

Department of State

Division of Publications

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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission: Department of Commerce and Insurance
Division: Insurance
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Revision Type (check all that apply):

- Amendment
- New
- Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only ONE Rule Number/Rule Title per row)

Chapter Number	Chapter Title
0780-01-79	Uniform Reporting System for the All Payer Claims Database
Rule Number	Rule Title
0780-01-79-.01	Purpose and Scope.
0780-01-79-.02	Definitions.
0780-01-79-.03	Health Care Claims Data Set Filing Description.
0780-01-79-.04	General Requirements for Health Care Claims Data Submission.
0780-01-79-.05	Submission Schedule.
0780-01-79-.06	Compliance With Data Standards and Penalties for Non-Compliance.
0780-01-79-.07	Severability Provision.

Chapter 0780-01-79
Uniform Reporting System for the All Payer Claims Database

New Rules

- 0780-01-79-.01 Purpose and Scope.
- 0780-01-79-.02 Definitions.
- 0780-01-79-.03 Health Care Claims Data Set Filing Description.
- 0780-01-79-.04 General Requirements for Health Care Claims Data Submission.
- 0780-01-79-.05 Submission Schedule.
- 0780-01-79-.06 Compliance With Data Standards and Penalties for Non-Compliance.
- 0780-01-70-.07 Severability Provision.

0780-01-79-.01 Purpose and Scope.

This Chapter contains the provisions for submission of health care claims data sets by health insurance issuers.

Authority: 2009 Public Acts, Chapter 611 and T.C.A. § 56-2-125.

0780-01-79-.02 Definitions.

Unless the context indicates otherwise, the following words and phrases shall have the following meanings:

- (1) "Address" means street address, post office box numbers, apartment numbers, e-mail addresses, web universal resource locator (URL) and internet protocol (IP) address number.
- (2) "Capitated services" means services rendered by a provider through a contract in which payments are based upon a fixed dollar amount for each member on a monthly basis.
- (3) "Commissioner" means the commissioner of the Tennessee Department of Commerce and Insurance.
- (4) "Comprehensive medical insurance policy" means an insurance policy covering all that a defined population might reasonably require in order to be in good health, including as a minimum, but not limited to, emergency care, inpatient hospital and physician care, ambulatory physician care and outpatient preventative medical services.
- (5) "Department" means the Tennessee Department of Commerce and Insurance.
- (6) "Designee" means an entity with which the Department and/or the department of finance and administration have entered into an arrangement pursuant to which the entity performs data management and collecting functions, and under which the entity is strictly prohibited from using or releasing the information and data obtained in such a capacity for any purposes other than those specified in the agreement.
- (7) "Direct identifier" means any information, other than case or code numbers used to create anonymous or encrypted data, that plainly discloses the identity of an individual, including:
 - (a) Patient names;
 - (b) Patient Street addresses other than town or city, state and zip code;
 - (c) All elements of patient birth dates, except year of birth;
 - (d) Patient telephone numbers;

- (e) Patient facsimile numbers;
 - (f) Patient electronic mail addresses;
 - (g) Patient social security numbers;
 - (h) Medical record numbers;
 - (i) Health Plan beneficiary numbers;
 - (j) Patient account numbers;
 - (k) Patient certificate/license numbers;
 - (l) Vehicle identifiers and serial numbers including license plates;
 - (m) Device identifiers and serial numbers;
 - (n) Web universal resource locators (URLs);
 - (o) Internet protocol (IP) address numbers;
 - (p) Biometric identifiers, including fingerprints, voice prints, and genetic code;
 - (q) Full-face photographic images and any comparable images; or
 - (r) Any other unique patient identifying number, characteristic, or code except encrypted index numbers assigned prior to the transmission by health insurance issuers to the state or designated entity for the purpose of linking procedures by patient, provided a patient's identity cannot be known from the encrypted index number.
- (8) "Group health plan" means an employee welfare benefit plan, as defined in the Employee Retirement Income Security Act of 1974 ("ERISA") § 3(1), codified in 29 U.S.C. § 1002(1), to the extent that the plan provides medical care to employees or their dependents, as defined under the terms of the plan, or an administrator of such a plan. For purposes of this rule, "group health plan" shall not mean any plan which is offered through a health insurance issuer;
- (9) "Health care claims data" means information consisting of, or derived directly from, member eligibility files, medical claims files, and pharmacy claims files submitted by health insurance issuers. .
- (10) "Health care practitioner" means physicians and all others certified, registered or licensed in the healing arts, including, but not limited to:
- (a) Nurses;
 - (b) Advanced practice nurses
 - (c) Podiatrists;
 - (d) Optometrists;
 - (e) Pharmacists;
 - (f) Chiropractors;
 - (g) Physical therapists;
 - (h) Psychologists; and

