



Jeannette B. DeJesús
SPECIAL ADVISOR TO THE GOVERNOR
OFFICE OF HEALTH REFORM & INNOVATION
STATE OF CONNECTICUT

NOTICE OF INTENT TO ADOPT A REGULATION

In accordance with section 4-168(a) of the Connecticut General Statutes, notice is hereby given that the Office of Health Reform & Innovation and the Office of Policy and Management, pursuant to the authority of section 1 of Public Act No. 12-166, propose to adopt a regulation concerning an All-Payer Claims Database.

Statement of purpose: To promulgate regulations relating to an All-Payer Claims Database.

The Office of Health Reform & Innovation is carrying out various aspects of the regulatory review process on behalf of the Office of Policy and Management.

All interested persons are invited to submit written data, views or arguments in connection with the proposed action within thirty days following publication of this notice in the Connecticut Law Journal to the State of Connecticut, Office of Health Reform & Innovation, Attention: Roberta Schmidt, 210 Capitol Avenue, Hartford, CT 06106.

Copies of the proposed regulation may be obtained by writing to the Office of Health Reform & Innovation at the above address or sending an e-mail to Matt Salner at matthew.salner@ct.gov. The proposed regulation may also be viewed by visiting the Office of Health Reform & Innovation website at <http://healthreform.ct.gov>.

In addition to accepting written public comments, the Office of Health Reform & Innovation will hold a public hearing on the proposed regulations on November 19, 2012 at 10:00a.m., at the Legislative Office Building, 300 Capitol Avenue, Hartford, CT 06106. Oral comments presented at the hearing should summarize written comments submitted to the Office of Health Reform & Innovation prior to the hearing. Oral comments will be limited to five minutes and must address the proposed regulations.

The Office of Health Reform & Innovation does not discriminate on the basis of disability in admission to, access to, or operation of its programs, services or activities, in accordance with Title II of the Americans with Disabilities Act of 1990. Individuals requiring auxiliary aids for communication or other accommodation are invited to make their needs known to Matt Salner at (860) 524-7353.

Jeannette DeJesús
Special Advisor to the Governor on Healthcare Reform
Director, Office of Health Reform & Innovation

R-39 Rev. 03/2012
(Title page)

IMPORTANT: Read instructions on back of last page (Certification Page) before completing this form. Failure to comply with instructions may cause disapproval of proposed Regulations

State of Connecticut **REGULATION** of

NAME OF AGENCY

Office of Health Reform & Innovation

Concerning

SUBJECT MATTER OF REGULATION

All-Payer Claims Database

All-Payer Claims Database

Sec. 1. The Regulations of Connecticut State Agencies are amended by adding Section xx-xxx-1 to xx-xxx-7, inclusive, as follows:

(NEW) Section xx-xxx-1: Definitions.

As used in sections xx-xxx-2 to xx-xxx-7, inclusive, of the Regulations of Connecticut State Agencies:

- (1) “Administrator” means the Special Advisor to the Governor on Healthcare Reform.
- (2) “APCD” means the Connecticut All Payer Claims Database as established under Public Act 12-166.
- (3) “Day” means a calendar day.
- (4) “Dental Claims Data File” means a data file composed of service level remittance information including, but not limited to, member demographics, provider information, charge and payment information, and current dental terminology codes from all Member paid claims and encounters.
- (5) “Eligibility Data File” means a data file composed of demographic information for each Member who is eligible to receive medical, pharmacy, or dental coverage provided or administered by a Reporting Entity for one or more days of coverage during the reporting month.
- (6) “HIPAA” means 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, as amended from time to time.
- (7) “Historic Data” means Eligibility Data File(s), Medical Claims Data File(s), Pharmacy Claims Data File(s) and Provider File(s) for the period commencing January 1, 2010 through December 31, 2012, or such later three year period specified by the Administrator.

