

**RULES AND REGULATIONS PERTAINING TO THE RHODE
ISLAND ALL-PAYER CLAIMS DATABASE**

[R23-17.17- RIAPCD]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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INTRODUCTION

These *Rules and Regulations Pertaining to the Rhode Island All-Payer Claims Database [R23-17.17-RIAPCD]* are promulgated pursuant to the authority conferred under Chapters 23-17.17 and 42-35 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting regulations designed to implement the provisions of Chapter 23-17.17 of the Rhode Island General Laws, as amended, including the details and format for the Rhode Island All-Payer Claims Database (RIAPCD).

Pursuant to the provisions of §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at these regulations: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact on small business. Based on the available information, no known alternative approach, duplication or overlap was identified.

These *Rules and Regulations Pertaining to the Rhode Island All-Payer Claims Database* establish a framework for the submission of health care claims data and related datasets for the purpose of creating a health care quality and value database known as the Rhode Island All Payer Claims Dataset (APCD), to meet and inform the following goals:

- (1) *Determine the capacity and distribution of existing resources;*
- (2) *Identify health care needs and inform health care policy;*
- (3) *Evaluate the effectiveness of intervention programs on improving patient outcomes;*
- (4) *Compare costs between various treatment settings and approaches;*
- (5) *Provide information to consumers and purchasers of health care;*
- (6) *Improve the quality and affordability of patient health care and health care coverage;*
- (7) *Strengthen primary care infrastructure;*
- (8) *Strengthen chronic disease management;*
- (9) *Encourage evidence-based practices in health care.*

The purpose of the *Rules and Regulations Pertaining to the Rhode Island All-Payer Claims Database* is:

- (1) To define the reporting requirements for health plans and Insurers to submit data and information to APCD for the purpose of developing and maintaining the All-Payer Claims Dataset (APCD); and
- (2) To define the parameters for release of data, including the administrative process for release in a manner that maximizes public access while adhering to the highest standards of data privacy and security as permitted by applicable state and federal law.

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PART I *Definitions, General Provisions and Confidentially*

Section 1.0 *Definitions*

Wherever used in these Regulations, the following terms shall be construed as follows:

- 1.1 **“Analytic file”** means the set of files that is created from RIAPCD submissions. Analytic Files may include information created through the application of analytic tools or derived from other data sources.
- 1.2 **“Applicant”** means an individual or organization that requests health care data and information in accordance with the procedures and requirements instituted by the Department pursuant to these regulations.
- 1.3 **“Data aggregator”** means a vendor selected by the Director that has a contract to act on behalf of the Department to collect and process health care claims data on behalf of the Director.
- 1.4 **“De-identified health information”** means information that does not identify an individual provider, patient, member or enrollee. De-identification means that such health information shall not be individually identifiable and shall require the removal of direct personal identifiers associated with patients, members or enrollees.
- 1.5 **“Department”** means the Rhode Island Department of Health.
- 1.6 **“Director”** means the Director of the Department of Health or his or her duly authorized designee.
- 1.7 **“Direct Personal Identifier”** means any information, as to a member, other than case or code numbers used to create anonymous or encrypted data, that plainly discloses the identity of an individual, including:
 - (a) Names;
 - (b) Business names when that name would serve to identify a person;
 - (c) Elements of patient birth dates, except for year of birth or year of birth within an age band;
 - (d) Postal address information other than town or city, state and 5-digit ZIP code;
 - (e) Specific latitude and longitude or other geographic information that would be used to derive postal address;
 - (f) Telephone and fax numbers;
 - (g) Electronic mail addresses;
 - (h) Social Security numbers;
 - (i) Vehicle identifiers and serial numbers, including license plate numbers;
 - (j) Medical record numbers;
 - (k) Health plan beneficiary numbers;
 - (l) Patient account numbers;
 - (m) Personal Internet protocol (IP) addresses and uniform resource locators (URL), including those that identify a business that would serve to identify a person;
 - (n) Biometric identifiers, including finger and voice prints; and

- (o) Personal photographic images;
 - (p) Any other unique patient identifying number, characteristic, but not including the Encrypted Unique Identifier.
- 1.8 **“Disclosure”** means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.
- 1.9 **“Encrypted unique identifier”** means a code or other means of record identification to allow each patient, member or enrollee to be tracked across the data set, including across payers and over time, without revealing direct personal identifiers. Encrypted unique identifiers are assigned to each patient, member or enrollee in order that all direct personal identifiers can be removed from the data when data is submitted. Using the encrypted unique identifier, all records relating to a patient, member or enrollee can be linked for analytical, public reporting and research purposes without identifying the patient, member or enrollee.
- 1.10 **“Encrypted unique identifier vendor”** means a vendor selected and approved by the Director to collect demographic data only from Insurers, assign an encrypted unique identifier to each patient, member, or enrollee, and transmit that identifier to the Insurer.
- 1.11 **“Encryption”** means a method by which the true value of data has been disguised in order to prevent the identification of persons or groups, and which does not provide the means for recovering the true value of the data.
- 1.12 **“Hashing”** means a one-way method by which the true value of data has been transformed (through the conversion of the information into an unrecognizable string of characters) in order to prevent the identification of persons or groups. True value of hashed elements is deliberately non-recoverable by any recipient, including the Data Aggregator.
- 1.13 **“Health benefit plan”** means a policy, contract, certificate or agreement entered into, or offered by an Insurer to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.
- 1.14 **“Health care data set”** means a collection of individual data files, including medical claims files, pharmacy claims files, member eligibility files and provider files, whether in electronic or manual form.
- 1.15 **“Health care facility”** shall have the same meaning as contained in RIGL Chapter 23-17 and the regulations promulgated pursuant to that Chapter.
- 1.16 **“Health care provider”** means any person or entity licensed to provide or lawfully providing health care services, including, but not limited to, a physician, hospital, intermediate care facility or other health care facility, dentist, nurse, optometrist, podiatrist, physical therapist, psychiatric social worker, pharmacist or psychologist, and any officer, employee, or agent of that provider acting in the course and scope of his or her employment or agency related to or supportive of health care services.
- 1.17 **“HIPAA”** means the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (45 CFR Parts 160-164).