- (i) Physicians' assistants.
- (11) "Health insurance issuer" means an entity subject to the insurance laws of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide health insurance coverage, including but not limited to, an insurance company, a health maintenance organization and a nonprofit hospital and medical service corporation. In addition, a "health insurance issuer" also means a pharmacy benefits manager, a third party administrator, and an entity described in § 56-2-121.
- (12) "Hospital" means a licensed acute or specialty care institution.
- (13) "Medical claims file" means a data file composed of service level remittance information for all non-denied adjudicated claims for each billed service including, but not limited to:
 - (a) Member demographics;
 - (b) Provider information;
 - (c) Charge/payment information; and
 - (d) Clinical diagnosis/procedure codes.
- (14) "Member" means the subscriber and any spouse and/or dependent who is covered by the subscriber's policy.
- (15) "Member eligibility file" means a data file containing demographic information for each individual member eligible for medical or pharmacy benefits for one or more days of coverage at any time during the reporting month.
- (16) "Pharmacy benefits manager" means a person, business or other entity and any wholly or partially owned subsidiary of the entity, that administers the medication and/or device portion of pharmacy benefits coverage.
- (17) "Pharmacy claims file" means a data file containing service level remittance information from all non-denied adjudicated claims for each prescription including, but not limited to:
 - (a) Member demographics;
 - (b) Provider information;
 - (c) Charge/payment information; and
 - (d) National drug codes.
- (18) "Plan sponsor" means any person, other than an insurer, who establishes or maintains a plan covering residents of the state of Tennessee, including, but not limited to, plans established or maintained by employers or jointly by one or more employers and one or more employee organizations, committee, joint board of trustees or other similar group of representatives of the parties that establish or maintain the plan.
- (19) "Provider" means a health care facility, health care practitioner, health product manufacturer, health product vendor or pharmacy.
- (20) "Sub-contractor" means any entity that contracts with a group health plan or health insurance issuer to provide insurance services.
- (21) "Subscriber" means the certificate holder.

- (22) "Third party administrator" means an entity that, on behalf of a health insurance issuer, employer or other entity, provides health benefits coverage or health insurance coverage, as defined in T.C.A. § 56-2-125(a)(5), to individuals in this state, receives or collects charges, contributions or premiums for, or adjudicates, processes or settles claims in connection with, any type of health benefit provided in, or as an alternative to, health insurance coverage.

Authority: 2009 Public Acts, Chapter 611 and T.C.A. § 56-2-125.

0780-01-79-.03 Health Care Claims Data Set Filing Description.

