

Title 25. HEALTH SERVICES
Part I. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 421 HEALTH CARE INFORMATION [COUNCIL]
Subchapter A. COLLECTION AND RELEASE OF HOSPITAL DISCHARGE DATA
Amendments, §§421.1-421.10

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department), proposes amendments to §§421.1 - 421.10, concerning the collection and release of hospital discharge data.

BACKGROUND AND PURPOSE

Sections 421.1 – 421.10 establish the rules regarding the collection requirements and release specifications of hospital inpatient discharge data from Texas hospitals. The rules were originally developed and adopted by the Texas Health Care Information Council (council) and were transferred to the Department of State Health Services as result of the consolidation of health and human service agencies under House Bill 2292 (HB 2292), 78th Texas Legislature.

The amendments are necessary to comply with Health and Safety Code, Chapter 108, which requires the Executive Commissioner to adopt rules to implement the data submission requirements for hospitals required under Chapter 108 to submit inpatient discharge data to the department. The proposed amendments to the rules will require the submission of a new data element, not previously collected, that cannot be required to be submitted to the department before the 90th day after the date the rule is adopted and must take effect not later than the first anniversary after the date the rule is adopted.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 421.1 – 421.10 have been reviewed and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

In response to the consolidation of the council into the department, the terms “Council” or “Executive Director” are replaced with the term “department” throughout Subchapter A and the referenced section numbers are updated throughout the subchapter to reflect the numbers assigned when the rules were transferred to the department in 2004.

The amendments to §421.1 delete the terms “Council”, “Executive Director”, and “Scientific Review Panel” and add the terms “Institutional Review Board” and ”department” to update the language in response to consolidation, and the terms are renumbered accordingly. The amendments to §§421.2 - 421.4 and 421.6 revise references to old rules and legacy council references.

Section 421.5 deletes obsolete references to Council members.

Section 421.7 deletes an incorrect reference to the law on civil penalties.

The Centers for Medicare and Medicaid Services (CMS) have specified that they are requiring a code indicating whether a diagnosis was present at the time a patient was admitted to the hospital, to check on the quality of care and to reduce payments to those facilities that fail to meet some level of quality of care for Medicare patients. This indicator code will be collected and used by the department for public reporting on the quality of care in the hospitals. The “Diagnosis Present on Admission” indicator code is critical for Patient Safety and Pediatric Quality reporting methodologies developed by the United States Department of Health and Human Services, Agency for Healthcare Quality and Research and used by the department for public reporting. The amendments to §421.8 add the data element “Diagnosis Present On Admission” as subparagraph §421.8(c)(11)(III). This requires the department to include this new data element in the public use data file. The public use data file is an electronic file with patient level data that identifies facilities and provides consumers and researchers with data for making informed decisions regarding healthcare or for analysis of the level of care provided in those Texas hospitals required to submit data. The amendment to §421.8(1)(1) updates the name of the request form and replaces “executive director” with “department” and replaces where the form is to be submitted from the “Council’s executive director” to the “department”. The amendments to §421.8(1)(3) and (4) replace the Council’s “Scientific Review Panel” with the department’s “Institutional Review Board”. Section 421.8 deletes references to an abolished committee and deletes §421.8(e)(3) and (4) as these paragraphs refer to data collected in 1998 and data released in 1999.

The amendment to §421.9 adds the data element “Diagnosis Present on Admission” to the list of data elements required to be submitted. The data element is added as paragraph §421.9(d)(48). This requires hospitals required to comply with Health and Safety Code, Chapter 108, to submit applicable diagnosis present on admission indicator codes for each secondary diagnosis.

The amendments to §421.10 replace the Council’s “Scientific Review Panel” with the department’s “Institutional Review Board” as the entity authorized to review and grant or deny release of hospital discharge research data to requestors as specified in Chapter 108.

Subsections §421.10(c), (d) and the paragraphs (1), (2), (4), (5) and (6) in subsection (e) are deleted as they are no longer required for enforcement of the rules of this subchapter or Health and Safety Code, Chapter 108, as a result of the consolidation.

The amendment to §421.10(f)(2) replaces “executive director, in consultation with the Council” with “department” regarding who sets the fees for data files and deletes the requirement to consult with the Council, as a result of the consolidation.

The amendment to §421.10(f)(3) replaces the word “Executive Director” with “department” regarding the determination to waive or reduce fees charged for public use data files or the research data file.

Paragraph §421.10(f)(5) is deleted, as a result of the consolidation.

The amendment to §421.10(g) replaces the term “Executive Director” with the term “department” regarding who shall receive the written report from the Chair of the Institutional Review Board/ Scientific Review Panel.

FISCAL NOTE

Ramdas Menon, Ph.D., Director, Center for Health Statistics, has determined that for each calendar year of the first five years that the amended sections are in effect, there will be fiscal implications to the state as a result of enforcing or administering the sections as proposed. The effect on state government will be a one time cost for the department of \$28,500 for development and modification to the current health care data collection system (data file format, file structures, logs, reports and three associated data software tools) and the University of Texas Medical Branch at Galveston stated a one time cost of \$1500 for programming to submit the data as required by the proposed rule. The following four years there will be no additional costs to the department. The following state hospital systems responded to an inquiry on the cost to implement the proposed amendments that there would be no additional costs: Texas Center for Infectious Disease, Department of State Health Services Mental Hospitals, the University of Texas M.D. Anderson and the University of Texas Health Center at Tyler. The other state facilities provided no response. The fiscal implications of submitting the “Diagnosis Present on Admission” indicator codes as proposed for local governments that own or operate hospitals of systems will vary dependent on the complexity of the hospitals’ information technology and contract requirements with any vendors involved.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Dr. Menon anticipates that those hospitals required to report under Health and Safety Code, Chapter 108, that submit data to CMS would not incur additional costs for the collection of the “Diagnosis Present on Admission” indicator, since this data element will be required for all providers that submit to CMS. Those hospitals that do not submit data to CMS will incur additional costs dependent on the complexity of their information technology system. Dr. Menon anticipates that all hospitals that are required to submit under Health and Safety Code, Chapter 108, will modify or have modified their computer systems to capture and submit the “Present on Admission” code for the associated secondary diagnosis codes. Hospitals that are small businesses or micro-businesses that contract with a vendor or have built a computer system that is separate from their billing system will incur varying costs, depending upon the complexity of their systems and contract requirements with any vendors involved with the hospitals information technology systems on submitting the “Diagnosis Present on Admission” indicator codes as proposed. There are no other anticipated economic costs to persons who are required to comply with the sections as proposed. There will be no effect on local employment.