- 1.18 **“Insurer”** means any entity subject to the insurance laws and regulations of Rhode Island, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including, without limitation, an insurance company offering accident and sickness insurance, a health maintenance organization, as defined by RIGL §27-41-1, a nonprofit hospital or medical service corporation, as defined by RIGL §§ 27-19 and 27-20, or any other entity providing a plan of health insurance or health benefits. For the purpose of these Regulations, a third-party payer, third-party administrator, or Medicare or Medicaid health plan sponsor is also deemed to be an *Insurer*.
- 1.19 **“Medical claims file”** means all submitted and non-denied adjudicated claims for each billed service paid by an Insurer as defined in §1.18 on behalf of a Member as defined in §1.20 regardless of where the service was provided. This data file includes but is not limited to service level remittance information including, but not limited to, member encrypted unique identifier, provider information, charge/payment information, and clinical diagnosis/procedure codes as will be described further in the RIAPCD Technical Specification Manual.
- 1.20 **“Member”** means a Rhode Island resident who is a subscriber and any spouse or dependent who is covered by the subscriber’s policy under contract with an Insurer. The term also includes members of a small employer health insurance plan as defined by RIGL §27-50-3 regardless of the state of residency of the member.
- 1.21 **“Member eligibility file”** means a data file composed of demographic information for each individual member eligible for medical or pharmacy benefits as specified in the RIAPCD Technical Specification Manual, for one or more days of coverage at any time during the reporting month.
- 1.22 **“Patient”** means any person in the data set that is the subject of the activities of the claim submitted to and/or paid by the Insurer or covered by the health benefits plan.
- 1.23 **“Personally identifiable information”** means information, as to a member, relating to an individual that contains direct personal identifiers.
- 1.24 **“Pharmacy benefits manager”** or **“PBM”** means any person or entity that develops or manages pharmacy benefits, pharmacy network contracts, or the pharmacy benefit bid process pursuant to a contract held with an Insurer for the provision of such services.
- 1.25 **“Pharmacy claims file”** means a data file composed of service-level remittance information including, but not limited to, member demographics, provider information, charge/payment information, and national drug codes from all submitted and non-denied adjudicated claims for each prescription filled.
- 1.26 **“Public use files”** means the analytic files derived from records submitted by Insurers that contain only data elements that have been determined by the Department to be public use data elements listed in Appendix A-2 of these Regulations.
- 1.27 **“Restricted release files”** means the analytic files derived from records submitted by Insurers that contain data elements that have been determined by the Department to be restricted release data elements listed in Appendix A-2 of these Regulations.

- 1.28 **“Rhode Island All-Payer Claims Database” or “RIAPCD”** means a health care quality and value database for the collection, management and reporting of eligibility, claims and provider data submitted pursuant to RIGL Chapter 23-17.17.
- 1.29 **“RIAPCD Technical Specification Manual”** means the document issued by the Department, or its contracted agent, that sets forth the required data file format, record specifications, data elements, definitions, code tables and edit specifications.
- 1.30 **“RIGL”** means the General Laws of Rhode Island, as amended.
- 1.31 **“Subscriber”** means the individual responsible for payment of premiums to an Insurer or whose employment is the basis for eligibility for membership in a health benefit plan.
- 1.32 **“These Regulations”** means all parts of the *Rules and Regulations Pertaining to the Rhode Island All-Payer Claims Database [R23-17.17-RIAPCD]*.
- 1.33 **“Third-party administrator” or “TPA”** means any person with a certificate of authority, issued pursuant to RIGL § 27-20.7-12, who directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, or adjusts or settles claims on members, pursuant to RIGL § 27-20.7-2(1).
- 1.34 **“Third-party payer”** means a state agency that pays for health care services, or an Insurer, carrier, including a carrier that provides only administrative services for plan sponsors, nonprofit hospital, medical services organization, or managed care organization licensed in Rhode Island.

Section 2.0 General Provisions

- 2.1 **Purpose.** These Regulations establish a framework for the submission of health care claims data and related datasets for the purpose of developing and maintaining a health care quality and value database known as the Rhode Island All-Payer Claims Database (RIAPCD).
- 2.2 **Applicability.** Unless specifically exempted pursuant to §2.3, these Regulations apply to all Insurers, as defined in §1.18 of these Regulations.
- 2.3 **Exemptions.** The requirements of these Regulations shall not apply to:
- (a) An Insurer that on January 1 of a reporting year with less than three thousand (3,000) enrolled or covered members; or
 - (b) Insurance coverage providing benefits for:
 - (1) *Hospital confinement indemnity;*
 - (2) *Disability income;*
 - (3) *Accident only;*
 - (4) *Long-term care;*
 - (5) *Medicare supplement;*
 - (6) *Limited benefit health insurance as defined by RIGL §27-50-3(x);*

- (7) *Specified disease indemnity;*
- (8) *Sickness or bodily injury or death by accident or both; or*
- (9) *Other limited benefit policies, including but not limited to those exempt from the application of RIGL § 27-50-3 pursuant to subsection (t)(2)-(4) of that statute.*

2.4 **Optional Consent**

- (a) A covered insurer must permit enrolled or covered members to “opt out” of having any information or health care claims relating to them submitted to the RIAPCD.
 - (1) Each covered Insurer shall develop an “Opt out” process independently to create a system that works most efficiently for that entity.

Section 3.0 Confidentiality

3.1 **Access to RIAPCD Information.** Health care data sets and any other information submitted pursuant to these Regulations, by and between Insurers, the Rhode Island All-Payer Claims Database (RIAPCD), the Data Aggregator, and the Encrypted Unique Identifier Vendor:

- (a) Shall not be a public record as defined pursuant to RIGL § 38-2-2. No disclosure of any RIAPCD data set(s) or health information shall be made unless specifically authorized by the Director pursuant to these Regulations and as otherwise may be prescribed by law or regulation.
- (b) Shall be transmitted in accordance with the rules adopted in HIPAA (45 CFR Parts 160-164), Confidentiality of Health Care Communications and Information Act (RIGL § 5-37.3) and other applicable law(s).