- (1) Beginning on June 1, 2010, and continuing thereafter in accordance with the submission schedule set forth in Rule 0780-01-79-.05, each health insurance issuer shall submit to the Department, or its designee, a completed health care claims data set for all residents of Tennessee. Each health insurance issuer shall also submit all health care claims processed by any sub-contractor on its behalf. The health care claims data set shall include member eligibility files (for the pharmacy benefit and the medical benefit), a medical claims file, and a pharmacy claims file.
- (2) The Department, or its designee, shall provide a phone number, e-mail address and mailing address of a contact person who can provide information on the status of data files submitted.
- (3) The Department will prepare the All Payer Claims Database Procedure Manual that will list the variables to be reported, their descriptions and reporting format, the thresholds required for a submission to be deemed complete, the method for sending data, and other information associated with data submission. The Department shall make future changes in the Procedure Manual when the Commissioner deems changes to be necessary. Reporting entities will be notified in writing by the Department of all revisions. These revisions become effective one hundred and eighty (180) calendar days following the date of written notification. At that time, failure to meet the amended requirements are subject to the penalties as prescribed by T.C.A. § 56-2-125.
- (4) The minimum data set for each reported member eligibility file will include the following elements, except as otherwise set forth in the All Payer Claims Database Procedure Manual:
 - (a) Eligibility;
 - (b) Type of insurance;
 - (c) Coverage type;
 - (d) Encrypted index numbers for linking procedures by patient;
 - (e) Member's relationship to subscriber;
 - (f) Member gender;
 - (g) Member year of birth;
 - (h) Member age in months; and
 - (i) Member city, state, and zip code of residence.
- (5) The minimum data set for each reported medical claims file will include the following elements, except as otherwise set forth in the All Payer Claims Database Procedure Manual:
 - (a) National Plan ID;

- (b) Insurance type;
- (c) Payer claim control number;
- (d) Claim line counter;
- (e) Insured group or policy number for non-individual groups;
- (f) Encrypted index numbers for linking procedures by patient;
- (g) Member's relationship to subscriber;
- (h) Member gender;
- (i) Member year of birth;
- (j) Member age in months;
- (k) Member city, state, and zip code of residence;
- (l) Paid date;
- (m) Admission time and date;
- (n) Admission type;
- (o) Source of admission;
- (p) Discharge hour;
- (q) Discharge status;
- (r) Service provider number;
- (s) Service provider tax ID;
- (t) National service provider ID;
- (u) Type of service provider;
- (v) Service provider name;
- (w) Service provider specialty;
- (x) Service provider address;
- (y) Type of bill;
- (z) Place of service;
- (aa) Claim status;
- (bb) Admitting diagnosis;
- (cc) E-code;
- (dd) Principal diagnosis;
- (ee) Other diagnoses;

- (ff) Onset of diagnosis code;
 - (gg) Revenue code;
 - (hh) ICD-9-CM procedure codes;
 - (ii) Current claims terminology;
 - (jj) Health care common procedural coding system;
 - (kk) Dates of service;
 - (ll) Quantity of services performed;
 - (mm) Charge amount;
 - (nn) Paid amount;
 - (oo) Prepaid amount;
 - (pp) Copay amount;
 - (qq) Coinsurance amount;
 - (rr) Deductible amount;
 - (ss) DRG and version number;
 - (tt) APC and version number;
 - (uu) Drug code;
 - (vv) Billing provider number; and
 - (ww) Billing provider name.
- (6) The minimum data set for each reported pharmacy claims file will include the following elements, except as otherwise set forth in the All Payer Claims Database Procedure Manual:
- (a) National Plan ID;
 - (b) Insurance type;
 - (c) Payer claim control number;
 - (d) Claim line counter;
 - (e) Insured group or policy number;
 - (f) Encrypted index numbers for linking procedures by patient;
 - (g) Member's relationship to subscriber;
 - (h) Member gender;
 - (i) Member year of birth;
 - (j) Member age in months;

- (k) Member city, state, and zip code of residence;
 - (l) Date service approved;
 - (m) Pharmacy number;
 - (n) Pharmacy Tax ID;
 - (o) Pharmacy country code;
 - (p) Claims status;
 - (q) Drug code;
 - (r) Drug name;
 - (s) New prescription or refill;
 - (t) Generic drug indicator;
 - (u) Dispense as written code;
 - (v) Compound drug indicator;
 - (w) Date prescription filled;
 - (x) Quantity dispensed;
 - (y) Days of supply;
 - (z) Gross amount due;
 - (aa) Total amount paid;
 - (bb) Ingredient cost/list price;
 - (cc) Postage amount claimed;
 - (dd) Dispensing fee paid;
 - (ee) Copay;
 - (ff) Coinsurance amount;
 - (gg) Prescribing physician name; and
 - (hh) Prescribing physician number.
- (7) The Department, or its designee, shall also provide an electronic newsletter or other method of communicating information to health insurance issuers regarding the receipt, processing and loading of data files.
- (8) Health insurance issuers that are not pharmacy benefits managers and that paid a total of less than \$5,000,000 for covered residents of Tennessee during the previous calendar year shall not be required to submit their health care claims data set. In calculating its paid claims, each health insurance issuer must include all health care claims for covered individuals processed by any subcontractor on its behalf.