- (8) "Medical Claims Data File" means a data file composed of service level remittance information including, but not limited to, member demographics, provider information, charge and payment information, and clinical diagnosis/procedure codes from all Member paid claims and encounters.
- (9) "Member" means: (A) a Connecticut resident or (B) an individual who resides elsewhere but is covered under a Small Group Health Plan issued in Connecticut and purchased through the Connecticut Health Insurance Exchange, including the subscriber and any spouse or dependent, for whom a Reporting Entity adjudicates claims.
- (10) "Pharmacy Claims Data File" means a data file composed of service level remittance information including, but not limited to, member demographics, provider information, charge and payment information and national drug codes from all Member paid claims for each prescription filled.
- (11) "Provider File" means a data file that includes additional information, as specified in section xx-xxx-2 (b) (4) of the Regulations of Connecticut State Agencies, about the individuals and entities that submitted claims that are included in a Medical Claims Data File or Dental Claims Data File.
- (12) "Reporting Entity" has the same meaning as provided in Section 19a-724(a) (2) (B) of the 2012 Supplement to the General Statutes.
- (13) "Small Group Health Plan" means a health plan issued to a small employer as defined in Section 38a-564 of the Connecticut General Statutes.
- (14) "Submission Guide" means the document published by the Administrator that sets forth the data elements, formats, minimum thresholds and other specifications for Reporting Entities' submission of Eligibility Data Files, Medical Claims Data Files, Dental Claims Data Files, Pharmacy Claims Data Files, and Provider Files to the Administrator or his/her designee.
- (15) "Subscriber" is the individual eligible for coverage under an insured or self-funded health plan.

(NEW) Section xx-xxx-2: Reporting Requirements.

(a) General.

- (1) Each Reporting Entity shall submit complete and accurate Eligibility Data Files, Medical Claims Data Files, Pharmacy Claims Data Files, Dental Claims Data Files, and Provider Files to the Administrator or his/her designee for all of their Members in accordance with the Submission Guide and the requirements of this section. Each Reporting Entity shall also submit all Medical Claims Data Files, Dental Claims Data Files, Pharmacy Claims Data Files, and associated Provider Files for any claims processed by any subcontractor on the Reporting Entity's behalf.

- (2) Reporting Entities that are in a contractor/subcontractor arrangement with each other and Reporting Entities that perform certain components of the claims adjudication process for the same Members under a shared services arrangement shall coordinate with each other to avoid duplicative submissions. Any Reporting Entity that administers claims of Members as a subcontractor of another Reporting Entity or can otherwise demonstrate that its submission of data regarding certain Members would result in a duplicative submission may request the Administrator to waive its obligation to submit data files for such Members as part of the annual registration process described in subsection (f) of this section.

(b) Minimum Data Elements.

- (1) Each Eligibility Data File shall contain (A) demographic information about the Member, including but not limited to, name, unique Member identifier (including Social Security Number when available), gender, date of birth, and race and ethnicity, (B) coverage information, including, but not limited to, payer name, plan ID, type of coverage, and year and month of eligibility, and (C) relevant provider-related information specified by the Administrator which may include, but is not limited to, the Member's primary care clinician and information about the Member's enrollment in an Accountable Care Organization or similar organization.
- (2) Each Medical Claims Data File shall contain information regarding each claim, including, but not limited to (A) demographic information about the Member, including but not limited to, name, unique Member identifier (including Social Security Number when available), gender, and date of birth, (B) coverage information, including, but not limited to, payer name, plan ID, and type of coverage, and (C) information about the claim, including but not limited to, when the service was provided, diagnosis information, procedure codes, payment information (including amount charged, amount paid by the plan, and Member responsibility) and provider information.
- (3) Each Pharmacy Claims Data File shall contain information regarding each claim, such as (A) demographic information about the Member, including, but not limited to, name, unique Member identifier (including Social Security Number when available), gender, and date of birth, (B) coverage information, including, but not limited to, payer name, plan ID, and type of coverage, and (C) information about the claim, including but not limited to, information about the prescription filled, such as the drug name and code, quantity and day's supply, payment information (including amount charged, amount paid by the plan and Member responsibility), and provider information.
- (4) Each Provider File shall contain information about the provider, including, but not limited to, name, address information, identification numbers, and specialty codes.
- (5) Each Dental Claims Data File shall contain information regarding each claim, including, but not limited to (A) demographic information about the Member, including but not limited to, name, unique Member identifier (including Social Security Number when available), gender, and date of birth, (B) coverage information, including, but not limited to, payer name, plan ID, and type of coverage, and (C) information about the claim, including but not limited to, when the service was provided; diagnosis information; procedure codes; codes specific to dental services such as tooth number, surface code or tooth surface, and dental quadrant; payment information (including amount charged, amount paid by the plan and Member responsibility); and provider information. As an

alternative to requiring the submission of a separate Dental Claims Data File, the Administrator may require that specific dental-related elements be added to the Medical Claims Data File, such as tooth number, surface code or tooth surface, and dental quadrant.