3.2 **Removal of Personally Identifiable Information.** All health care data sets submitted to the Director or Data Aggregator pursuant to § 4.0 of these Regulations shall be protected by the removal of all personally identifiable information and/or hashed. Under no circumstances shall any Personal Health Information containing Personally Identifiable Information be submitted to the Director or Data Aggregator.

3.3 **Encrypted Unique Identifier.** Insurers shall submit a member eligibility file, as specified in Appendix A-1 of these Regulations, for each of its members to the encrypted unique identifier vendor to effectuate this requirement in accordance with the timeline outlined in § 5.2 of these Regulations. Under no circumstances shall the insurer submit any Personal Health Information to the encrypted unique identifier vendor at any time or for any reason. Only member demographic information, devoid of all Personal Health Information of any kind, shall be submitted to the encrypted unique identifier vendor.

- (a) Demographic data elements include but are not limited to: member name, date of birth, Social Security number if available and date of enrollment.
- (b) The encrypted unique identifier vendor shall assign each member an encrypted unique identifier and transmit that information to the Insurer.

- (c) The encrypted unique identifier vendor shall maintain records wholly separately from the Director, the Department, the Data Aggregator and the All-Payer Claims Database as defined by RIGL Chapter 23-17.17 and referenced by RIGL § 23-17.17-10(b).
- (d) Notwithstanding any contractual arrangements, any member's personally identifiable information sent by an Insurer to the Encrypted Unique Identifier Vendor shall not be shared with any other party including the Department, the Director, the Data Aggregator or with the All-Payer Claims Database.
- (e) Data which is required to be sent to the Encrypted Unique Identifier Vendor by the Insurers shall not be considered data collected by the Department, the Director, the Data Aggregator or the All-Payer Claims Database.

3.4 **Transmission of Encrypted Unique Identifier to Insurers.** The encrypted unique identifier vendor shall provide the encrypted unique identifier assigned to a member to the Insurer of record for that member. Prior to sending data sets to the Data Aggregator, the Insurer shall attach the assigned encrypted unique identifier to each record. Prior to transmitting the data sets and encrypted unique identifier to the Data Aggregator, all direct personal identifiers shall be removed and/or hashed.

- (a) The Insurer and/or payer shall maintain a record of the assignment of the encrypted unique identifier assigned to each member in such a way that would permit an audit or ongoing maintenance by the Director if necessary. Under no circumstance shall such audit or ongoing maintenance allow the Department, the Director, the Data Aggregator, or the RIAPCD to re-identify a Member.
- (b) The Insurer and/or payer being audited may request that such audit include a third-party review of the Unique Encrypted Identifier Vendor's process for assignment and transmission of the encrypted unique identifier assigned to each member of that submitter. However, approval of a third-party review shall be at the sole discretion of the Director.

PART II *Requirements for the Rhode Island All-Payer Claims Database*

Section 4.0 *Submission Requirements*

4.1 Specific Submission Requirements.

- (a) Except as specifically exempted pursuant to § 2.3 of these Regulations, each Insurer shall submit to the Director a health care data set including claims-line detail for all health care services provided to a member, whether or not the health care was provided within Rhode Island. Such data shall include, but shall not be limited to, fully-insured and self-funded accounts, all commercial medical products for all individuals and all group sizes and Medicare or Medicaid health plans. Under no circumstances shall such data include personally identifiable information.
 - (1) Should the Insurer have insufficient information to populate a provider file in compliance with § 4.3(b) of these Regulations for services provided to a Member by an out-of-state, out-of network provider, the Insurer may omit the provider file from an otherwise complete health care data file submission.
 - (2) Each Insurer shall also be responsible for the submission of all health care claims processed by any sub-contractor on its behalf unless such sub-contractor is already submitting the identical data as an Insurer in its own right.
 - (3) The health care data set submitted shall include, where applicable, a member eligibility file, not including any personally identifiable information, but utilizing the unique encrypted identifier assigned to the member, covering every member enrolled during the reporting month whether or not the member utilized services during the reporting period and a provider file, to be defined in the RIAPCD Technical Specification Manual.
 - (4) The data submitted shall also include supporting definition files for payer specific provider specialty taxonomy codes and procedure and/or diagnosis codes.
- (b) The health care data sets shall be submitted to the Data Aggregator in the format required in the RIAPCD Technical Specification Manual.
 - (1) All health care data sets submitted to the Data Aggregator will have a Unique Identifier attached and shall be protected by the removal of all personally identifiable information and/or hashed.
- (c) Insurers shall transmit the required health care data sets by means of a secure file transfer system to the Data Aggregator in a manner that is fully compliant with HIPAA and applicable Rhode Island statute and regulation.

4.2 RIAPCD Contact and Enrollment Update Form.

- (a) Each Insurer shall submit to the Director or his or her designee by December 31st of each year, in a format outlined in the RIAPCD Technical Specification Manual, a contact and enrollment update form indicating if health care claims are being paid for members and, if applicable, the types of coverage and estimated enrollment for the following calendar year.

- (b) It shall be the responsibility of the Insurer to resubmit or amend the form whenever modifications occur relative to the health care data files, type(s) of business conducted, or contact information.