PUBLIC BENEFIT

Dr. Menon has also determined that for each year of the first five years the amendments are in effect, the public will benefit from the adoption of the amended sections. The public benefit

anticipated as a result of collecting and reporting of this data element is the ability to provide the public with additional data regarding whether a diagnosis was present at the time the patient was admitted to the hospital or after the patient had been admitted to the hospital. The public will benefit from health care provider reports and information about the quality of care being provided in hospitals. The standardized data and the reports and information developed from the data will assist the consumer in making informed decisions on healthcare issues. The public will also benefit by having this subchapter of rules updated to reflect the current organization of the Department of State Health Services.

REGULATORY ANALYSIS

The department has determined that the proposed amendments are not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. The proposed amendments are not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed amendments do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Bruce M. Burns, D.C., Center for Health Statistics, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512/458-7740 or by E-mail to Bruce.Burns@dshs.state.tx.us . Comments will be accepted for 30 days following publication of the proposal in the Texas Register.

LEGAL CERTIFICATION

The Department of State Health Services, Deputy General Counsel, Linda Wiegman, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed amendments are authorized by Health and Safety Code, §§108.006, 108.009, 108.010 and 108.011, which require the Executive Commissioner to adopt rules regarding which data elements are to be required for submission to the department and which data elements are to be released in a public use data file; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human

Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed amendments affect the Health and Safety Code, Chapter 108 and Government Code, Chapter 531. Review of the sections implements Government Code, §2001.039.

Legend:

Single Underline = Proposed new language

[Bold Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§421.1. Definitions. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Accurate and Consistent data--Data that has been edited by the department **[Council]** and subjected to provider validation and certification.

(2) – (3) (No change.)

(4) Certification Process--The process by which a provider confirms the accuracy and completeness of the encounter data set required to produce the public use data file as specified in §421.7 **[\$1301.17]** of this title (relating to Certification of Discharge Reports).

(5) - (6) (No change.)

[(7) Council--The Texas Health Care Information Council.]

(7) **[(8)]** Data format--The sequence or location of data elements in an electronic record according to prescribed specifications.

(8) Department – Department of State Health Services.

(9) Discharge--The formal release of a patient by a hospital; that is, the termination of a period of hospitalization by death or by disposition to a residence or another health care provider.

(10) Discharge claim--A set of computer records as specified in §421.9 **[\$1301.19]** of this title (relating to Discharge Reports--Records, Data Fields and Codes) relating to a specific patient. "Discharge claim" corresponds to the ANSI 837 Institutional Guide term, "Transaction set."

(11) Discharge report--A computer file as defined in §421.9 **[\$1301.19]** of this title **[(relating to Discharge Reports--Records, Data Fields and Codes)]** periodically submitted on or on behalf of a Hospital in compliance with the provisions of this chapter. "Discharge report" corresponds to the ANSI 837 Institutional Guide terms, "Communication Envelope" or "Interchange Envelope."

(12) - (13) (No change.)

(14) Edit--An electronic standardized process developed and implemented by the department **[Council]** to identify potential errors and mistakes in data elements by reviewing data fields for the presence or absence of data and the accuracy and appropriateness of data.

(15) - (17) (No change.)

[(18) Executive director--The chief administrative officer of the Council, or, in the event the Council is without an executive director, the person designated by the chairperson of the Council to perform the functions and exercise the authority of the executive director.]

(18) [(19)] Facility Type Indicators--An indicator that provides information to the data user as to the type of facility or the primary health services delivered at that facility (e.g., Teaching, Acute Care, Rehabilitation, Psychiatric, Pediatric, Cancer, Skilled Nursing, Long Term Acute Care or other Long Term Care Facility). A facility may have more than one indicator. Hospitals may request updates to this field.

(19) [(20)] Geographic identifiers--A set of codes indicating the public health region and county in which the patient resides.

(20) [(21)] HCPCS--HCFA's Common Procedure Coding System (HCFA - Health Care Finance Administrations (Now called Centers for Medicare and Medicaid Services)).

(21) [(22)] Health care facility--A hospital, an ambulatory surgery center licensed under Chapter 243 of the Health and Safety Code, a chemical dependency treatment facility licensed under Chapter 464 of the Health and Safety Code, a renal dialysis center, a birthing center, a rural health clinic or a federally qualified health center as defined by 42 United States Code, §1396(1)(2)(B).

(22) [(23)] HIPPS--Health Insurance Prospective Payment System.

(23) [(24)] Hospital--A public, for-profit, or nonprofit institution licensed or owned by this state that is a general or special hospital, private mental hospital, chronic disease hospital or other type of hospital.

(24) [(25)] ICD--International Classification of Disease.

(25) [(26)] Inpatient--A patient, including a newborn infant, who is formally admitted to the inpatient service of a hospital and who is subsequently discharged, regardless of status or disposition. Inpatients include patients admitted to medical/surgical, intensive care, nursery, subacute, skilled nursing, long-term, psychiatric, substance abuse, physical rehabilitation and all other types of hospital units.

