SUBCHAPTER A. GENERAL PROVISIONS
28 TAC §§12.1, 12.2, 12.4, 12.5, and 12.6

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28 TAC §§12.101 - 12.106, 12.108, and 12.110

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SUBCHAPTER F. RANDOM ASSIGNMENT OF INDEPENDENT REVIEW ORGANIZATIONS
28 TAC §12.501 and §12.502

1. INTRODUCTION. The Texas Department of Insurance (Department) proposes amendments to §§12.1, 12.2, 12.4, 12.5, 12.101 - 12.106, 12.108, 12.201, 12.202, 12.204 - 12.208, 12.301, 12.302, 12.402 - 12.406, 12.501 and 12.502, and new §§12.6, 12.110, and 12.303, concerning independent review organizations (IROs). These amendments and new sections are necessary to: (i) implement House Bill (HB) 4519, 81st Legislature, Regular Session, effective September 1, 2009, which establishes requirements for the Commissioner of Insurance (Commissioner) to adopt new requirements and restrictions applicable to IROs; (ii) implement HB 4290, 81st Legislature, Regular Session, effective September 1, 2009, which effectively revises the definition of “adverse determination” in the Insurance Code Chapter 4201 to include retrospective reviews and determinations regarding the experimental or investigational nature of a service; and (iii) make other changes deemed necessary by the Department

to improve and clarify the IRO rules and effectively enforce the Insurance Code Chapter 4202.

HB 4519

The Insurance Code §4202.002, relating to Adoption of Standards for Independent Review Organizations, mandates that the Commissioner adopt standards and rules for the certification, selection, and operation of IROs to perform independent review described by the Insurance Code Chapter 4201, Subchapter I, and the suspension and revocation of the certification of registration issued to IROs. The Insurance Code §4202.002(b) specifies what must be ensured by standards adopted under the Insurance Code §4202.002, and the standards required by the Insurance Code §4202.002(b) have previously been adopted into rule. However, HB 4519 amends the Insurance Code §4202.002 by adding new subsection (c), which specifies that in addition to the standards adopted under the Insurance Code §4202.002(b), the Commissioner shall adopt standards and rules that prohibit: (i) more than one IRO from operating out of the same office or other facility; (ii) an individual or entity from owning more than one IRO; (iii) an individual from owning stock in or serving on the board of more than one IRO; (iv) an individual who has served on the board of an IRO whose certification was revoked for cause from serving on the board of another IRO before the fifth anniversary of the date on which the revocation occurred; (v) an attorney who is, or has in the past served as, the registered agent for an IRO from representing the IRO in legal proceedings; and (vi) an IRO from disclosing confidential patient information, except to a provider who is under contract to perform the review.

Additionally, the Insurance Code §4202.002(c) states that the Commissioner shall adopt standards and rules that require: (i) an IRO to be based and certified in this state and to locate the organization's primary offices in this state; (ii) an IRO to voluntarily surrender the organization's certification while the organization is under investigation or as part of an agreed order; and (iii) an IRO to apply for and receive a new certification after the organization is sold to a new owner. A proposed amendment to §12.5 adds a new, redesignated paragraph (27) to define the term “primary office” to clarify how an IRO may comply with the requirement in the Insurance Code §4202.002(c)(2)(A) mandating location of the IRO’s primary offices in this state. A proposed amendment to §12.103 adds paragraph (10) to require an applicant for an initial or a renewal certificate of registration to submit as part of the application process evidence that the applicant is based in this state. The proposed amendment also provides that an IRO must be based in this state and locate its primary office in this state and is similarly necessary to implement the requirement in the Insurance Code §4202.002(c)(2)(A) mandating location of the IRO’s primary offices in this state. Proposed new §12.110 is necessary to implement the requirement in the Insurance Code §4202.002(c)(2)(C) mandating the Commissioner to adopt standards and rules that require an IRO to apply for and receive a new certification after the organization is sold to a new owner. The proposed new section is also necessary to ensure that the Department obtains reasonable notice of pending sales and to clarify the effect of the pending sale upon: (i) the IRO’s obligations concerning previous and pending independent reviews; and (ii) the random assignment of independent reviews in the 45 days prior to the date that the sale is