4.3 **Health Care Data Files to be Submitted**

- (a) **Medical Claims File.** Insurers shall submit data files consisted with the definition contained in § 1.21 of these Regulations. As detailed in the RIAPCD Technical Specification Manual, payers shall report information about services provided to members under all reimbursement arrangements, including but not limited to fee for service, capitated arrangements, and any other claims-based payment methods.
- (b) **Pharmacy Claims File.** Insurers shall submit data files consistent with the definition contained in §1.25 of these Regulations for all pharmacy paid claims for covered pharmacy benefits that were actually dispensed to Members.
- (c) **Member Eligibility File.** Insurers shall submit a data set that contains information on every member enrolled during the reporting month whether or not the member utilized services during the reporting period. Under no circumstances shall this data submission include the member's personally identifiable demographic information. The submission will have a Unique Identifier attached and shall be protected by the removal of all personally identifiable information and/or hashed.
- (d) **Provider File.** Insurers shall submit a dataset that contains information that will uniquely identify health care providers and allow retrieval of related information from eligibility, medical and pharmacy claims files.
 - (1) Tax id numbers shall be submitted as part of the dataset except in the case that a provider uses their personal social security number as their tax id number in which case the tax id number need not be submitted.

4.4 **Information Collected in Addition to the Health Care Data Set.**

- (a) The Director may require Insurers to submit and periodically update information about the insurance product covering each member, including covered services, market sector, plan characteristics, total premiums, deductibles, co-insurance and copayments as set forth in the RIAPCD Technical Specification Manual.
- (b) The Director may require Insurers to report information about payments received under all reimbursement arrangements, including, but not limited to, fee-for-service, capitated arrangements, pay-for-performance and any other payment methods.

Section 5.0 *Technical Requirements*

- 5.1 **Code Sources and File Specifications.** Only code sources and file specifications specified in these Regulations and/or the RIAPCD Technical Specification Manual shall be utilized in submission of the health care claims data sets required pursuant to § 4.0 of these Regulations.

5.2 **Schedule for Submissions.** Insurers shall submit information to the RIAPCD and the Encrypted Unique Identifier Vendor in the specified format in accordance with the following schedule:

(a) Test Data Submissions

- (1) Within one hundred twenty (120) days of the release of the final RIAPCD Technical Specification Manual, Insurers shall submit test files containing a month of representative member eligibility files as defined in Appendix A-1 of these Regulations from January 2009 or as specified in the RIAPCD Technical Specification Manual to the Encrypted Unique Identifier Vendor.
- (2) The Encrypted Unique Identifier Vendor shall return the member eligibility file to the Insurer with an assigned Encrypted Unique Identifier within fifteen (15) days of a test file submission by an Insurer.
- (3) Within one hundred and fifty (150) days of the release of the final RIAPCD Technical Specification Manual, Insurers shall submit part one of their test files containing a month of representative member eligibility files, provider information, and medical and pharmacy claims paid as defined in Appendix A-2 of these Regulations during January 2009 or as specified in the RIAPCD Technical Specification Manual to the Data Aggregator.

(b) Historical Data Submissions

- (1) Within two hundred and seventy (270) days of the release of the final RIAPCD Technical Specification Manual, Insurers shall submit files containing member eligibility as defined in Appendix A-1 of these Regulations for calendar years 2009, 2010, 2011, and 2012, or as specified in the RIAPCD Technical Specification Manual to the Encrypted Unique Identifier Vendor.
- (2) The Encrypted Unique Identifier Vendor shall return the historical member eligibility file to the Insurer with an assigned Encrypted Unique Identifier within thirty (30) days of a submission of historical files by an Insurer.
- (3) Within three hundred and thirty (330) days of the release of the final RIAPCD Technical Specification Manual, Insurers shall submit files containing member eligibility, provider information, and medical and pharmacy claims paid as defined in Appendix A-2 of these Regulations during calendar years 2009, 2010, 2011, and 2012, or as specified in the RIAPCD Technical Specification Manual, to the Data Aggregator.
 - (i) This submission period may be extended within the discretion of the Director to up to three hundred and sixty (360) days from the date of release of the final RIAPCD Technical Specification Manual.
- (4) Submissions of additional health care data sets for remaining dates of service in calendar year 2013 for months up to thirty (30) days prior to three hundred and thirty (330) days from the date of release of the final RIAPCD Technical Specification Manual shall be submitted according to a schedule provided within the RIAPCD Technical Specification Manual.

(c) Regular Data Submissions

- (1) Upon completion of Historical Data Submissions as required by § 5.2(b) of these Regulations, Insurers shall commence Regular Data Submissions.
 - (i) The timeline for Regular Data Submissions shall commence with the next month following the completion of Historical Data Submissions.
 - (2) Insurers shall submit a member eligibility file for each of its members, as defined in Appendix A-1 of these Regulations, on a monthly basis to the Encrypted Unique Identifier Vendor.
 - (i) Monthly data files are due twenty-one (21) business days after the month's end.¹
 - (3) The Encrypted Unique Identifier Vendor shall return the member eligibility file to the Insurer with an assigned Encrypted Unique Identifier within ten (10) business days of a regular data submission by an Insurer.
 - (4) Effective upon ten (10) business days after the receipt of the member eligibility file from the Encrypted Unique Identifier Vendor, Insurers shall submit files containing member eligibility, provider information, and medical and pharmacy claims paid as defined in Appendix A-2 of these Regulations to the Data Aggregator.
 - (i) Monthly health care data files are due within ten (10) business days of receipt of the assigned Encrypted Unique Identifier by the Insurer.²
 - (5) Within five (5) business days of the Insurer's submission to the Data Aggregator, the Insurer will submit data resubmissions as required by the Data Aggregator which will communicate discrepancies, failures and resubmissions.
- (d) All health care data sets submitted to the Data Aggregator will have a Unique Identifier attached and shall be protected by the removal of all personally identifiable information and/or hashed. Under no circumstances shall any Personal Health Information containing Personally Identifiable Information be submitted to the Director or Data Aggregator.
 - (e) The Director has the authority within his or her discretion to modify the RIAPCD Technical Specification Manual to effect changes to the submissions schedule.

Section 6.0 *Compliance with Data Standards*

- 6.1 **Standards.** The Data Aggregator Vendor shall evaluate each member eligibility file, provider file, medical claims file and pharmacy claims file in accordance with the following standards:

¹ (For example, files containing data relating to eligibility during September 2013 shall be submitted by October 30, 2013 (accounts for weekends and holidays).)