- (9) Pharmacy benefit managers that paid a total of less than \$1,000,000 for covered residents of Tennessee during the previous calendar year shall not be required to submit their health care claims data set. In calculating its paid claims, each pharmacy benefits manager must include all health care claims for covered individuals processed by any subcontractor on its behalf.
- (10) In instances where more than one entity is involved in the administration of a policy, the health insurance issuer responsible for submitting the claims data on policies shall be the one that has written the policies.
- (11) The Department may enter into an agreement with a third party designee to collect and process the data. The agreement shall provide that the third party designee shall be strictly prohibited from collecting direct identifiers and from releasing or using data or information obtained in its capacity as a collector and processor of the data for any purposes other than those specifically authorized by the agreement.

Authority: 2009 Public Acts, Chapter 611 and T.C.A. § 56-2-125.

0780-01-79-.04 General Requirements for Health Care Claims Data Submission.

- (1) Capitated services claims. Claims for capitated services shall be reported with all medical and pharmacy file submissions.
- (2) Claim records. Records for medical and pharmacy claims file submissions shall be reported at the visit, service, or prescription level. The submission of the medical and pharmacy claims shall be based upon the paid dates and not upon the dates of service associated with the claims.
- (3) Specific/Unique Coding. With the exception of provider codes and provider specialty codes, specific or unique coding systems shall not be permitted as part of the health care claims data set submission.
- (4) Medical Claims File Exclusions. Claims for stand-alone insurance policies shall be excluded if the stand-alone coverage is provided for the following types of services:
 - (a) Specific disease;
 - (b) Accident;
 - (c) Injury;
 - (d) Hospital indemnity;
 - (e) Disability;
 - (f) Long-term care;
 - (g) Vision coverage; or
 - (h) Durable medical equipment.
- (5) Claims for the types of services in (4) above shall be included in the medical claims file submission if they are covered by a comprehensive medical insurance policy.
- (6) Behavioral or Mental Health Claims. All claims related to behavioral, mental health, or substance abuse treatment shall be included in the medical claims file.
- (7) Claims related to Medicare supplemental, TRICARE supplemental, or other supplemental health insurance policies are to be excluded if the plan of benefits are not considered to be primary. If the policies cover health care services entirely excluded by the Medicare, TRICARE, or other program, the claims must be submitted.

- (8) Member Eligibility File Exclusions. Members without medical and/or pharmacy coverage during the month reported shall be excluded.
- (9) Pharmacy Claims File Exclusions. Claims for pharmacy services generated from non-retail pharmacies that do not contain national drug codes shall be included in the following files:
 - (a) If the pharmacy claims are covered under the medical benefit they shall be included in the medical claims file and not the pharmacy claims file;
 - (b) If the claim is covered under the prescription benefit then the claim shall be included in the pharmacy claims file;
 - (c) If the claims are submitted as standard UB04, NSF, or ANSI 935 formatted transactions without NDC codes, the claim shall be included in the medical claims file.
- (10) Registration Form.
 - (a) Each health insurance issuer, whether they are subject to the reporting requirements of Rule 0780-01-79-.05 or not, shall submit an annual registration form to the Department, or the Department's designee, every year by July 1. The form shall be in the format approved by the Commissioner.
 - (b) At a minimum, the form shall contain the following information:
 - 1. Company name;
 - 2. NAIC code;
 - 3. Mailing address;
 - 4. Information about whether the company conducts health insurance-related business;
 - 5. Number of Tennessee members covered;
 - 6. The total amount paid by the health insurance issuer during the year on covered lives in Tennessee; and,
 - 7. Name, e-mail address and address of the person completing the form.
 - (c) Health insurance issuers shall submit a registration form by April 1, 2010, and annually thereafter.
- (11) No health insurance issuer shall replace a complete data file submission more than one year after the end of the month in which the file was submitted unless it can establish exceptional circumstances for the replacement. Any replacements after this period shall be approved by the Department. Individual adjustment records shall be submitted with a monthly data file submission.