(26) Institutional Review Board--The department's appointees or agent who have experience and expertise in ethics, patient confidentiality, and health care data who review and approve or disapprove requests for data or information other than the public use data as described in §421.10 of this title (relating to Institutional Review Board). The Institutional Review Board acts as the Scientific Review Panel described in the Health and Safety Code, §108.0135.

(27) Operating or Other Physician--The "physician" licensed by the Texas **[State Board of] Medical Board [Examiners]**, or "other health professional" licensed by the State of Texas who performed the principal procedure or performed the surgical procedure most closely related to the principal diagnosis.

(28) - (29) (No change.)

(30) Patient account number--A number assigned to each patient by the hospital, which appears on each computer record in a patient discharge claim. This number is not consistent for a given patient from one hospital to the next, or from one admission to the next in the same hospital. The department **[Council]** deletes or encrypts this number to protect patient confidentiality prior to release of data.

(31) - (32) (No change.)

(33) Provider quality data--A report or reports authored by the department **[Council]** on provider quality or outcomes of care, as defined in Chapter 108 of Health and Safety Code, created from data collected by the department **[Council]** or obtained from other sources.

(34) – (35) (No change.)

(36) Required minimum data set--The list of data elements which hospitals are required to submit in a discharge claim for each inpatient stay in the hospital. The required minimum data set is specified in §421.9(d) **[§1301.19(d)]** of this title. (relating to Discharge Reports--Records, Data Fields and Codes). This list does not include the data elements that are required by the ANSI 837 Institutional Guide to submit an acceptable discharge report. For example: Interchange Control Headers and Trailers, Functional Group Headers and Trailers, Transaction Set Headers and Trailers and Qualifying Codes (which identify which qualify subsequent data elements).

(37) Research data file--A customized data file, which includes the data elements in the public use file and may include data elements other than the required minimum data set submitted to the department **[Council]**, except those data elements that could reasonably identify a patient or physician. The data elements may be **[maybe]** released to a requestor when the requirements specified in §421.8 **[§1301.18(I)]** of this title (relating to Hospital Discharge Data Release) are completed.

(38) - (39) (No change.)

[(40) Scientific Review Panel—The Council's appointees or agent who have experience and expertise in ethics, patient confidentiality, and health care data who review and approve or disapprove requests for data or information other than the public use data. Described in §1301.20 of this title (relating to Scientific Review Panel).]

(40) **[(41)]** Service Unit Indicator--An indicator derived from submitted data (based on Bill type or Revenue Codes) and represents the type of service unit or units (e.g., Coronary Care Unit, Detoxification Unit, Intensive Care Unit, Hospice Unit, Nursery, Obstetric Unit, Oncology

Unit, Pediatric Unit, Psychiatric Unit, Rehabilitation Unit, Sub acute Care Unit or Skilled Nursing Unit) where the patient received treatment.

(41) [(42)] Severity adjustment--A method to stratify patient groups by degrees of illness and mortality.

(42) [(43)] Submission--The transfer of a set of computer records as specified in §421.9 [§1301.19] of this title [(relating to Discharge Reports--Records, Data Fields and Codes)] that constitutes the discharge report for one or more hospitals.

(43) [(44)] Submitter--The person or organization, which physically prepares discharge reports for one or more hospitals and submits them to the department [Council]. A submitter may be a hospital or an agent designated by a hospital or its owner.

(44) [(45)] THCIC Identification Number--A string of six characters assigned by the department [Council] to identify health care facilities for reporting and tracking purposes.

(45) [(46)] Uniform facility identifier--A unique number assigned by the department [Council] to each health care facility licensed in the state. For hospitals, this will include the hospital's state license number. For hospitals operating multiple facilities under one license number and duplicating services, the department [Council] will assign a distinguishable uniform facility identifier for each separate facility. The relationship between facility identifier and the name and license number of the facility is public information.

(46) [(47)] Uniform patient identifier--A unique identifier assigned by the department [Council] to an individual patient and composed of numeric, alpha, or alphanumeric characters, which remains constant across hospitals and inpatient admissions. The relationship of the identifier to the patient-specific data elements used to assign it is confidential.

(47) [(48)] Uniform physician identifier--A unique identifier assigned by the department [Council] to a physician or other health professional who is reported as attending or treating a hospital inpatient and which remains constant across hospitals. The relationship of the identifier to the physician-specific data elements used to assign it is confidential. The uniform physician identifier shall consist of alphanumeric characters.

(48) [(49)] Validation--The process by which a provider verifies the accuracy and completeness of data and corrects any errors identified before certification.

§421.2. Collection of Hospital Discharge Data

(a) All hospitals in operation for all or any of the reporting periods described in §421.3 [§1301.13] of this title (relating to Schedule for Filing Discharge Reports) shall submit discharge claims as specified in §421.9 [§1301.19] of this title (relating to Discharge Reports--Records, Data Fields and Codes) on all discharged inpatients to the department [Council]. To the extent the admission, treatment, or discharge is made by a health professional, other than a physician, data elements specified in §421.9(d)(36)-(41) of this title [§1301.19(d)(36)-(41)] shall be filled

accordingly or data elements (38) or (41) shall be marked with one of the department [Council] approved temporary "Physician" or "Other health professional" code numbers and data elements (36)(A-C) or (39)(A-C) may be left blank. Hospitals owned by the federal government and hospitals exempted as rural providers may submit hospital discharge claim.

(b) All inpatient discharges shall be reported. Except as noted in paragraphs (1)-(4) of this subsection, one or more discharge claims shall be submitted for each patient for each discharge covering all services and charges from admission through discharge.

(1) – (2) (No change.)

(3) For all patients for which the hospital prepares one or more bills for inpatient services, the hospital shall submit a discharge claim corresponding to each bill containing the data elements required by §421.9 [§1301.19] of this title **[(relating to Discharge Reports--Records, Data Fields and Codes)]**. For all patients for which the hospital does not prepare a bill for inpatient services, the hospital shall submit a discharge claim containing the required minimum data set.