² For example, files containing data relating to services paid during September 2013 shall be submitted to the Data Aggregator by November 29, 2013 (accounts for weekends and holidays).

- (a) The applicable code for each data element shall be as identified in the RIAPCD Technical Specification Manual and shall be included within eligible values for the element;
 - (b) Coding values indicating “data not available”, “data unknown”, or the equivalent shall not be used for individual data elements unless specified as an eligible value for the element;
 - (c) The encrypted unique identifier assigned to each member shall be consistent across files; and
 - (d) Files submitted to the Data Aggregator shall not contain personally identifiable information.
- 6.2 **Notification.** Upon completion of this evaluation, the Director or his or her designee will notify each Insurer whose data submissions do not satisfy the standards for any reporting period. This notification will identify the specific file and the data elements that are determined to be unsatisfactory.
- 6.3 **Response.** Each Insurer notified under § 6.2 of these Regulations shall resubmit within ten (10) business days of the date of notification with the required changes.
- (a) The Director shall have the discretion to require a response as required by this subsection in a reasonable time commensurate with the level of difficulty for the level of correction required to a data submission.
- 6.4 **Compliance.** Failure to file, report, or correct health care claims data sets in accordance with the provisions of these Regulations may be considered a violation of RIGL Chapter 23-17.17 except that an Insurer may seek a variance as specified in § 9.0 of these Regulations.

Section 7.0 *Procedures for the Approval and Release of Claims Data*

- 7.1 **Purpose.** This subsection pertains to the Rhode Island All Payer Claims Database created pursuant to RIGL Chapter 23-17.17-9.
- 7.2 All users of the RIAPCD analytic files, public use files or restricted release files, including the Department, other Rhode Island state agencies, including vendors with whom they hold a Business Associate Agreement, and any approved data use applicants shall comply with all data security and privacy requirements as provided by state and federal law and regulation.
- 7.3 **Release Policies and Procedures.**
- (a) **General Provisions.**
 - (1) The Department may release restricted release files to a person or organization engaged in improving, evaluating or otherwise measuring health care provided to members.

- (2) The Department may provide pre-determined analytic files at different levels of detail to meet requests for public use and restricted release analytic files.

(b) Public Use Data Elements.

- (1) Pre-developed analytic files may be made available on the Department's website in a format approved by the Director.
- (2) Additional requests for public use data may be made by submitting a written request to the Department in conformance with a format to be provided by the Department.

(c) Unavailable Data Elements. Data elements that are not designated in Appendix A-2 of these Regulations either as public use health care data elements or restricted release data elements shall not be available for release or use outside of the Department or other state agencies in any data set or disclosed in publicly released reports in any circumstance or for any reason.

(d) Restricted Release Files.

(1) Data Use Request Documentation and Agreement. All applicants shall:

- (i) Submit a written application using the format provided by the Department. The applicant shall specify the data requested, including a justification for the requested data elements;
- (ii) Specify the purpose and intended use of the data requested, including a detailed project description that describes any other data sources to be used for the project;
- (iii) Specify security and privacy measures that will be used to safeguard patient privacy and to prevent unauthorized access to or use of such data;
- (iv) Specify the applicant's methodology for maintaining data integrity and accuracy;
- (v) Describe how the results of the applicant's analysis will be published, including level of aggregation of data that will be presented;
- (vi) Agree that cells with six (6) observations or fewer shall never display the actual number of observations in the cell;
- (vii) Agree to the data disclosure restrictions and prohibitions on re-release of the data;
- (viii) Agree that any public report or publication containing information derived from the data include a provision stating the year or years from which the data was obtained;
- (ix) Attest that the data received pursuant to this application shall never be used for any purpose other than the project that has been expressly approved through the application process; and
- (x) Obtain written agreement from any recipient of data or agent that processes data on behalf of the applicant to adhere to the provisions of this agreement.

- (2) All applications will be posted on the Department's website for a minimum of ten (10) business days to invite written public comments on the applications. However, the Department will not post those portions of applications that specify security measures or applications from law enforcement entities to the extent that posting the application on the website may impede the investigatory process.
- (3) Data shall not be re-released in any format to anyone except personnel identified and approved within the original application.
- (4) The Department shall be provided with a copy of any proposed public report or publication containing information derived from the data at least fifteen (15) days prior to any publication or release to allow the Department to review the proposed public report or publication and confirm that the conditions of the written agreement have been applied.
 - (i) When multiple public reports or publications, derived from the same data and of a similar nature, are to be published or released, the Department may, upon request, waive the requirement that any subsequent reports or publications be provided to the Department prior to release by the requesting party.
- (5) Applicants for restricted release files shall demonstrate a need for each restricted data element requested. The Department shall release only those data elements that are determined to be necessary to accomplish the applicant's intended use.
- (6) Applicants requesting Medicare data shall conform to requirements established by the federal Centers for Medicare and Medicaid Services (CMS) in order to obtain and use applicable data.
- (7) Medicaid data shall not be included in the public use or restricted release files unless the release of such data conforms to all applicable federal and state laws and regulations, including laws and regulations governing the de-identification of such data.
- (8) Rhode Island state agencies seeking restricted release data must comply with data use application processes and procedures.
- (9) Restricted Release Data shall not be combined with any other available data source that could potentially re-identify a member, patient or payer-specific claims payment amounts.
- (e) **Data Release Review Board.** The Department shall establish a review board for the purposes of reviewing predetermined analytic files to be made available on the Department's website, additional requests for public use data, and requests for public use of restricted release files.
- (f) The Board shall have a chairperson and members appointed annually by the Director. The appointments to the Board shall be made in such a way as to provide demonstrated and acknowledged expertise in a diverse range of health care areas including, but not limited to, state and federal privacy law and data security. The committee shall be comprised of eleven (11) members and shall include but not be limited to:

