957 CMR 5.00: HEALTH CARE CLAIMS, CASE MIX AND CHARGE DATA RELEASE PROCEDURES

5.01: General Provisions

Scope and Purpose. 957 CMR 5.00 governs the disclosure of certain payer data, hospital case mix data and hospital charge data submitted by health care payers and providers pursuant to M.G.L. c. 12C. The purpose of 957 CMR 5.00 is to specify: (a) the process by which data will be released to certain requesters as required by M.G.L. c. 12C; and (b) the application and data release process for all other requests for certain payer, hospital case mix and hospital charge data collected and maintained by the Center for Health Information and Analysis.

5.02: Definitions

All defined terms in 957 CMR 5.00 are capitalized. As used in 957 CMR 5.00, unless the context otherwise requires, the following words shall have the following meanings:

Acute Hospital Case Mix Databases. The CHIA databases housing Case Mix Data and Charge Data, including the outpatient emergency department database, the inpatient discharge database and the outpatient observation database.

APCD. The All Payer Claims Database.

APCD Data. Information submitted to CHIA by Payers, including, but not limited to, data regarding member eligibility, products, providers, encounters, and medical, pharmacy, or dental claims.

Applicant. An individual or organization that requests Data or a Summarized Data Report in accordance with 957 CMR 5.00.

Case Mix Data. Case specific, diagnostic discharge data that describe socio-demographic characteristics of the patient, the medical reason for the admission, treatment and services

provided to the patient, and the duration and status of the patient's stay in the hospital. Case Mix data includes hospital inpatient data, outpatient observation data, and hospital outpatient emergency department data.

Charge Data. The full, undiscounted total and service-specific charges billed by the hospital to the general public. Charge Data includes hospital inpatient data, outpatient observation data, and hospital outpatient emergency department data, and associated administrative bulletins.

CHIA. The Center for Health Information and Analysis.

CMS. The federal Centers for Medicare & Medicaid Services.

Data. APCD Data, Case Mix Data or Charge Data as defined in 957 CMR 5.02.

Data Recipient. Any entity that receives Data pursuant to 957 CMR 5.00.

Data Subject. Any individual whose personal patient identifiers are subject to release under 957 CMR 5.00.

Data Use Agreement. A document detailing a Data Recipient's commitments to data privacy and security, as well as restrictions on the disclosure and use of Data.

De-identified Data. Information that does not identify an individual patient and with respect to which there is no reasonable basis to believe the data can be used to identify an individual patient. CHIA shall de-identify Data using the standards and methods required by the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-1320d-8, and its implementing regulations, including 45 C.F.R. Parts 160, 162 and 164.

Direct Patient Identifiers. Personal information, such as name, social security number, and date of birth, that uniquely identifies an individual or that can be combined with other readily available information to uniquely identify an individual.

Disclosure. The release, transfer, provision of, access to, or divulging in any manner of Claims Data, Case Mix Data or Charge Data.

Government Agency. For purposes of this regulation, Government Agency shall mean any state agency, department or authority of the Commonwealth of Massachusetts, as well as federal agencies and departments of the United States of America and excludes the governments of other states as well as other political subdivisions of the Commonwealth of Massachusetts. Data requests from Government Agencies shall be reviewed pursuant to 957 CMR 5.03 while Data requests from other governmental bodies shall be reviewed pursuant to 957 CMR 5.06.

Payer. An entity that submits health care claims data to CHIA pursuant to M.G.L. c. 12C, § 10.

Protected Health Information. Protected Health Information includes any individually identifiable health information (including any combination of data elements) that relates to the past, present, or future physical or mental health or condition of an individual; or the past, present

or future payment for the provision of health care to an individual; and (a) identifies an individual, or (b) with respect to which there is a reasonable basis to believe that the information can be used to identify an individual patient.

Provider. A health care provider that submits data to CHIA pursuant to M.G.L. c. 12C, § 8 and/or M.G.L. c. 12C, § 9.

Provider Organization. A health care provider organization that submits data to CHIA pursuant to M.G.L. c. 12C, § 8 and/or M.G.L. c. 12C, § 9.

Researchers. Academic researchers, including those affiliated with public and private universities and medical schools, as well as other organizations and researchers undertaking health care research or health-care related projects funded by CMS, the National Institute of Health, Government Agencies and other governmental bodies.