finalized. Proposed amendments to §12.204 are necessary to: (i) revise the section title to more accurately reflect the new content of the section; and (ii) specifically implement the prohibitions mandated in the Insurance Code §4202.002(c)(1)(A) – (E) concerning prohibited activities and relationships of IROs and individuals or entities associated with IROs by adding new subsections (c) – (h). Proposed amendments to §12.208(b) and (f) are necessary to implement the prohibition mandated in the Insurance Code §4202.002(c)(1)(F) concerning the prohibited disclosure of confidential patient information. Proposed new §12.303 is necessary to implement the requirement in the Insurance Code §4202.002(c)(2)(B) mandating the Commissioner to adopt standards and rules that require an IRO to voluntarily surrender its certificate of registration while the IRO is under investigation or as part of an agreed order. Proposed new §12.303 is also necessary to define the term “investigation” for purposes of the section, to clarify the effect of the voluntary surrender upon the random assignment process, and to clarify the continuing requirements concerning maintenance and confidentiality of information generated and obtained by the IRO in the course of its operations. The proposed amendment to §12.502(e), related to the random assignment of independent reviews to IROs, is also necessary to revise the subsection for clarity.

Additionally, a proposed applicability date of October 16, 2010, is included in §12.4(b) to give IROs time to come into compliance with the rules adopted to implement HB 4519 and to give IROs that either are not able to come into compliance with the requirements or choose to not come into compliance with the requirements and

prohibitions adopted pursuant to HB 4519 time to complete the last reviews assigned to them under the current rules.

HB 4290

The Senate Committee on State Affairs Bill Analysis for HB 4290 specifies the legislative intent of HB 4290:

"Texas consumers with managed care health plans regulated by the [Department]…currently are entitled to an independent review of their carriers' decisions to deny a preauthorization of treatment based on a carrier's decision that the treatment is not medically necessary, but current law does not require an independent review of a carrier's conclusion that treatment should be denied because it is experimental or investigational. In addition, current law does not provide for an independent review of a carrier's conclusion after the fact that a treatment was not medically necessary. Health plans may deny a requested service for the reason that the plan deems it to be experimental or investigational, and the provider or claimant does not have access to an administrative process to seek review both prospectively and retroactively through a process coordinated by TDI. A study by a national association of health plans found that a majority of states currently have independent review programs that cover either all adverse determinations or all adverse determinations involving medical necessity or services deemed to be experimental. Texas is the only state with limitations on retrospective reviews of denials based on medical necessity and the only state with an independent review law that does not extend to retrospective reviews of at least emergency and urgent care. TDI has received numerous complaints regarding these

issues, but there is little TDI can do to address them. Carriers have varying standards for what is considered experimental and investigational and, in regard to retrospective reviews, TDI's data regarding workers' compensation claim denials show that carriers incorrectly issue retrospective denials more often than prospective denials, with retrospective medical necessity decisions, including experimental and investigational denials, overturned 68% of the time after an independent review is conducted, while prospective medical necessity decisions are overturned approximately 30% of the time. C.S.H.B. 4290 amends current law relating to retrospective utilization review and utilization review to determine the experimental or investigational nature of a health care service." TEXAS SENATE STATE AFFAIRS COMMITTEE, BILL ANALYSIS (Committee Report, Substituted), C.S.H.B. 4290, 81st Leg., R.S. (May 12, 2009).

The Insurance Code §4201.002(1) provides the definition for "adverse determination" as used in the Insurance Code Chapter 4201. Although the Insurance Code §4201.002(1) defined "adverse determination" prior to the enactment of HB 4290 to mean a utilization review agent's determination that health care services "provided" or proposed to be provided to a patient are not medically necessary or appropriate, the provision was not interpreted to include retrospective review of medical necessity. This interpretation was based upon the Insurance Code §4201.002(13) definition of "utilization review" as a system for "prospective or concurrent" review of the medical necessity and appropriateness of health care services being provided or proposed to be provided to an individual in this state; the definition arguably did not include retrospective review. HB 4290 addresses applicability of independent review on a