- (1) At least two members representing health Insurers;
 - (2) At least one member representing health care facilities;
 - (3) At least one member representing physicians;
 - (4) At least one member representing health care consumers;
 - (5) At least one member representing a privacy protection advocacy organization;
 - (6) At least one member representing researchers;
 - (7) At least one member representing the Department;
 - (8) At least one member representing OHIC;
 - (9) At least one member representing EOHHS.
- (g) The Board will review predetermined analytic files to be made available on the Department's website, additional requests for public use data, and requests for public use of restricted release files to ensure that members, patients and payer-specific claims payment amounts cannot be identified in any product of the proposed work to be made available.
 - (h) The Board shall provide a non-binding recommendation to the Director that shall be based upon the application criteria set forth in § 7.3(d) of these Regulations.
 - (i) The Board and Director, as part of their review of whether member, patient and payer-specific claims payment amounts are safeguarded shall also consider if any other data available to the applicant or public that the Board or Director is aware of or reasonably should be aware of could be used to re-identify the member, patient or payer-specific claims payment amounts.
 - (j) The Director may approve the application for use of restricted release files if he or she is also satisfied that the applicant has demonstrated it is qualified to undertake the study or accomplish the intended use, the applicant requires such files in order to undertake the study or accomplish the intended use; and the applicant has demonstrated appropriate privacy and security controls for access to and storage of restricted release files.
 - (k) Upon a denial of an application for use of restricted release files by the Director, the Department shall within fifteen (15) days provide written notice to the applicant of the basis for denial of the application.
 - (l) The Director's decisions to approve or deny applications for use of restricted release files are final except as provided for in Rhode Island statute.

7.4 **Fees.** The fee for health care data sets from the RIAPCD, which have been approved for release by the Department, includes the costs for programming and report generation, duplicating charges and other costs associated with the production and transmission of data sets.

- (a) The Department and other state agencies may issue reports that are available to the public at no charge.

- (b) The fee for an annual public use file consisting of unrestricted fields and data elements shall be equal to the cost required for the Department to process, package and ship the data set, including any electronic medium used to store the data, or a reasonable equivalent if an alternative file delivery model is provided.
- (c) The fee for a restricted release file approved by the Department shall be equal to the cost charged by the Department's designated vendor to program and process the requested data extract, including any consulting services and reasonable costs to package and ship the data set on particular electronic medium.
- (d) The fee for preparing customized files shall be equal to the cost charged by the Department's designated vendor to program and process the requested customized data extract, including any consulting services and reasonable costs to package and ship the data set on a particular electronic medium.
- (e) The fee for access to a secure internet portal to create specialized reports based on restricted data or any other report delivery mechanism not otherwise described shall be set to reflect the reasonable cost of providing such data.
- (f) The fee may be reduced or waived for the following entities at the discretion of the Department:
 - (1) CMS;
 - (2) Rhode Island state agencies; and
 - (3) Submitting Insurers.
- (g) The Director shall have a record of payment in full prior to providing data to approved applicants.

PART III *Compliance, Variances, Practices and Procedures and Severability*

Section 8.0 *Compliance and Enforcement*

8.1 Enforcement Options.

- (a) The Director may pursue any combination of the following administrative and judicial enforcement actions, depending upon the circumstances and gravity of each case:
- (1) Compliance orders pursuant to RIGL § 23-1-20;
 - (2) Immediate compliance orders pursuant to RIGL § 23-1-21;
 - (3) Enforcement of compliance orders pursuant to RIGL § 23-1-23; and
 - (4) Criminal penalties pursuant to RIGL § 23-1-25.
- (b) The imposition of one or more remedies and/or penalties provided in § 8.1(a) of these Regulations shall not prevent the Director from jointly exercising any other remedy or penalty available to him or her by statute or regulation.
- (c) **Consent Agreement/Order.** Nothing in these Regulations shall preclude the Director from resolving outstanding violations or penalties through a Consent Agreement or Consent Order at any time he or she deems appropriate.

Section 9.0 *Variance Procedure*

- 9.1 The Department may grant a variance from the provisions of a rule or regulation in a specific case if it finds that enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest, public health and/or health and safety of residents

Section 10.0 *Rules Governing Practices and Procedures*

- 10.1 All hearings and reviews required under the provisions of RIGL Chapter 23-17.17 shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*.³

Section 11.0 *Severability*

- 11.1 If any provision of these Regulations or their applicability to any person or circumstance shall be held invalid, such holding shall not affect the provisions or application of the Regulations that can be given effect, and to this end the provisions of the Regulations are declared to be severable.

³ Current copies of all regulations issued by the RI Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: <http://www.sos.ri.gov/rules/>

- (a) If the effect of such a holding that a provision or application of these Regulations is invalid is to compromise any of the patient privacy or data security measures contained herein, such that personally identifiable information may be in any way put at risk of disclosure, the Director shall have the authority, upon his or her discretion, to suspend the release of all health care data set(s) and/or analytic files for a period of time sufficient to address such concerns.

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Wednesday, 12 June 2013

APPENDIX A-1

**DATA ELEMENTS FOR PUBLIC USE AND RESTRICTED RELEASE
AND DATA TO BE SUBMITTED BY INSURER**

MEMBER ELIGIBILITY FILE TO ENCRYPTED UNIQUE IDENTIFIER VENDOR

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Payer Name/Code	No	No	Yes
National Plan ID	No	No	Yes
Insurance Type /Product/Plan Code	No	No	Yes
Year	No	No	Yes
Month	No	No	Yes
Days Eligible	No	No	Yes
Policy I.D. Number	No	No	Yes
Group Number	No	No	Yes
Group/Employer Name	No	No	Yes
Employer Address	No	No	Yes
Employer City	No	No	Yes
Employer State	No	No	Yes
Employer ZIP Code	No	No	Yes
Employee Status	No	No	Yes
Government Employee	No	No	Yes
Subscriber/Policyholder Last Name	No	No	Yes
Subscriber/Policyholder First Name	No	No	Yes
Subscriber/Policyholder Middle Initial	No	No	Yes
Subscriber/Policyholder Address 1	No	No	Yes
Subscriber/Policyholder Address 2	No	No	Yes
Subscriber/Policyholder Address 3	No	No	Yes
Subscriber/Policyholder City	No	No	Yes
Subscriber/Policyholder State	No	No	Yes

