider Data, to the extent that it includes PHI, will be subject to and protected under HIPAA and any other applicable law.

- C. Market Reports will not contain Provider Data that can identify a Subscriber or an individual Subscriber-User. Market Reports will contain only analysis of such data.

Quality Reports

- D. Users from a Subscriber will have access to the aggregate Subscriber-level Quality Reports for that Subscriber (for example, a report describing the performance of all Users in the Subscriber practice in the aggregate for a specific quality measure in such a way that does not directly identify scores associated with an individual User).
- E. A Subscriber and its Users will not be able to access the Quality Reports of another Subscriber or its respective Users.
- F. As a default setting, Subscriber-Users will have access to only their own User-level Quality Reports. The Subscriber, however, may designate certain Users associated with the Subscriber to have access to the User-level reports for all Users at the Subscriber.
- G. CancerLinQ will not make Subscriber-level and User-level Quality Reports available outside of the Subscriber practice without an opt-in by the Subscriber or Subscriber-User, respectively. For example, if CancerLinQ is approved as a qualified clinical data registry under the Physician Quality Reporting System, a Subscriber-User who permits CancerLinQ to submit his/her quality data to the Centers for Medicare and Medicaid Services could opt in to such reporting by CancerLinQ.

Application:

Applies to CancerLinQ™

History:

Approved by CancerLinQ Board of Governors on October 13, 2015