Authority: 2009 Public Acts, Chapter 611, T.C.A. §§ 56-2-125 and 56-2-301.

0780-01-79-.05 Submission Schedule.

- (1) Health insurance issuers shall report historical health care claims data according to the following schedule:

Time Span	Submission Due Date
January 1-31, 2009	June 1, 2010
February 1 – June 30, 2009	July 1, 2010

July 1, 2009 – September 30, 2010	November 1, 2010
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- (2) Once each health insurance issuer has completed submitting historical health care claims data, it shall submit health care claims data monthly. Submissions are due on the first day of the month for health care claims data covering the time span of the month preceding the prior month, or according to the following schedule:

Time Span	Submission Due Date
October	December 1
November	January 1
December	February 1
January	March 1
February	April 1
March	May 1
April	June 1
May	July 1
June	August 1
July	September 1
August	October 1
September	November 1

- (3) The commissioner, in the commissioner's discretion, may allow some health insurance issuers to submit data on a quarterly basis.
- (4) Group health plans shall be exempt from the data reporting requirements of T.C.A. § 56-2-125 and this rule to the extent that they do not use health insurance issuers to administer health benefits. However, such group health plans may submit data in accordance with this rule.

Authority: 2009 Public Acts, Chapter 611, T.C.A. §§ 56-2-125 and 56-2-301.

0780-01-79-.06 Compliance With Data Standards and Penalties for Non-Compliance.

- (1) Compliance.
- (a) Health insurance issuers shall make every effort to report the data fields as described in the Procedure Manual if the data field is present in any part of their data systems. Health insurance issuers shall submit data fields even in circumstances where the data is integrated from multiple systems. The Procedure Manual shall include minimum thresholds for submissions to be considered complete.
 - (b) The Department, or its designee, shall evaluate each member eligibility file, medical claims file and pharmacy claims file to determine compliance with the Procedure Manual.
 - (c) Upon completion of the evaluation, the Department or its designee shall promptly notify each health insurance issuer whether its data submissions satisfy the standards. This notification shall identify the specific file and the data elements that do not satisfy the standards.
 - (d) Each health insurance issuer notified of a non-compliant data submission shall respond within 10 business days of the notification by making the changes necessary to satisfy the standards.
- (2) Penalties for Non-Compliance.
- (a) The Department may assess a civil penalty of up to one hundred dollars (\$100.00) per day for delinquent claims submissions.

- (b) Failure to conform to the requirements for submission shall result in the rejection of the applicable data file(s). All rejected files shall be resubmitted in the appropriate, corrected form to the Department, or their designee, within 10 business days. The Department may assess a civil penalty of up to one hundred dollars (\$100.00) per day for rejected files not resubmitted within 10 business days.
- (c) The Commissioner has the authority to delay, reduce, or waive any penalty for not correcting any particular data element if:
 - 1. Correcting the failure would be excessively onerous for the health insurance issuer on technical grounds such as: the health insurance issuer does not gather the particular data element or does not store the particular data element;
 - 2. The health insurance issuer is working diligently, in the Commissioner's judgment, to correct the failure; or,
 - 3. The failure to correct is due to force majeure or other events of extraordinary circumstances clearly beyond the control of the health insurance issuer.

Authority: 2009 Public Acts, Chapter 611, T.C.A. §§ 56-2-125 and 56-2-301.

0780-01-70-.07 Severability Provision.

If any Rule or portion of a Rule of this Chapter or its applicability to any person or circumstance is held invalid by a court, the remainder of the Chapter or the applicability of the provision to other persons or circumstances shall not be affected. To this end, the provisions of this chapter are declared severable.