MEMBER ELIGIBILITY FILE TO ENCRYPTED UNIQUE IDENTIFIER VENDOR

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Subscriber/Policyholder ZIP Code	No	No	Yes
Subscriber/Policyholder Data	No	No	Yes
Subscriber/Policyholder SSN	No	No	Yes
Subscriber/Policyholder Gender	No	No	Yes
Type of Coverage	No	No	Yes
Subtype of Coverage	No	No	Yes
Pharmacy Benefits Outsourced	No	No	Yes
PBM Name	No	No	Yes
BIN	No	No	Yes, if available
PCN	No	No	Yes
Pharmacy Group Number	No	No	Yes
Pharmacy Policy ID Number	No	No	Yes
Mental Health Benefits Outsourced	No	No	Optional
Mental Health Carrier Name	No	No	Optional
Network Indicator	No	No	Optional
Name of Network	No	No	Optional
Medicare Part D Indicator	No	No	Optional
Begin Coverage Date	No	No	Optional
End of Coverage Date	No	No	Optional
Relationship to Policy	No	No	Optional
Dependent Indicator	No	No	Optional
Student Indicator	No	No	Optional
Dependent Last Name	No	No	Optional
Dependent First Name	No	No	Optional
Dependent Middle Initial	No	No	Optional
Dependent Address 1			

APPENDIX A-2

**DATA ELEMENTS FOR PUBLIC USE AND RESTRICTED RELEASE
AND DATA TO BE SUBMITTED BY INSURER**

MEMBER ELIGIBILITY FILE TO DATA AGGREGATOR

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Payer Name/Code	No	Yes	Yes
National Plan ID	No	Yes	Yes
Insurance Type /Product/ Plan Code	No	Yes	Yes
Year	Yes	Yes	Yes
Month	Yes	Yes	Yes
Days Eligible	Yes	Yes	Yes
Insured Group or Policy Number	No	No	Yes
Coverage Level Code	Yes	Yes	Yes
Plan Specific Contract Number	No	No	Yes
Encrypted Unique Identifier	No	Yes	Yes
Unique Member ID (encrvpted)	No	Yes	Yes
Unique Subscriber ID (encrvpted)	No	Yes	Yes
Individual Relationship Code	Yes	Yes	Yes
Member Gender	Yes	Yes	Yes
Member City Name	No	Yes	Yes
Member State or Province	Yes	Yes	Yes
Member ZIP Code	Yes: 3 digits	Yes: 5 digits (but reported at 3)	Yes
Medical Coverage	Yes	Yes	Yes
Prescription Drug Coverage	Yes	Yes	Yes
Race and Ethnicity	Yes, if available	Yes, if available	Yes
Primary Insurance Indicator	Yes	Yes	Yes
Coverage Type	Yes	Yes	Yes
Market Category Code	No	No	Yes
Special Coverage	No	No	Yes
Record Type	Yes	Yes	Yes

MEMBER ELIGIBILITY FILE TO DATA AGGREGATOR

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
(Hashed) Subscriber SSN	No	No	Yes
(Hashed) Subscriber last name	No	No	Yes
(Hashed) Subscriber first name	No	No	Yes
(Hashed) Subscriber middle initial	No	No	Yes
(Hashed) Member SSN	No	No	Yes, if available
(Hashed) Member last name	No	No	Yes
(Hashed) Member first name	No	No	Yes
(Hashed) Member middle initial	No	No	Yes
(Hashed) Member Date of Birth	Age or age bands will be displayed.	Age or age bands will be displayed.	Yes

MEDICAL CLAIMS DATA FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Payer	No	Yes	Yes
National Plan ID	No	Yes	Yes
Insurance Type/Product/Plan Code	No	Yes	Yes
Payer Claim Control Number	Hashed	Hashed	Yes
Line Counter	Yes	Yes	Yes
Version Number	No	No	Yes
Carrier Specific Insured Group or Policy Number	No	No	Yes
Plan Specific Contract Number	No	No	Yes
Encrypted Unique Identifier	No	Yes	Yes
Unique Member Identification	No	Yes	Yes
Unique Subscriber ID (encrypted)	No	Yes	Yes
Individual Relationship Code	Yes	Yes	Yes
Member Gender	Yes	Yes	Yes
Member Date of Birth	Age or age bands will be displayed.	Age or age bands will be displayed.	Yes
Member City Name	No	Yes	Yes
Member State or Province	Yes	Yes	Yes
Member ZIP Code	3 digit	5 digits in file, but reported out at 3 digit level	Yes
Date Service Approved/ Accounts Payable Date/ Actual Paid Date	No	MMYY	Yes
Admission Date	If Needed,	If Needed, MMYY	Yes
Admission Hour	No	If Needed	Yes
Admission Type	If Needed	If Needed	Yes
Service Provider Number	No	Yes	Yes
Service Provider Tax ID Number	No	If Needed	Yes
Service National Provider ID	No	If Needed	Yes

MEDICAL CLAIMS DATA FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Service Provider Entity Type Qualifier	Yes, If Needed	Yes	Yes
Service Provider First Name	No	If Needed	Yes
Service Provider Middle Name	No	No	Yes
Service Provider Last Name or Organization Name	No	If Needed	Yes
Service Provider Suffix	No	No	Yes
Service Provider Specialty	Yes	Yes	Yes
Service Provider City Name	Yes	Yes	Yes
Service Provider State or Province	Yes	Yes	Yes
Service Provider ZIP Code	Yes	Yes	Yes
Type of Bill – Institutional	Yes	Yes	Yes
Facility Type - Professional	Yes	Yes	Yes
Admitting Diagnosis	Yes	Yes	Yes
E-Code	Yes	Yes	Yes
Diagnosis present on Admission (1-25)	Yes	Yes	Yes
Principal Diagnosis (1)	Yes	Yes	Yes
Other Diagnosis (2-25)	Yes	Yes	Yes
Revenue Code	Yes	Yes	Yes
Procedure Code (HCPCS includes CPT)	Yes	Yes	Yes
Procedure Modifier – 1	Yes	Yes	Yes
Procedure Modifier – 2	Yes	Yes	Yes
ICD-9-CM Procedure Code (1 through 25)	Yes	Yes	Yes
Date of Service – From	MMYY	DDMMYY	Yes
Date of Service – Thru	MMYY	DDMMYY	Yes
Quantity	No	Yes	Yes
Charge Amount	Yes, If Needed	Yes	Yes
Paid Amount	Yes	Yes	Yes
Prepaid Amount	Yes	Yes	Yes
Co-pay Amount	Yes	Yes	Yes