Treatment and Coordination of Care. Treatment and Coordination of Care means the provision, coordination or management of health care services.

Website. The website of the Center for Health Information and Analysis located at www.chiamass.gov.

5.03: Requests from Government Agencies

(1) All Government Agency requests for Data shall be made in writing as set forth in an agreement between the parties or as provided on CHIA's Website.

(2) When requesting Protected Health Information, Government Agencies shall identify the public purposes for which the Data is sought and the security measures designed to protect the Data from inadvertent and/or unauthorized disclosure.

(3) CHIA shall fulfill Government Agency requests for Protected Health Information to the extent permissible under state and federal laws protecting patient privacy and data security. To the extent required by such laws, Government Agencies may be required to establish to CHIA's satisfaction that they are seeking the minimum amount of Protected Health Information necessary to accomplish the public purpose for which access to such data is given and that appropriate data security measures are in place.

(4) Government Agencies requesting Protected Health Information of Medicaid recipients will be required to demonstrate compliance with 42 U.S.C. §1396a(a)(7) to the satisfaction of both CHIA and the Executive Office of Health and Human Services.

(5) Government Agencies requesting Medicare Data will be required to demonstrate compliance with CMS requirements regarding access to and use of such Data.

(6) Prior to the receipt of any Data, Government Agencies shall enter into a written agreement with CHIA governing its use and disclosure.

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5.04: Requests from Payers, Providers, Provider Organizations and Researchers for De-Identified Data

(1) Requests from Payers, Providers, Provider Organizations and Researchers for De-identified Data shall be made in writing by filing an application with CHIA in a form specified by CHIA as provided on its Website.

(2) CHIA shall fulfill requests from Payers, Providers, Provider Organizations and Researchers for De-identified Data based upon an application that establishes to CHIA's satisfaction that the Data will exclusively be used for the purposes of lowering total medical expenses, coordinating care, benchmarking, quality analysis and other research, administrative or planning purposes. Such purposes exclude purposes that CHIA determines are contrary to the public interest.

(3) Payer, Provider, Provider Organization and Researcher requests for De-identified Data for any other uses, including commercial uses involving the resale or re-use of Data, shall be reviewed under 957 CMR 5.06.

(4) Payers, Providers, Provider Organizations and Researchers shall enter into a Data Use Agreement with CHIA prior to the receipt of Data. The Data Use Agreement shall, at a minimum:

(a) restrict the use of the Data to those uses identified in the application;
(b) require the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized disclosure or use of the Data;
(c) require the Data Recipient to notify CHIA of any unauthorized use or disclosure of the Data; and
(d) permit CHIA, at its discretion, to audit the Data Recipient's compliance with the provisions of the Data Use Agreement.

5.05 Requests from Payers, Providers and Provider Organizations for Data with Direct Patient Identifiers for Treatment and Coordination of Care

(1) Payer, Provider and Provider Organization requests for Data with Direct Patient Identifiers shall be made in writing by filing an application with CHIA in a form specified by CHIA as provided on its Website.

(2) CHIA shall fulfill Payer, Provider and Provider Organization requests for Direct Patient Identifiers for Treatment and Coordination of Care to the extent permissible under state and federal laws protecting patient privacy and data security. Payers, Providers and Provider Organizations may be required to establish to CHIA's satisfaction that Data Subjects have consented to the release of the Data for the specific use described in the Payer, Provider or Provider Organization's request.

(3) Payer, Provider and Provider Organization requests for Protected Health Information for uses other than requests for Direct Patient Identifiers for Treatment and Coordination of Care shall be reviewed under 957 CMR 5.06.

(4) Payers, Providers and Provider Organizations requesting Protected Health Information of Medicaid recipients will be required to demonstrate compliance with 42 U.S.C. § 1396a(a)(7) to the satisfaction of both CHIA and the Executive Office of Health and Human Services.

(5) Payers, Providers and Provider Organizations requesting Medicare Data will be required to demonstrate compliance with CMS requirements regarding access to and use of such Data.