(4) For all patients that are covered by 42 USC 290dd-2 and 42 CFR Part 2.1, a hospital shall submit a discharge claim containing the required data elements specified by §421.9 [§1301.19] of this title **[(relating to Discharge Reports--Records, Data Fields and Codes)]**. The hospital shall replace the patient identifying information with the default values specified in §421.9(e) [§1301.19(e)] of this title **[(relating to Discharge Reports--Records, Data Fields and Codes)]** or submit the patient identifying information if release of patient identifying information is authorized in writing by the patient or patient's guardian.

(c) All hospitals shall file discharge reports by electronic filing unless the hospital receives an exemption letter from the department [Council].

(d) All hospitals shall submit discharge claims and discharge reports in the format specified in §421.9 [§1301.19] of this title **[(relating to Discharge Reports--Records, Data Fields and Codes)]**.

(e) Hospitals shall submit discharge reports, data certifications, exemption requests and other required information to the department [Council] or its contractors [agents] at physical or telephonic addresses specified by the department [executive director]. The department [executive director] shall notify all hospitals and submitters in writing and by publication in the *Texas Register* at least 30 calendar days before any change in the addresses.

(f) Hospitals may submit discharge reports, or may designate an agent to submit the reports. If a hospital designates an agent, it shall inform the department [Council] of the designation in writing at least 30 calendar days prior to the agent's submission of any discharge report. The hospital shall inform the department [Council] in writing at least 30 calendar days prior to changing agents or making the submissions itself. Designation of an agent does not relieve the hospital of responsibility for compliance with this chapter or other related law.

(g) If requested by the department [Council], a hospital shall provide the department [executive director or the director's agent, the Texas Department of Health,] access to, copies of and/or information from the hospital documents and records underlying and documenting the discharge reports submitted, as well as other patient related documentation deemed necessary to audit hospital data to verify its accuracy and reliability. Each request from the department [Council] shall detail the reasons for such request, provide the hospital with at least 14 calendar days advance notice, and ensure that confidentiality of patient records is maintained.

§421.3. Schedule for Filing Discharge Reports.

(a) Hospitals [For discharges occurring on or after January 1, 1998, hospitals] shall file discharge reports according to the following schedule as shown in paragraphs (1)-(4) of this subsection unless a hospital has received an exemption letter from the department [Council].

(1) - (4) (No change.)

(b) Extensions to processing due dates may be granted by the department [executive director] for a maximum of ten working days in response to a written request signed by the hospital's chief executive officer. Requests must be in writing, must be received at least five working days prior to the due date and must be accompanied by adequate justification for the delay.

(c) (No change.)

§421.4. Instructions for Filing Discharge Reports.

(a) Magnetic Media. A discharge report may be filed on computer diskettes, nine track tapes or other magnetic media approved by the department [executive director]. All discharges shall be reported using the same file and record formats specified in §421.9 [§1301.19] of this title (relating to Discharge Reports--Records, Data Fields and Codes) regardless of medium.

(1) Media specifications are:

(A) - (B) (No change.)

(C) Other magnetic media: Discharge reports may be filed on other magnetic media only with the prior written approval of the department [executive director]. The department [executive director] will not normally approve any medium which the department [Council] is not currently equipped to read.

(2) - (3) (No change.)

(4) In addition to the provisions of this section, the department [Council] shall document instructions for filing discharge reports on magnetic media and shall make this documentation available to hospitals at no charge and to the public for the cost of reproduction.

The department [Council] shall notify hospitals or their designated agents directly in writing at least 90 days in advance of any change in instructions for filing discharge reports on magnetic media. The department's [Council's] instructions shall follow Department of Information Resources standards for magnetic media established under 1 TAC Chapter 201.

(b) Electronic Data Interchange. Discharge reports may be filed by modem using electronic data interchange (EDI). All discharges shall be reported using the same file and record formats specified in §421.9 [§1301.19] of this title [(relating to Discharge Reports--Records, Data Fields and Codes)] regardless of the medium of transmission, unless the hospital has obtained an exemption authorized by §421.5 [§1301.15] of this title (relating to Exemptions from Filing Requirements). The department [Council] shall document instructions for filing discharge reports by EDI and shall make this documentation available to hospitals at no charge and to the public for the cost of reproduction. The department [Council] shall notify hospitals and their designated agents directly in writing at least 90 days in advance of any change in instructions for filing discharge reports by EDI. The department's [Council's] instructions shall follow Department of Information Resources standards for EDI.

§421.5. Exemptions from Filing Requirements.

(a) Types of Exemptions.

(1) Exemption as a rural provider or other exempted provider. All hospitals except those owned by the federal government shall submit discharge reports to the department [Council] unless the department [Council] determines that the hospital is a rural provider or other exempted provider. The department [executive director] shall make a determination of which hospitals are entitled to this exemption at least annually and shall notify qualifying hospitals by publication in the *Texas Register* and by regular United States mail. Hospitals which are not initially given an exemption may apply for an exemption. This exemption, if granted, may be revoked by the department [Council] should the hospital cease to meet the criteria for exemption based upon the most current data issued by the United States Bureau of the Census or changes in hospital ownership or management relationships. Hospitals that cease to be exempted as rural providers or as other exempted providers shall be responsible for submitting discharge claims on all discharges that occur 30 days after loss of the exemption. The initial discharge report shall not be due until 90 days after notice is given. Subsequent discharge reports are due as specified in 421.3(a) [§1301.13(a)] of this title (relating to Schedule for Filing Discharge Reports).

(2) Exemptions from Quarterly Filing of Discharge Reports. Hospitals that wish to submit discharge reports to the department [Council] more often than quarterly may do so by requesting an exemption to the standard submission schedule. The department [Council] may also issue general exemptions based on the processing arrangements for data collection. Exemption requests meeting the following criteria as shown in subparagraphs (A)-(D) of this paragraph will normally be approved.

(A) - (B) (No change.)