Authority: 2009 Public Acts, Chapter 611, T.C.A. §§ 56-2-125 and 56-2-301.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
N/A					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner of Commerce and Insurance on 6-7-10 (mm/dd/yyyy), and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 3/11/10

Rulemaking Hearing(s) Conducted on: (add more dates). 5/5/10



Date: 6-7-10

Signature: Leslie A Newman

Name of Officer: Leslie A. Newman

Title of Officer: Commissioner of Commerce and Insurance

Subscribed and sworn to before me on: 6-7-10

Notary Public Signature: Denise M Lewis

My commission expires on: 3-5-12

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

RE Cooper Jr
 Robert E. Cooper, Jr.
 Attorney General and Reporter
6-9-10
 Date

Department of State Use Only

Filed with the Department of State on: 6/10/10

Effective on: 9/8/10

Tre Hargett
 Tre Hargett
 Secretary of State

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Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

Comment 1

0780-01-79-.02(4)

It was commented that the defined term "Comprehensive medical insurance policy" is not actually used in the regulation, but instead, the regulation uses the term "medical insurance policy" (in definition of "health insurance issuer", Rule 0780-01-79-.02(11)), and the term "medical care to employees" (in the definition of "group health plan", Rule 0780-01-79-.02(8)). Furthermore, it was commented that this defined term is not consistent with the rule's exclusions for stand alone insurance. It was commented that the definition of "comprehensive medical insurance policy" be eliminated, or be modified to capture all health care coverage that falls within the purview of the regulation.

Agency Response to Comment 1

The term "Comprehensive medical insurance policy" is used in Rule 0780-01-79-.04(5). Currently, "Health insurance issuer" means an entity subject to the insurance laws of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide health insurance coverage, including but not limited to, an insurance company, a health maintenance organization and a nonprofit hospital and medical service corporation. In addition, a "health insurance issuer" also means a pharmacy benefits manager, a third party administrator, and an entity described in T.C.A. § 56-2-121. The term "medical insurance policy" is not used in the definition of "health insurance issuer." The Department believes that the definition of "Comprehensive medical insurance policy" is appropriate.

Comment 2

0780-01-79-.02(9)

It was commented that the regulation includes in the definition of "Health care claims data" the phrase "submitted by health care claims processors", but the regulation does not define what a health care claims processor is. Instead, it was commented that the rule defines a "group health plan" (Rule 0780-01-79-.02(8)) and it also defines a "third party administrator" (0780-01-79-.02(22)), but neither of these definitions, nor the regulations themselves, defines the term "health care claims processor." It was commented that the phrase "health care claims processor" be eliminated or modified to use actually defined terms, such as medical claims file, or third party administrator and health insurance issuer.

Agency Response to Comment 2

The department agrees with this comment and has changed the definition of "Health care claims data" to remove the phrase "submitted by health care claims processors" and substitute it with the phrase "submitted by health insurance issuers".

Comment 3

0780-01-79-.03(1)

It was commented that the effective date of the rule should reflect the actual first effective date when data shall be required, not the now historical date of May 1, 2010.

Agency Response to Comment 3

The Department agrees and the date May 1, 2010 has been changed to June 1, 2010.

Comment 4

Rule 0780-01-79-.03(3)

It was commented that, as an inherent part of the regulation, the Procedure Manual should only be changed on a prospective basis after a reasonable notice and appropriate oversight by the State. It was commented that Rule 0780-01-79-.03(3) should include the following language:

Changes to the Procedure Manual shall be prospective only and shall be effective only after a 120 day advance written notice of the changes and approval by the Tennessee Health Information Committee.

Agency Response to Comment 4

The Department does not agree with comment. Rule 0780-01-79-.03(3) already states that the “Department shall make future changes in the Procedure Manual when the Commissioner deems changes to be necessary. Reporting entities will be notified by the Department of all revisions. These revisions become effective one hundred and eighty (180) calendar days following the date of notification.” The Department believes that this rule provides greater notice than the 120 days proposed by the comment. The Department, however, has modified Rule 0780-01-79-.03(3) to require that notice be provided in writing.