(c) **Reporting Schedule.**

(1) **Medical Claims Data and Pharmacy Claims Data.**

- (A) **Test Files.** Reporting Entities shall submit a test file of Eligibility Data, Medical Claims Data and Pharmacy Claims Data and associated Provider Files for a consecutive twelve month period to the Administrator or his/her designee on a date specified by the Administrator. The Administrator shall provide notice to Reporting Entities of the due for the test file by written notice published on the website of the Office of Health Reform and Innovation, which due date shall in no event be less than 150 days after the issuance of the Submission Guide.
- (B) **Historic Data.** Reporting Entities shall submit complete and accurate Historic Data that conforms to Submission Guide requirements to the Administrator no later than 90 days after the due date for the test file specified in subparagraph (A) of this subdivision.
- (C) **Year-to-date Data.** Reporting Entities shall submit complete and accurate Eligibility Data Files, Medical Claims Data Files, Pharmacy Claims Data Files and Provider Files covering the period from January 1, 2013, or such later date specified by the Administrator, through a date to be specified by the Administrator, by no later than 45 days after the due date for Historic Data specified in subparagraph (B) of this subdivision.
- (D) **Monthly Reporting.** On a monthly basis thereafter, Reporting Entities shall submit complete and accurate monthly Eligibility Data Files, Medical Claims Data Files, Pharmacy Claims Data Files, and Provider Files to the Administrator. Monthly files shall be submitted no later than the last day of the month following the end of the reporting month.
- (E) **Extensions.** Any request for an extension of time by a Reporting Entity shall be submitted to the Administrator in writing at least 45 days prior to the established deadline. The Administrator may consider requests submitted after that date in situations where the Reporting Entity subsequently discovers a technical problem that was not reasonably foreseeable on the date the extension request would otherwise have been due. The Administrator shall provide a written response to all requests for extensions.

(2) **Dental Claims Data.**

The Administrator shall establish a similar schedule for the reporting of Dental Claims Data by Reporting Entities, provided said schedule and detailed reporting specifications shall be incorporated into the Submission Guide. Notification of such changes shall be provided to Reporting Entities in accordance with subsection (e) of this section.

- (d) **Waivers of Data Submission Requirements.** The Administrator may waive data submission requirements for Reporting Entities that demonstrate to the Administrator's satisfaction that the required data elements are not available in the Reporting Entity's systems, or for Historic Data, if the Reporting Entity is not required to file data as of the effective date of these regulations due to insufficient enrollment as determined under subdivision (2) of subsection (g) of this section. As a condition for granting a waiver, the

Administrator may require a Reporting Entity to submit a plan for improving conformance to data submission requirements. An approved waiver shall:

- (1) specify the data elements or files to which the waiver applies;
- (2) specify the timeline for improved compliance, as applicable;
- (3) identify the reason for the waiver; and
- (4) specify the duration of the waiver, provided that all waivers shall expire at the end of the calendar year, unless the waiver explicitly states otherwise.

(e) **Submission Guide.**

- (1) The Administrator will produce and publish the Submission Guide to provide instructions to Reporting Entities on data elements, formats, minimum thresholds and other specifications for the Eligibility Data Files, Medical Claims Data Files, Dental Claims Data Files, Pharmacy Claims Data Files, and Provider Files to be submitted by Reporting Entities. The Administrator will publish the Submission Guide on the website of the Office of Health Reform and Innovation and thereafter the Administrator may amend the Submission Guide as necessary.
- (2) Prior to making any material revision to the Submission Guide, the Administrator will provide electronic notice of such proposal to all Reporting Entities that are registered and publish the proposed revisions on the website of the Office of Health Reform and Innovation. Reporting Entities and any other member of the public will be allowed to submit written comments to the Administrator concerning such proposed revisions for thirty (30) days after the notice on the Office's website. The Administrator may, at his or her discretion, hold a public hearing concerning proposed revisions to the Submission Guide. The Administrator will publish the final revisions on such website. Any such revisions shall not be effective until 180 days following publication of the final revisions on the website of the Office of Health Reform and Innovation.
- (3) The Administrator also may issue technical bulletins to clarify aspects of these regulations or the Submission Guide, provided that such technical bulletins will be published online on the website of the Office of Health Reform and Innovation. The Administrator may immediately implement technical or conforming revisions to the Submission Guide, provided that such revisions are made available on the website of the Office of Health Reform and Innovation.