(C) The exemption request will not result in data on any discharge being submitted to the department [**Council**] at a later date than it would have been if the standard schedule had been followed.

(D) The hospital agrees to adhere to the schedule specified in the exemption request until the hospital notifies the department [**executive director**] in writing that it wishes to end the exemption and report according to the standard schedule, or until a new exemption letter is issued.

(b) Requests for exemptions shall be submitted and processed using the following procedures as shown in paragraphs (1)-(4) of this subsection.

(1) A hospital requesting an exemption shall submit to the department [**executive director**] a letter requesting the exemption and providing all information necessary to establish the hospital's entitlement to the exemption. The exemption request shall be signed by the chief executive officer of the hospital who shall certify that all information contained in the request is true and correct.

(2) The department [**executive director**] shall review the request for exemption. The department executive director may request additional information from the hospital relevant to the exemption request. Within 30 days of receipt of a request, the department [**executive director**] shall issue a letter granting or denying the exemption. If denied, the letter shall state in detail the reasons for the denial. [**The executive director shall notify Council members of exemptions requested and the disposition of these requests for information only.**]

(3) If the department [**executive director**] denies an exemption request the hospital may:

(A) resubmit the request along with any additional information or analysis the hospital deems relevant to the department [**executive director**]. The resubmission shall be considered in the same manner as an initial submission; or

(B) appeal the department's [**executive director's**] decision to the commissioner of the department [**Council**]. The hospital may make an appeal directly to the commissioner of the department [**Council**]. In making its determination, the department [**Council**] will consider only those facts and issues which have been previously presented to the department [**executive director**]. [**The Council will decide exemption appeals by majority vote of members present.**]

(4) The department [**executive director**] may revoke any type of exemption if facts indicate that a hospital no longer meets the criteria required for an exemption. The department [**executive director**] shall give the hospital written notice of the revocation at least 30 days prior to the effective date of the revocation. The notice shall include a detailed statement of the facts on which the revocation is based. A hospital may challenge the revocation of its exemption by:

(A) requesting the department [executive director] to reconsider the revocation by submitting any information or analysis the hospital deems relevant to the department [executive director] in writing at least ten days prior to the effective date of the revocation; and

(B) by appealing to the commissioner of the department [Council] if the department [executive director] does not grant the request for reconsideration. In making its determination, the commissioner of the department [Council] will consider only those facts and issues which have been previously presented to the department [executive director]. **[The Council will decide exemption appeals by majority vote of members present.]**

(c) Reporting loss of exemptions. Hospitals shall notify the department [executive director] in writing within 30 days of their loss of an entitlement to an exemption authorized by subsection (a) of this section.

§421.6. Acceptance of Discharge Reports and Correction of Errors.

(a) To verify the accuracy of all discharge claims prior to public release, the department [executive director] shall establish procedures for the review of all discharge reports to determine whether the report is acceptable, as required by Health and Safety Code, §108.011.

(b) Upon receipt of a discharge report, the department [executive director] shall determine if it satisfies minimum criteria for processing. If it does not, the department [executive director] shall return the discharge report in the same submission format and media that is approved for that provider and state the deficiencies in writing within ten calendar days of receipt. The hospital shall resubmit the report within ten calendar days of notification by the department [executive director]. A discharge report does not meet minimum standards for processing under the following circumstances as shown in paragraphs (1)-(3) of this subsection.

(1) The physical media and labeling do not conform to the specifications in §421.4 [§1301.14] of this title (relating to Instructions for Filing Discharge Reports).

(2) (No change.)

(3) The file structure does not conform to the specifications in §421.9 [§1301.19] of this title (relating to Discharge Reports--Records, Data Fields and Codes), unless the hospital has received a letter from the department [Council] authorizing filing in another format.

(c) Correction of Errors.

(1) The department [executive director] shall review all discharge reports accepted for processing and will process all discharge claims against the editing criteria established by this section and by the department [executive director]. Within 10 calendar days of receipt of an accepted discharge report, the department [executive director] shall notify the hospital in detail of all errors detected in the discharge report.

(2) Within 30 calendar days of receiving initial notice of errors in a discharge report, the hospital shall correct all discharge claims containing errors, add any discharge claims determined to be missing from the initial discharge report and resubmit the corrected and/or previously missing discharge claims. If the hospital disagrees with any identified error, the hospital may indicate that the discharge claim is as accurate as it can be or cannot be corrected. Each hospital shall submit such modified and/or additional discharge claims as may be required to allow the chief executive officer or the chief executive officer's designated agent to certify the quarterly discharge report as required by §421.7 [§1301.17] of this title (relating to Certification of Discharge Reports). Corrections to a discharge report shall be submitted on approved media and formats as specified in §421.4 [§1301.14] of this title [(relating to Instructions for Filing Discharge Reports)] and §421.9 [§1301.19] of this title [(relating to Discharge Reports-Records, Data Fields and Codes)] unless the department [executive director] approves another medium or format.

(3) Within ten calendar days of receiving corrections to a discharge report from a hospital, the department [executive director] shall notify the hospital of any remaining errors. The hospital shall have ten calendar days from receipt of this notice to correct the errors noted or indicate why the data should be deemed acceptable and complete. This process may be repeated until the data is substantially accurate and the hospital is able to certify the discharge report as required by §421.7 [§1301.17] of this title [(relating to Certification of Discharge Reports)] or the deadline for submitting corrections prior to certification is reached. Corrected data is required to be submitted on or before the following dates for the respective quarter's discharges; Quarter 1 - August 1, Quarter 2 - November 1, Quarter 3 - February 1, Quarter 4 - May 1. No individual hospitals will be granted extensions to the dates. The department [executive director] may grant an extension to all hospitals when deemed necessary.