Comment 5

Rule 0780-01-79-.03

It was commented that the data sets required by the regulation include highly sensitive and confidential data, including allowed amounts (Rule 0780-01-79-.03 (5)(mm) and (nn)) and ingredient cost (Rule 0780-01-79-.03(6)(aa) and (bb)), but the regulations do not specify whether, when submitting this information, the information in its raw form will remain a non-public document. It was commented that this information in its raw form should not be public. Further it was commented that this information is also considered proprietary and confidential by health plan business partners such as physicians, hospitals, and pharmaceutical companies.

Agency Response to Comment 5

The data usage and release will be determined by the Tennessee Health Information Committee, not the Department of Commerce and Insurance. In addition, TCA § 56-2-125(c)(1)(C) prohibits the public release of individual patient level claims data. The commenter’s concerns have been noted and will be addressed by the Tennessee Health Information Committee when it is establishing procedures for the release and use of the data collected pursuant to this rule and T.C.A. § 56-2-125.

Comment 6

Rule 0780-01-79-.06(1)

It was commented that Rule 0780-01-79-.06(1) requires that a health insurance issuer report data that is “present in any part of its system” and that a data submitter submit from across varied systems. It was commented that this regulation must be modified to focus the requirement on information a data submitter actually retains and uses in its ordinary payment and health care operations activities. It was commented that Rule 0780-01-79-.06(1) should include the following language: “shall make every effort to report the data fields described in the Procedural Manual or this regulation regarding data stored in an orderly form within the data submitter’s systems for the data submitter’s payment and health care operations activities as defined and limited by HIPAA”.

Agency Response to Comment 6

The Commissioner has the authority under 0780-01-79-.06 (2) (c) to delay, reduce, or waive any penalty for reasons including that correcting the failure would be excessively onerous to the health insurance issuer. The Department has modified the rule to clarify that the Commissioner may delay, reduce, or waive a fee for a health insurance issuer that does not store a particular data element.

Comment 7
0780-01-79

It was commented that the rules should explicitly allow public access to de-identified data and that all health care stakeholders, including data contributors, providers, payers, policymakers, and researchers should have access to the patient de-identified claims data sets. It was commented that the following definition be added: "Public use data set" means a data set which contains no patient identifiable data or confidential financial data, and from which all known direct or indirect identifiers about health insurance issuers and plan sponsors have been removed. Public use data sets shall consist of the medical claims files and pharmacy claims files submitted by health insurance issuers. (2) Except as otherwise provided by law, upon request the Department shall release public use data sets. (3) The Department shall maintain records of releases of public use data sets and make them available for public inspection on an internet website.

Agency Response to Comment 7

The data usage and release will be determined by the Tennessee Health Information Committee, not the Department of Commerce and Insurance. In addition, TCA § 56-2-125(c)(1)(C) prohibits the public release of individual patient level claims data. The commenter's concerns have been noted and will be addressed by the Tennessee Health Information Committee when it is establishing procedures for the release and use of the data collected pursuant to this rule and T.C.A. § 56-2-125.

Comment 8
0780-01-79

It was commented that the rules should include restrictions and/or conditions on the use of data to prevent putting health plans at an economic disadvantage due to the reporting of the following data elements for medical or pharmacy claims: National Plan ID, Charge amount, Paid amount, Prepaid amount, Gross amount due, Total amount paid, and Ingredient cost/list price. It was commented that the rule should include following language: (1) The state shall not publish any confidential financial data, including any data which would result in the health insurance issuer being placed in a competitive economic disadvantage. (2) Data elements related to charge/payment information shall only be released at an aggregate level that will not allow a charge/paid ratio to be completed for each type of service rendered for any individual health insurance issuer or provider. Requesting parties are prohibited from simultaneously arraying and/or displaying data elements related to payments for specific health care services by individual health insurance issuers and providers. The Department may create public reports or tables arrayed in this manner when all applicable provider claims for a specific service have been aggregated to produce the total price paid.

Agency Response to Comment 8

The data usage and release will be determined by the Tennessee Health Information Committee, not the Department of Commerce and Insurance. In addition, TCA § 56-2-125(c)(1)(C) prohibits the public release of individual patient level claims data. The commenter's concerns have been noted and will be addressed by the Tennessee Health Information Committee when it is establishing procedures for the release and use of the data collected pursuant to this rule and T.C.A. § 56-2-125.