- (f) **Annual Registration.** Beginning October 1, 2013, and annually thereafter, each Reporting Entity shall register with the Administrator on a form designated by the Administrator. The registration form shall indicate if the Reporting Entity is adjudicating claims for Members and, if applicable, the types of coverage, and its current enrollment. Reporting Entities may also request waivers of data submission requirements as part of the annual registration process.

(g) **Exclusions.**

- (1) Claims related to the following types of policies shall be excluded from the files submitted by Reporting Entities: hospital confinement indemnity coverage; disability income protection coverage; accident only coverage; long term care coverage; specified accident coverage; Medicare supplement coverage; specified disease coverage; TriCare Supplemental Coverage; travel health coverage; and single service ancillary coverage, with the exception of dental and prescription drug coverage.

- (2) Reporting Entities that, as of October 1st of any calendar year, have less than a total of 3,000 Members enrolled in plans that are offered or administered by the Reporting Entity are exempt from the data submission requirements set forth in subsections (a) to (c) of this section for the following calendar year. However, all Reporting Entities shall comply with the annual registration requirements contained in subsection (f) of this section.

(NEW) Section xx-xxx-3: Non-Compliance and Penalties.

- (a) A Reporting Entity that fails to submit required data to the APCD in accordance with section xx-xxx-2 of the Regulations of Connecticut State Agencies, or fails to correct submissions rejected because of errors, shall be deemed a non-compliant Reporting Entity. If the Administrator finds that a Reporting Entity is non-compliant, the Administrator will provide written notice to the non-compliant Reporting Entity describing the deficiency. The non-compliant Reporting Entity shall provide the required information, or otherwise correct the deficiency, within thirty (30) days following receipt of said written notice.
- (b) If a non-compliant Reporting Entity does not provide the required information or correct the deficiencies within thirty (30) days, the Administrator may issue a notice of civil penalty to the non-compliant Reporting Entity. Such notice shall describe with specificity each failure on the part of the non-compliant Reporting Entity to provide data in accordance with section xx-xxx-2 of the Regulations of Connecticut State Agencies, the date that non-compliance began, and the per day civil penalty amount to be imposed. The Administrator may impose a civil penalty up to \$1,000 per day for each day the Reporting Entity is not in compliance.
- (c) Not later than fifteen days after receipt of the notice described in subsection (b) of this section, the non-compliant Reporting Entity may respond in writing to the Administrator detailing its efforts to comply with the relevant data submission requirements and any other facts the non-compliant Reporting Entity deems relevant to mitigate the civil penalty imposed.
- (d) Not later than fifteen days after the time for the non-complaint Reporting Entity to respond has expired, the Administrator shall issue a final notice of civil penalty. In addition to the items detailed in subsection (b) of this section, the final notice of civil penalty shall address the issues raised in the Reporting Entity's reply and, if applicable, detail the reasons for the Administrator's decision to reduce the amount of the civil penalty initially imposed. The final notice of civil penalty shall constitute a final decision by the Administrator for purposes of appeal to the Superior Court pursuant to 4-183 of the Connecticut General Statutes.

(NEW) Section xx-xxx-4: Data Utilization and Disclosure.

- (a) The Administrator will utilize data in the APCD to provide health care consumers in the state with information through a web-based portal concerning the cost and quality of health care services that will allow such consumers to make economically sound and informed health care decisions.
- (b) The Administrator will make available to the public standard, aggregated reports and data files containing information regarding utilization, cost and quality of services.
- (c) The Administrator may provide custom data sets and reports to health care consumers and public and private entities engaged in reviewing health care utilization, cost, or quality of

health care services, including community and public health assessment activities, subject to the procedures contained in xx-xxx-5 of the Regulations of Connecticut State Agencies and the limitations and conditions thereunder.

(NEW) Section xx-xxx-5: Procedures for the Approval and Release of Claims Data.