(6) Payers, Providers and Provider Organizations shall enter into a Data Use Agreement with CHIA prior to the receipt of data with Direct Patient Identifiers. The Data Use Agreement will strictly limit the use of such Data for Treatment and Coordination of Care and will specify the security measures taken to protect the Data from further disclosure. The Data Use Agreement shall also, at a minimum:

(a) commit the Data Recipient to return or destroy the Data received from CHIA upon completion of the project for which the use of the Data was approved. All Data destruction must comport with M.G.L. c. 93I and any other applicable state or federal law;
(b) require the Data Recipient to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of the Data;
(c) require the Data Recipient to notify CHIA of any unauthorized use or disclosure of the Data; and
(d) permit CHIA, at its discretion, to audit the Data Recipient's compliance with the provisions of the Data Use Agreement.

5.06. All Other Requests for Data

(1) Requests for Data that do not fall under the categories described in 957 CMR 5.03, 5.04 or 5.05 shall be made in writing by filing an application with CHIA in a form specified by CHIA as provided on its Website.

(2) In any application for Data under 957 CMR 5.06, each Applicant shall:

(a) identify and demonstrate a need for the Protected Health Information requested and for those specific data elements CHIA deems necessary to protect individual privacy;
(b) specify the purpose of the request, including the intended use(s) of the Data, a detailed project description that describes any other data sources to be used for the project and, if applicable, the research methodology;
(c) specify security and privacy measures that will be taken in order to safeguard patient privacy and prevent unauthorized access to or use of the Data;
(d) specify the Applicant's methodology for maintaining data integrity and accuracy; and
(e) describe how, or if, the results of the Applicant's analysis will be published;

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(3) Applicants requesting Protected Health Information of Medicaid recipients will be required to demonstrate compliance with 42 U.S.C. § 1396a(a)(7) to the satisfaction of both CHIA and the Executive Office of Health and Human Services.

(4) Applicants requesting Medicare Data will be required to demonstrate compliance with CMS requirements regarding access to and use of such Data.

(5) Applications for Data filed under 957 CMR 5.06 will be posted on CHIA's Website. CHIA will not post those portions of applications that specify an Applicant's proposed data security measures.

(6) CHIA will invite public comments on applications for at least 10 business days following the day on which the application is posted on the Website.

(7) Applications for Data under 957 CMR 5.06 shall be reviewed by a Data Privacy Committee comprised of CHIA employees or contractors with relevant experience in data privacy, data security, information technology and research.

(a) In reviewing each application for Data submitted pursuant to 957 CMR 5.06, the Data Privacy Committee shall determine whether the Applicant has met the criteria for release specified in 957 CMR 5.06(9).

(b) The Data Privacy Committee shall prepare a written recommendation for the Executive Director specifying whether the application should be approved, approved with conditions or denied.

(8) All applications for Data under 957 CMR 5.06 shall be reviewed by the Data Release Committee established under 957 CMR 5.08.

(9) The Executive Director will approve an application if he or she determines that the Applicant has met the following criteria:

(a) There is no more than a minimal risk to individual privacy based on:

1. an adequate plan to protect Protected Health Information;
2. a written commitment to return or destroy Data upon completion of the project for which the Data is sought; and
3. written assurances restricting the use of Data to the specific uses identified in the application.

(b) The Applicant cannot meet its research or project objectives without the requested Data.

(c) The Data sought by the Applicant is the minimum amount necessary to achieve the Applicant's research or project objectives.

(d) The purpose for which the Data is requested is in the public interest. Uses that serve the public interest include, but are not limited to:

1. health cost and utilization analysis to formulate public policy;
2. studies that promote improvement in population health, health care quality or access;
3. health planning and resource allocation studies; and
4. studies directly tied to evaluation or improvement of Massachusetts state government initiatives.

(e) The Applicant has demonstrated it is qualified to undertake the study or accomplish the intended use.

(10) The Executive Director's decisions to approve or deny applications for Data are final and not subject to further review or appeal.

(11) The Executive Director may impose conditions on the subsequent use and disclosure of any Data released under 957 CMR 5.06.