retrospective basis by amending the definition of “utilization review” to specifically include retrospective review of the medical necessity and appropriateness of health care services. HB 4290 further amends the term to include a system for prospective, concurrent, or retrospective review to determine the experimental or investigational nature of health care services. The Insurance Code §4201.002 provides that the definitions in that section apply to Chapter 4201; however, pursuant to the Insurance Code §4202.002, the standards and rules adopted under that section relate to the certification, selection, and operation of IROs that perform independent review described by the Insurance Code Chapter 4201. Therefore, the definitions in the Insurance Code Chapter 4201 are relevant to the activities regulated by the Insurance Code Chapter 4202. Sections that had previously been adopted pursuant to the Insurance Code §4202.002 make reference to adverse determinations made under the Insurance Code Chapter 4201 and utilize the language used to define the term “adverse determination” in the Insurance Code Chapter 4201. Amendments proposed in §12.5(1), (16), and (30), concerning the definitions of “adverse determination,” “independent review,” and “review criteria” respectively, are necessary to revise rule text which references or uses the definition of “adverse determination” to accurately reflect the use of that term as revised by HB 4290. An amendment to proposed §12.103(1) adds subparagraph (B) to require an applicant for an initial or renewal certificate of registration to submit as part of the application process a summary of its independent review plan that includes a summary description of review criteria and review procedures to be used to determine the experimental or investigational nature of health

care. This amendment further implements the statutory expansion of adverse determinations to include determinations concerning the experimental or investigational nature of health care as provided in the Insurance Code §4201.002(1).

Other necessary amendments

In addition to the need to implement HB 4519 and HB 4290, the Department has determined that other amendments are necessary to effectively enforce the Insurance Code Chapter 4202. These other necessary proposed amendments are described in the following paragraphs.

First, the Insurance Code §4202.002(a) requires the Commissioner to adopt "standards and rules for. . . the certification, selection, and operation of independent review organizations." To implement these requirements, current rules at §§12.101 - 12.109 require a certified IRO to annually submit an application for renewal of certificate of registration. If the application for renewal of certificate of registration is not submitted, the IRO will lose its certification. Additionally, current rules at §12.502 establish a process of random assignment of independent reviews to IROs. However, the current process establishing random assignment of independent reviews can result in an independent review being assigned to an IRO that needs to complete its annual renewal of certificate of registration, and the current rules do not address what should be done if the IRO is assigned an independent review but then fails to have its certificate of registration renewed before it completes the assigned review. To address this issue, amendments are proposed in §12.108(c) and §12.502(f)(2) that preclude assignment of an independent review to an IRO within the 30 days before the IRO is required to

submit its application for the annual renewal of the certificate of registration unless and until the Department receives the IRO's completed application and the application fee.

Second, a memorandum of understanding between the Department Enforcement Division (Enforcement) and the Texas Department of Insurance Division of Workers' Compensation (TDI-DWC) has been executed to formally establish the roles and responsibilities of Enforcement and TDI-DWC as they relate to particular enforcement functions subject to the authority and responsibility of the Commissioner of Workers' Compensation, and the Department and TDI-DWC specifically continue to coordinate oversight and enforcement activities in Texas. To facilitate the TDI Enforcement Division's handling of such matters, it is necessary to revise §12.302 to address the actions the Commissioner of Insurance or designees of the Commissioner may take in regard to the Labor Code.

Third, as noted previously, the Insurance Code §4202.002(a) requires the Commissioner to adopt "standards and rules for. . . the certification, selection, and operation of independent review organizations." To implement these requirements, the Commissioner requires each IRO to develop an independent review plan that includes the criteria used by the IRO as a tool in its review process. Current rules use the term "screening criteria" to describe the criteria used in the IRO's review process. However, the term "screening criteria" is more appropriately applied to the utilization review process rather than the independent review process, while the term "review criteria" is more reflective of the independent review process. Therefore, the Department proposes amendments to replace the term "screening criteria" with "review criteria"