Regulatory Flexibility Addendum

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

The Department of Commerce and Insurance has considered whether the proposed new rule in this notice of rule making hearing are such that they will have an economic impact on small business (business with fifty (50) or fewer employees). The proposed amendment is anticipated not to have a significant economic impact affecting small business. The proposed amendment will require health insurance issuers to report health care claims data to the Department of Commerce and Insurance or the Department's designee. The proposed Rule is necessary for the Department to implement 2009 Public Acts, Chapter 611, now codified at T.C.A. § 56-2-125.

The outcome of the analysis set forth in Tenn. Code Ann. § 4-5-403 is as follows:

- (1) The proposed rule will only apply to small businesses that are insurance companies licensed to do business in this State and pay Five Million Dollars (\$5,000,000) or greater in health care insurance claims to residents of this State each year. The proposed rule will also apply to small business that are licensed third party administrators in this State that administer group health plans, as defined by T.C.A. § 56-2-125, that pay Five Million Dollars (\$5,000,000) or greater in health care insurance claims to residents of this State each year. At this time, approximately 67 companies will have to report their health care claims data.
- (2) The proposed rule requires insurance companies and third party administrators for group health plans to submit health care claims data in accordance with a procedures manual adopted by the Tennessee Health Information Committee. The costs of reporting the data vary from company to company. Most of the companies subject to this rule are already reporting similar types and amounts of data in other states. For those companies, they already have the professional skills necessary for submitting the claims data.
- (3) The effect on small businesses is negligible. The proposed amendment will have no effect on consumers and will only affect a small number of insurers and third party administrators who constitute the largest health insurance issuers in this State.
- (4) There are no alternative methods to make the rule less costly, less intrusive or less burdensome.
- (5) Comparable rules have been implemented in Maine, Minnesota, New Hampshire and Vermont. This rule is comparable to their data reporting requirements. However, some of these states also collect claims data on dental claims. At this time, the Tennessee Health Information Committee has elected not to collect dental claims data.
- (6) Small businesses are already exempt from this rule. For this rule to apply, a health insurance issuer must pay Five Million Dollars (\$5,000,000) or more in claims to residents of this State. Under the rule, all health insurance issuers must register, but only those paying Five Million Dollars (\$5,000,000) or more in claims to residents of this State must submit claims data. There is no registration fee. To date, approximately, 250 health insurance issuers have registered. Out of those, only about 67 health insurance issuers pay more than Five Million Dollars (\$5,000,000) to residents of this State. Approximately 183 of the smaller health insurance issuers are exempt from submitting claims data under this rule.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

- (A)** A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rules are new rules to establish registration requirements and reporting procedures for health insurance issuers and group health plans that utilize health insurance issuers to administer the group health plans' claims so that the all payer claims database may commence collecting data after Chapter 611 of the Public Acts of 2009 becomes effective in January, 2010.

- (B)** A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

This notice of rulmaking hearing rule is promulgated pursuant to 2009 Public Acts, Chapter 611 and Tenn. Code Ann. § 56-2-125 and replaces and continues the emergency rule filed on March 11, 2010.

- (C)** Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

This rule will affect only those health insurers and group health plans that utilize health insurance issuers as administrators and pharmacy benefits managers who are above the minimum threshold as established by this rule. Chapter 611 of the Public Acts of 2009 requires health insurers, group health plans and pharmacy benefits managers to submit claims data to the Department of Commerce and Insurance or its designee. The Department of Finance and Administration urges the adoption of this rule.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

- (E)** An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

None.

- (F)** Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Larry C. Knight, Jr., Assistant Commissioner for Insurance; Tony Greer, Assistant General Counsel.

- (G)** Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Tony Greer, Assistant General Counsel.

- (H)** Office address and telephone number of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Second Floor, Davy Crockett Tower, 500 James Robertson Parkway, Nashville, Tennessee 37243, (615) 741-2199.

(l) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.