(12) All Applicants for Data shall enter into a Data Use Agreement with CHIA prior to the receipt of any Data. The Data Use Agreement shall, at a minimum:

(a) Restrict the use of the Data to those uses identified in the application and approved by the Executive Director;
(b) Commit the Applicant to return or destroy the Data received from CHIA upon completion of the project for which the use of the Data was approved. All data destruction must comport with M.G.L. c. 93I and any other applicable state or federal law;
(c) Require the Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of the Data;
(d) Require the Applicant to notify CHIA of any unauthorized use or disclosure of the Data;
(e) Permit CHIA, at its discretion, to review all analyses, research or other products created or based on Protected Health Information provided by CHIA prior to the release or disclosure of any such analysis, research or product; and
(f) Permit CHIA, at its discretion, to audit the Applicant's compliance with the provisions of the Data Use Agreement.

5.07 Requests for Summarized Data Reports

(1) Applicants may request a report generated by CHIA that is derived from Data (Summarized Data Reports). In determining whether to compile such a report, CHIA will consider the public interest served, the availability of its resources, the complexity of the request, and privacy concerns, i.e. that there is no more than a minimal risk to individual privacy in the public release of the report.

(2) Summarized Data Reports will contain only aggregate data (data summaries) and De-identified Data. Examples of Summarized Data Reports include: counts; totals; rates per thousand; index values; and other standardized metrics. Summarized Data Reports will be subject to CHIA's cell suppression policy and accordingly no cell (e.g., admittances, discharges, patients, services, etc.) less than 11 will be displayed, nor will percentages or other mathematical formulas allowing calculation of a cell less than 11.

(3) The Executive Director or his/her designee will approve or deny such requests. Such approval/denial is final and not subject to further review or appeal.

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5.08: Data Release Committee

(1) The Executive Director shall establish a Data Release Committee to advise the Executive Director on best practices regarding data release, data security and data protection.

(2) The Data Release Committee shall include, but not be limited to, representatives from health care plans, health care providers, health care provider organizations and consumers. The Executive Director may appoint additional members to the Committee.

(3) The Executive Director shall convene the Data Release Committee as necessary to review applications for Data and other issues related to the release of Data.

(4) The Data Release Committee shall review applications for Data submitted pursuant to 957 CMR 5.06.

(5) In reviewing each application for Data submitted pursuant to 957 CMR 5.06, the Data Release Committee shall make a recommendation to the Executive Director regarding whether the Applicant has met the criteria for release specified in 957 CMR 5.06(9).

(6) CHIA will post information about the Data Release Committee membership, scheduled meetings and meeting agendas on its Website.

(7) Data Release Committee recommendations on applications are not binding on the Executive Director.

5.09: Compliance and Penalties

(1) Sanctions. If a Data Recipient fails to comply with any of the requirements and conditions for receiving Data under 957 CMR 5.00, CHIA may:

(a) deny future access to Data;
(b) terminate current access to all Data; and/or
(c) demand and secure the destruction or return of all Data.

(2) Penalties. A Data Recipient that fails to comply with the requirements of 957 CMR 5.00 also will be subject to all penalties and remedies allowed by law, including but not limited to M.G.L. c. 214, § 1B and M. G.L. c. 93A. CHIA will notify state and federal law enforcement officials, as applicable, of any violations of 957 CMR 5.00 and the agreements made with Data Recipients thereunder.

5.10: Administrative Bulletins

CHIA may, from time to time, issue Administrative Bulletins to clarify its policies and procedures under 957 CMR 5.00 and to establish fees.

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5.11: Other Provisions

(1) Fees. CHIA shall charge a fee to all non-governmental entities requesting Data or a Summarized Data Report, as established under M.G.L. c. 12C, § 12(b). Fee schedules will be issued by CHIA by Administrative Bulletin and updated from time to time.

(2) Other Disclosures. CHIA may make other disclosures of Data as required by law, including, but not limited to, disclosures made pursuant to Civil Investigative Demands, law enforcement subpoenas or court orders.

(3) Confidentiality. Data, as defined in Section 5.02, released by CHIA pursuant to 957 CMR 5.00 are not a public record.

5.12 Severability

The provisions of 957 CMR 5.00 are severable. If any provision or the application of any provision is held to be invalid or unconstitutional, such invalidity shall not be construed to affect the validity or constitutionality of any remaining provisions of 957 CMR 5.00 or the application of such provisions.

REGULATORY AUTHORITY

957 CMR 5:00: M.G.L. c.12C