(4) Discharge claims that have not been previously submitted shall be submitted prior to the deadline for the following quarter's data. Correction and certification of these previously missing or additional discharge claims for the prior calendar quarter shall be made according to the deadlines established for following quarter in which the data that is scheduled to be processed as specified in §421.3(a)(1) [§1301.13(a)(1)] of this title (relating to the Schedule for Filing Discharge Reports), paragraph (3) of this subsection (relating to the Acceptance of Discharge Reports and Correction of Errors) and §421.7 [§1301.17] (b) and (d) of this title [(relating to the Certification of Discharge Encounter Data)]. Corrections to discharge claims previously submitted or that have a discharge date prior to calendar quarter immediately before the calendar quarter being processed scheduled will not be processed.

(d) The department [executive director] will document and the department [Council] will approve all acceptance and editing criteria utilized in reviewing discharge reports. If acceptance and editing criteria are incorporated into computer software, and if the software is the property of the department [Council], the department [executive director] will make copies of the portions of the software containing the criteria available on paper or magnetic media. The department [executive director] shall make this information available to submitters without charge and to others for the cost of reproduction.

(e) Failure to correct or comment on a discharge report which has been filed but contains errors or omissions, known to the hospital, within the due dates in §421.3 [**§1301.13**] of this title [**(relating to Schedule for Filing Discharge Reports)**] is punishable by a civil penalty pursuant to Health and Safety Code, §108.014.

§421.7. Certification of Discharge Reports.

(a) Within five months after the end of each reporting quarter, the department [**executive director**] shall compile one or more electronic data files for each reporting hospital using all discharge claims received from each hospital. The file shall have one record for each patient discharged during the reporting quarter and one record for any patient discharged during one prior reporting quarter for whom additional discharge claims have been received. This file will include all data submitted by the hospital, which the department [**executive director**] intends to use in the creation of the public use data file. The data files, including reports and any additional information returned to the hospital, allows the hospital to provide physicians and other health professionals the opportunity to review, request correction of, and comment on records of discharged patients for whom they are shown as "attending" or "operating or other". The department [**executive director**] shall determine the format and medium in which the quarterly file will be delivered to hospitals.

(b) The chief executive officer or chief executive officer's designated agent of each hospital shall indicate whether the hospital is certifying or not certifying the discharge encounter data specified in subsection (a) of this section, sign and return the form corresponding to the discharge report for each quarter using forms supplied by the department [**Council**]. The certification form may be signed by a person designated by the chief executive officer and acting as the officer's agent. Designation of an agent does not relieve the chief executive officer of personal responsibility for the certification. If the chief executive officer or chief executive officer's designated agent does not believe the quarterly file is accurate, the officer shall provide the department [**executive director**] with detailed comments regarding the errors or submit a written request (on a form supplied by the department [**Council**]) and provide the data necessary to correct any inaccuracy and certify the file subject to those corrections being made prior to the deadlines specified in this subsection. Corrections to certification discharge data shall be submitted on or prior to the following schedule: Quarter 1 - October 15; Quarter 2 - January 15; Quarter 3 - April 15; Quarter 4 - July 15. Chief Executive Officers or designees that elect not to certify shall submit a reasoned justification explaining their decision to not certify their discharge encounter data and attach the justification to the certification form. Election to not certify data does not prevent data from appearing in the public use data file. Data that is not corrected and submitted by the deadline may appear in the public use data file.

(c) The signed certification form shall represent that:

(1) - (3) (No change.)

(4) the hospital has provided physicians and other health professionals a reasonable opportunity to review and comment on the discharge data of patients for which they were reported in one of the available physician number and name fields provided on the

acceptable formats specified in §421.9 [§1301.19] of this title (relating to Discharge Reports--Records, Data Fields and Codes) (for example, "attending physician" or "operating or other physician" as applicable. The physicians or other health professionals may write comments and have errors brought to the attention of the chief executive officer or the chief executive officer's designated agent and the chief executive officer or the chief executive officer's designated agent, shall address any comments by the physicians or other health professionals.

(5) (No change.)

(d) Each hospital shall submit its certification form for each quarter's data to the department [Council] by the first day of the ninth month (Quarter 1 - December 1; Quarter 2 - March 1; Quarter 3 - June 1; Quarter 4 - September 1) following the last day of the reporting quarter as specified in §421.3 [§1301.13] (a) (1)-(4) of this title (relating to Schedule for Filing Discharge Reports). Individual hospital requests for an extension to these deadlines will not be granted. The department [executive director] may extend the deadline for all hospitals when deemed necessary.

(e) Hospitals, physicians or other health professionals may submit concise written comments regarding any data submitted by them or relating to services, they have delivered which may be released as public use data. Comments shall be submitted to the department [Council] on or before the dates specified in subsection (d) of this section, regarding the submission of the certification form. Commenters are responsible for assuring that the comments contain no patient or physician identifying information. Comments shall be submitted electronically using the method described in §421.4(a) [§1301.14(a)] and (b) of this title (relating to Instructions for Filing Discharge Reports).

[(f) Failure to submit a signed certification form that is supplied by the Council on or before the dates specified in subsection (d) of this section corresponding to discharge data previously submitted is punishable by a civil penalty pursuant to Health and Safety Code, §108.014.]

[(f)][(g)] Failure to either correct a discharge report which has been submitted and contains errors or omissions known to the hospital on or prior to the dates specified in subsection (b) of this section or to address in the comments the errors known to the hospital contained in the data and return the comments on or prior to the dates specified in subsection (d) of this section is punishable by a civil penalty pursuant to Health and Safety Code, §108.014(b).

§421.8. Hospital Discharge Data Release.

(a) Department [Council] records are public records under Government Code, Chapter 552, except as specifically exempted by Health and Safety Code, §108.010 and §108.013. Copies of such records may be obtained upon request and upon payment of user fees established by the department [Council]. The public use data file shall be available for public inspection during normal business hours. Discharge claims in the original format as submitted to the department [Council] are not available to the public, are not stored at the department's [Council's] office and are exempt from disclosure pursuant to Health and Safety Code, §108.010 and §108.013, and

shall not be released. Likewise, patient and physician identifying data collected by the department [Council] through editing of hospital data shall not be released.