MEDICAL CLAIMS DATA FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Coinsurance Amount	Yes	Yes	Yes
Coordination of Benefits Paid Amount	Yes	Yes	Yes
Deductible Amount	Yes	Yes	Yes
Patient Account/Control Number	No	Yes	Yes
Discharge Date	CCYYMM if	CCYYMM if	Yes
DRG	Yes if available	Yes if available	Yes
DRG Version	Yes if DRG is included	Yes if DRG is included	Yes
APC	Yes	Yes	Yes
APC Version	Yes if APC is included	Yes if APC is included	Yes
Drug Code	No	Yes	Yes
Billing Provider Number	No	Yes	Yes
National Billing Provider ID	No	Yes	Yes
Billing Provider Last Name or Organization Name	No	Yes	Yes
Record Type	Yes	Yes	Yes

PROVIDER FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Payer	No	Yes	Yes
National Provider ID/Plan Provider ID	No	No	Yes
Tax Id	No	No	Yes
UPIN Id	Yes	Yes	Yes
DEA ID	No	No	Yes
License Id	No	No	Yes
Medicaid Id	No	No	Yes
Last Name	No	Yes	Yes
First Name	No	Yes	Yes
Middle Initial	No	Yes	Yes
Suffix	Yes	Yes	Yes
Entity Name	Yes	Yes	Yes
Entity Code	Yes	Yes	Yes
Gender Code	Yes	Yes	Yes
DOB Date	No	No	Yes
Street Address1 Name	No	No	Yes
Street Address2 Name	No	No	Yes
City Name	Yes	Yes	Yes
State Code	Yes	Yes	Yes
Country Code	Yes	Yes	Yes
Zip Code	Yes	Yes	Yes
Taxonomy	Yes	Yes	Yes
Mailing Street Address1 Name	Yes	Yes	Yes
Mailing Street Address2 Name	Yes	Yes	Yes
Mailing City Name	Yes	Yes	Yes
Mailing State Code	Yes	Yes	Yes
Mailing Zip Code	Yes	Yes	Yes
Primary Specialty Code	Yes	Yes	Yes

PHARMACY FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Payer	No	Yes	Yes
National Plan ID	No	Yes	Yes
Insurance Type/Product/Plan Code	No	Yes	Yes
Payer Claim Control Number	Hashed	Hashed	Yes
Line Counter	No	No	Yes
Insured Group Number	No	No	Yes
Plan Specific Contract	No	No	Yes
Encrypted Unique Identifier	No	Yes	Yes
Unique Member Identification	No	Yes	Yes
Individual Relationship Code	Yes	Yes	Yes
Member Gender	Yes	Yes	Yes
Member Date of Birth	Age or age bands will be displayed, not DOB	Age or age bands will be displayed, not DOB	Yes
Member City	Yes	No	Yes
Member State or Province	Yes	Yes	Yes
Member ZIP Code	3 digit	5 digits in file, but reported out at 3 digit level	Yes
Date Service Approved (AP Date)	No	MMYY	Yes
Pharmacy Number	No	Yes	Yes
Pharmacy Tax ID Number	No	Yes	Yes
Pharmacy Name	No	Yes	Yes
National Provider ID Number	No	Yes	Yes
Pharmacy Location City	Yes	Yes	Yes
Pharmacy Location State	Yes	Yes	Yes
Pharmacy ZIP Code	Yes	Yes	Yes
Pharmacy Country Name	Yes	Yes	Yes
Claim Status	No	No	Yes
Drug Code	No	Yes	Yes

PHARMACY FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Drug Name	Yes	Yes	Yes
New Prescription or Refill	Yes	Yes	Yes
Generic Drug Indicator	Yes	Yes	Yes
Dispense as Written Code	Yes	Yes	Yes
Compound Drug Indicator	No	Yes	Yes
Date Prescription Filled	CCYYMM	CCYYMMDD	Yes
Quantity Dispensed	Yes	Yes	Yes
Days' Supply	Yes	Yes	Yes
Charge Amount	Yes	Yes	Yes
Paid Amount	Yes	Yes	Yes
Ingredient Cost/List Price	Yes	Yes	Yes
Postage Amount Claimed	Yes	Yes	Yes
Dispensing Fee	Yes	Yes	Yes
Co-pay Amount	Yes	Yes	Yes
Coinsurance Amount	Yes	Yes	Yes
Coordination of Benefits Paid Amount	Yes	Yes	Yes
Deductible Amount	Yes	Yes	Yes
Prescribing Provider ID	No	Yes	Yes
Prescribing Physician First Name	No	Yes	Yes
Prescribing Physician Middle Name	No	Yes	Yes
Prescribing Physician Last Name	No	Yes	Yes
Prescribing Physician Plan Number	No	Yes	Yes
Unique Subscriber ID (encrypted)	No	No	Yes
Prescribing Physician DEA No.	No	Yes	Yes
Prescribing Physician Lic. No.	No	Yes	Yes
Prescribing Physician Street Address	No	Yes	Yes
Prescribing Physician State	No	Yes	Yes

PHARMACY FILE

Data Element Name	Public Use	Restricted Release	Submitted Data Elements
Prescribing Physician City	No	Yes	Yes
Prescribing Physician ZIP	No	Yes	Yes
Mail Order Pharmacy	Yes	Yes	Yes