- (a) **Applications for Custom Data Sets.** An individual or entity seeking to obtain a custom data set containing data elements collected or generated by the Administrator or the Administrator's designee must submit a written application to the Administrator on a form prescribed by the Administrator.
- (1) Such application shall include:
 - (A) a description of the data elements requested;
 - (B) the purpose of the project;
 - (C) a description of the research design and methodology;
 - (D) the procedures that will be used to maintain the confidentiality of any data provided; and
 - (E) a certification that the requestor will execute a data use agreement in the form prescribed by the Administrator restricting the use and disclosure of the data.
 - (2) The Administrator may tailor the type and level of information required in the application depending on whether the data set requested is a public use data set as described in subsection (c) (1) of this section, a limited data set as described in subsection (c) (2) of this section, or a data set related to an IRB-approved research study as described in subsection (c)(3) of this section.
 - (3) The Administrator may approve an application if the Administrator determines that the request for data is consistent with the statutory purpose of the APCD, the applicant has demonstrated it is qualified to undertake the research or accomplish the intended use, the applicant requires such data in order to undertake the research or accomplish the intended use and the applicant can ensure the confidentiality and security of the data will be maintained. The Administrator's decision to approve or deny an application shall be final and shall not be subject to further review or appeal.
- (b) **Data Release Advisory Committee.** The Administrator shall consult with a data release advisory committee in deciding whether to approve an application for a limited data set or an IRB-approved research study data set, and may also consult with the committee regarding applications for custom public use data sets. The data release review committee shall be comprised of members appointed by the Administrator and, at a minimum, shall include:
- (1) At least one member representing health insurers;
 - (2) At least one member representing health care facilities;
 - (3) At least one member representing a physician organization;
 - (4) At least one member representing health care consumers;
 - (5) At least one member representing employers;
 - (6) At least one member representing health care researchers;
 - (7) At least one member representing the state Medical Assistance Program; and
 - (8) At least one member representing a pharmacy organization.

The Administrator may also consult with the committee on policies regarding the release and protection of data. The advice of the committee shall not be binding on the Administrator.

- (c) **Public Use Data Sets, Limited Data Sets, and Institutional Review Board (IRB)-Approved Research Study Data Sets.** The Administrator may provide data to requestors at the following level of detail consistent with HIPAA rules regarding the safeguarding of Protected Health Information and the de-identification of data, and in compliance with state confidentiality requirements.
- (1) Public use data sets do not contain any identifiers listed in 45 C.F.R. Section 164.514(b) (2)(i), which listed identifiers include, but are not limited to, name and Social Security Number. Public use data sets also do not contain payer or physician names.
 - (2) Limited data sets may contain: (A) date information and city and zip code information related to the Member, consistent with 45 C.F.R. 164.514(e)(2), and (B) payer and physician names with sufficient justification.
 - (3) Consistent with HIPAA rules, identifiers may be included in data sets provided to researchers conducting IRB-Approved research studies with the duly authorized consent of the participants.
- (d) **Data to State Agencies and Connecticut Health Insurance Exchange.** The Administrator may provide data to Connecticut state agencies and the Connecticut Health Insurance Exchange for projects relating to the review of health care utilization, cost or quality of health care services, including for planning and carrying out of health improvement activities, upon the submission of a data management plan containing appropriate safeguards to maintain the confidentiality and security of the data and the signing of an appropriate data use or business associate agreement.
- (e) **Means of Providing Data.** Data may be provided to approved applicants through secure file transfers and other electronic methods that protect the data from unauthorized access and disclosure, such as web-based query tools with customized, user-based access.

(NEW) Section xx-xxx-6: Fees.

The Administrator may charge a fee for data sets and reports.

(New) Section xx-xxx-7: Privacy and Confidentiality.

- (a) The Administrator may make data from the APCD available to public and private entities in accordance with section xx-xxx-5 when disclosed in a form and manner that is consistent with HIPAA rules regarding the safeguarding of Protected Health Information and the de-identification of data, and in compliance with state confidentiality requirements as well as state data security and confidentiality policies.
- (b) The Administrator shall institute appropriate administrative, physical and technical safeguards consistent with the HIPAA security rules contained in 45 C.F.R. Part 160 and Part 164, Subparts A and C, to ensure that data received from Reporting Entities is securely collected, compiled and stored.

Statement of Purpose

Pursuant to CGS Section 4-170(b)(3), "Each proposed regulation shall have a statement of its purpose following the final section of the regulation." Enter the statement here.

This proposed new regulation adopts rules for the operation of the all- payer claims data base program established under Public Act 12-166, including the reporting requirements for entities that are required to submit data, penalties for non-compliance, permitted uses of the data, procedures for the approval and release of data, collection of fees for data, and privacy and confidentiality requirements.