(b) Creation of codes and identifiers. The department [executive director] shall develop the following codes and identifiers, as listed in paragraphs (1)-(2) of this subsection, required for creation of the public use data file and for other purposes.

(1)-(2) (No change.)

(c) Creation of public use data file. The department [executive director] will create a public use data file by creating a single record for each inpatient discharge and adding, modifying or deleting data elements in the following manner as listed in paragraphs (1)-(11) of this subsection:

(1) - (6) (No change.)

(7) the minimum cell size required by §108.011(i)(2) of the Health and Safety Code shall be five, unless the department [executive director] determines that a higher cell size is required to protect the confidentiality of an individual patient or physician. **[When determining a higher cell size, the executive director shall consider comments submitted by a hospital and recommendations submitted by the technical advisory committee as identified in the Texas Health and Safety Code §108.003(g)(5)];**

(8) (No change.)

(9) add risk and severity adjustment scores utilizing an algorithm approved by the department [Council];

(10) (No change.)

(11) data elements to be included in the public use data file:

(A) - (HHHH) (No change.)

(III) Diagnosis Present On Admission.

(d) Release of public use data files. The department [Council] shall release in an aggregate form, without uniform patient, physician or other health professional identifiers, public use data relating to hospitals described by the Health and Safety Code, §108.0025(1) that are not rural providers because they do not meet the requirements of §108.0025(2).

(e) The department [executive director] will make available a public use data file on electronic, magnetic or optical media for each quarter:

(1) The department [executive director] shall release public use data from hospitals that have certified the data as required by §421.7 [§1301.17] of this title (relating to Certification of Discharge Reports). A hospital's failure to execute the certification form by the

dates specified in §421.7(d) [**§1301.17(d)**] of this title, or elects to not certify the discharge encounter data shall not prevent the department [**executive director**] from releasing the hospital's data if the department [**director**] believes the data submitted is reasonably accurate and complete. The department [**executive director, with the recommendation of the Hospital Discharge Data Committee,**] may suppress for any quarter's data one or more data elements if deemed necessary to comply with provisions of the statutes. If an element is ordered suppressed by a judicial authority, the department [**executive director**] may suppress the element[**without the recommendation of the Hospital Discharge Data Committee**].

(2) If additional discharge claims (not previously submitted as specified in §421.6(c)(4) [**§1301.16(c)(4)**] of this title (relating to Acceptance of Discharge Reports and Correction of Errors), excluding replacement, adjustments and void/cancel discharge claims become available after the initial release of the public use data file for any quarter, the department [**executive director**] will add the discharge claims, that are received on or prior to the date specified in §421.3(a)(1) [**§1301.13(a)(1)**] of this title (relating to Schedule for Filing Discharge Reports) of the following quarter, to the public use data file and make the additional records available to the public.

[(3) The other sections of these rules notwithstanding, the executive director shall not create a public use data file from the discharge reports covering discharges occurring in 1998. It is the intent of the Council to utilize this data only for testing and calibration of its data processing systems and to allow hospitals the opportunity to test and calibrate their own data reporting systems.]

[(4) The first public use data file available for release will cover discharges for the first and second quarter of 1999. The Council will initially release six months of data in order to provide a more reliable body of data for analysis and decision-making and to make available public use data files on a quarterly schedule thereafter.]

(f) (No change.)

(g) The department [**executive director**] shall establish procedures for screening all requests to assure that filling the request will not violate the provisions of Health and Safety Code, §108.013(c).

(h) The data elements specified for discharge reports in §421.9 [**§1301.19**] of this title (relating to Discharge Reports--Records, Data Fields and Codes) do not constitute "Provider Quality Data" as discussed in Health and Safety Code, §108.010.

(i) A public use data file which is specified by the requestor shall not be considered a "report issued by the department [**Council**]" as referenced in Health and Safety Code, §108.011(f).

(j) Requests for data files including data on one or more providers are matters of public record and copies of all requests shall be maintained by the department [**Council**] for two years from the date of receipt. The department [**executive director**] shall make available on the

department's [**Council's**] Internet site and publish in the department's [**Council's**] numbered letter for hospitals a summary of all requests received for public use data.

(k) With any public use data file prepared by the department [**Council**], the department [**executive director**] shall attach all comments submitted by providers, which relate to any data included in the file. The department [**Council**] shall also make these comments available at the department's [**Council's**] offices and on the department's [**Council's**] Internet site.

(l) A research data file may be released provided the following criteria are met:

(1) the department's Hospital Discharge Data [**Texas Health Care Information Council**] Research Data File Request Form is completed and submitted to the department [**Council's executive director**]; and

(2) the requestor has made payment according to the department's [**Council's**] fee schedule. The department's [**Council's**] fee includes a non-refundable "Review of Request Fee"; and

(3) the Institutional Review Board [**Scientific Review Panel**] reviews the research request and has determined the proposed research outcome can be achieved with the requested data; and

(4) the Institutional Review Board [**Council's Scientific Review Panel**] grants authorization to the request or restricts access to specified data elements determined to be inappropriate for the research proposal in accordance with §421.10 [**this subsection**] of this title (relating to Institutional Review Board [**Scientific Review Panel**]); and

(5) - (6) (No change.)

§421.9. Discharge Reports--Records, Data Fields and Codes.

(a) Hospitals that have not obtained an exemption letter authorized by §421.5 [**§1301.15**] of this title (relating to Exemptions from Filing Requirements) shall submit discharge reports, electronically in the file format for inpatient hospital bills defined by the American National Standards Institute (ANSI), commonly known as the ANSI ASC X12N form 837 Health Care Claims (ANSI 837 Institutional Guide) transaction for institutional claims and/or encounters. ANSI updates this format from time to time by issuing new versions.

(b) The department [**Council**] will make detailed specifications for these data elements available to submitters and to the public.

(c) In addition to the data elements contained in the ANSI 837 Institutional Guide, the department [**Council**] has defined the following data elements shown in this subsection and as defined the location in the ANSI 837 Institutional Guide where each element is to be reported. Data element content, format and locations may change as federal and state legislative

requirements change in regards to Public Law 104-191, Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended, is implemented.

(1) - (4) (No change.)

(d) Hospitals shall submit the required minimum data set for all patients for which a discharge claim is required by this title. The required minimum data set includes the following data elements as listed in this subsection:

(1) - (47) (No change.)

(48) Diagnosis Present On Admission.

(e) (No change.)

§421.10 Institutional Review Board [**Scientific Review Panel**]

(a) The department shall use [**Council establishes**] the Institutional Review Board [**Scientific Review Panel (Panel)**] for the purposes of:

(1) evaluating applications for various measures or variables that are found in the department's [**Council's**] hospital discharge data "research" file; and

(2) (No change.).

(b) The Institutional Review Board functions relating to §421.8(1) and this section are [**Scientific Review Panel is**] abolished at such time as the department [**Council**] ceases to maintain a hospital discharge data "research" file.

[(c) **The Council may establish the scientific review function through a contract with an existing institutional review board that meets federal guidelines or by appointing a separate review panel.**]

[(d) **Membership if scientific review panel is appointed.**]

[(1) **A person interested in membership on the Scientific Review Panel must submit an application, on a form specified by the Council, to the Executive Director of the Council.**]

[(2) **The Scientific Review Panel will consist of at least five members.**]

[(3) **The Council's Appointments Committee shall review all applications for membership and make recommendations to the Council. When making its recommendations, the Appointments Committee shall consider the qualification criteria in the Health and Safety Code, §108.0135 for each member and the restrictions on composition of committees in Government Code §2110.002.**]

[(4) The Council, at its, discretion, shall appoint persons to the Scientific Review Panel. Members shall have experience and expertise in ethics, patient confidentiality, and health care data.]

[(5) Members shall be appointed for three-year terms, except that for the initial appointees, the terms of one-third of the members shall be for three years, another one-third for two years, and the remaining members for one year. The Appointments Committee shall assign the initial term of each member or position so as to provide for a staggered system of terms.]

[(6) The Council may remove a member from the Scientific Review Panel if he or she is absent from three consecutive meetings. The Chair of the Scientific Review Panel may recommend the removal of a member for non-attendance to the Council's appointments committee, which shall review the matter and make a recommendation to the Council.]

[(7) If a vacancy on the Scientific Review Panel occurs, the Council shall appoint an individual to serve the unexpired portion of that term.]

[(8) The Chair of the Scientific Review Panel is designated by the Chair of the Council from current members of the Panel. This person shall serve in that capacity at the pleasure of the Council Chair.]

(c)[(e)] Meetings.

[(1) The Scientific Review Panel shall meet as necessary to conduct business, but in any case, at least once every three months if applications for all or part of the research file are pending.]

[(2) A simple majority of the members of the Scientific Review Panel shall constitute a quorum for the purpose of transacting business. All action of the Panel must be approved by majority vote. Each member shall have one vote and may not vote by proxy or in absentia.]

[(3)] Meetings of the Institutional Review Board [Panel or Subcommittees of the Panel**] shall be posted and conducted in accordance with the Texas Open Meetings [**Meets**] Act, Government Code, Chapter 551. All meetings of the Institutional Review Board [**Panel or any Subcommittee**] will be recorded.**

[(4) Minutes of all Panel and Subcommittee meetings shall be maintained by Council staff and shall include the names of members in attendance and a record of all formal actions and votes taken.]

[(5) Council staff shall provide administrative support for the Panel and any Subcommittees, including making of meeting arrangements. Each Panel or Subcommittee member shall be informed of a meeting at least ten calendar days prior to a meeting.]

[(6) The Panel and Subcommittees shall make decisions in the discharge of its duties without discrimination based on any person's race, creed, gender, religion, national origin, age, physical condition, or economic status.]

(d) **[(f)]** Decision-Making Guidelines.

(1) Requests should reasonably identify and justify the requested data elements. Requesters who have detailed information that would assist in justifying the records request are urged to provide such information in order to expedite the handling of the request. Envelopes in which written requests are submitted should be clearly identified as Open Records requests. Requests should include the fee or request determination of the fee.

(2) Fee structures for the public use data file and the research file shall be set by the department **[executive director, in consultation with the Council]**.

(3) Waiver or reduction of the fees charged for the public use data file or the research file may be made upon a determination by the department **[Executive Director]** when such waiver or reduction is in the department's **[Council's]** interest.

(4) All requests for data must be submitted in writing, either on the form provided by the department **[Council]** or on a similar form containing all of the same information. Denials of written requests will be in writing and will contain the reasons for the denial including, as appropriate, a statement that a document or data element requested is nonexistent or is not reasonably described, or is subject to one or more clearly described exemption(s). **[Denials will also provide the requester with appropriate information on how to exercise the right of appeal to the Council].**

[(5) In cases where there is an alleged conflict between the Texas Open Records Act and the Council's procedures, the Executive Director will refer the issue to the Office of the Attorney General.]

(5)**[(6)]** Only data elements requested by the requestor and approved for release by the Institutional Review Board **[Scientific Review Panel]**, shall be included in the research file for release to the requestor in accordance with this chapter.

(e) **[(g)]** Reports to the department **[Council]**. The Chair of the Institutional Review Board **[Scientific Review Panel]** shall file with the Program **[Executive]** Director **[of the Council]** a written report of all action taken relating to requests under this section at any meeting of the Institutional Review Board **[Panel]** or of a Subcommittee within 3 working days of such meeting, including a detailed list of how each participating member voted.