throughout Chapter 12. Specifically, the proposed amendments to reflect this more accurate terminology appear in proposed §§12.5(18) and (30), 12.103(1), 12.108, and 12.201(3). In addition, the Department proposes new and updated definitions in §12.5 and proposes amendments to §12.201 in order to provide more guidance in regard to what an IRO must take into consideration in preparing an independent review plan. Specifically, the Department proposes an amendment to update the term “medical and scientific evidence,” and proposes as a new defined term “evidence-based standards.” These terms are necessary to describe the basis for IRO review criteria required by §12.201. The amendment to the definition of “medical and scientific evidence” in §12.5(21) is also necessary to update reference sources and citations and to expand permitted bases of medical and scientific evidence as appropriate throughout the definition. The Department also proposes as new defined terms in §12.5 “best evidence,” “case-control studies,” “case series,” “cohort studies,” “evidence-based medicine,” “evidence-based standards,” “expert opinion,” and “randomized clinical trial.” It is necessary to define these terms because: (i) the term “evidence-based standards” is used in a proposed amendment in §12.201 in order to clarify what an IRO must take into consideration in developing review criteria; (ii) the terms “evidence-based medicine” and “best evidence” are used in defining “evidence-based standards;” and (iii) the remaining terms are used within the definition of “best evidence.” A proposed amendment in §12.201(3)(A) requires an IRO’s independent review plan to include the required use of written, medically acceptable review criteria that are, among other existing requirements, based upon medical and scientific evidence and utilize evidence-

based standards. Collectively, these proposed amendments to §12.5 and 12.201 provide for a more transparent framework for the independent review process while providing additional guidance to IROs about the necessary content of an independent review plan.

Fourth, six terms that are currently defined in §12.5 are not actually used within Chapter 12. These terms are “act,” “active practice,” “administrator,” “dental plan,” “emergency care,” and “open records law.” Because these terms are not used within the chapter, it is unnecessary that they be defined. For this reason, these terms are proposed to be deleted.

Fifth, the Labor Code §413.031(d) provides, in part, that “[a] review of the medical necessity of a health care service requiring preauthorization under Section 413.014 or commissioner rules under that section or Section 413.011(g) shall be conducted by an [IRO] under Chapter 4202, Insurance Code, in the same manner as reviews of utilization review decisions by health maintenance organizations.” The Labor Code §413.031(d) has been implemented by the DWC in rules located in 28 TAC Chapter 133, Subchapter D (relating to Dispute of Medical Bills). However, to bring Chapter 12 into accord with the Labor Code §413.031(d) and 28 TAC Chapter 133, references to address the applicability of and required compliance with applicable law concerning workers’ compensation insurance carriers and certified workers’ compensation health care networks are proposed to be added in: (i) §12.4(a), concerning applicability; (ii) §12.5(21), (24), and (31), respectively, defining the terms “medical and scientific evidence,” “payor,” and “TDI-DWC”; and (iii) 12.502(a),

concerning random assignment of independent reviews. These proposed amendments include additional terminology as required to clarify applicability in the context of independent review of health care services provided pursuant to the Labor Code Title 5. Additionally, an amendment is proposed in redesignated §12.201(3)(D) to address the development of review criteria used to review health care delivered pursuant to the Labor Code Title 5. New §12.202(f) is proposed to incorporate references to licensing and professional specialty requirements of personnel who perform independent review of health care services provided under the Labor Code Title 5 or the Insurance Code Chapter 1305. This proposed new subsection requires compliance with these additional licensing and specialty requirements for performance of such independent review, provides a more comprehensive regulatory framework, and makes it easier for IROs to identify applicable requirements.

Sixth, 28 TAC §1.503 and §1.504 (relating to Application of Fingerprint Requirement and Fingerprint Requirement, respectively) require an individual who is required to provide biographical information and has similar responsibilities to principals; partners; officers; directors; or controlling shareholders, including limited liability company members and managers, of entities that are applicants for a certification under the Insurance Code Chapter 4202, to submit a complete set of fingerprints at or near the same time that the individual submits the required biographical information. For accordance with these sections, a proposed amendment to §12.103(9)(A) adds the requirement for submission of fingerprints in compliance with §1.503 and §1.504.

Seventh, as previously noted, the Insurance Code §4202.002(a) requires the Commissioner to adopt "standards and rules for. . . the certification, selection, and operation of independent review organizations." In establishing standards for the operation of IROs, the current §12.207 addresses accessibility of IROs by telephone. However, §12.207 only addresses utilization review agent access to IROs by telephone and does not establish accessibility provisions regarding other persons or entities. At times, this has resulted in parties other than utilization review agents not being able to contact IROs or not having their telephone calls returned by IROs in a timely manner. To address this issue, amendments are proposed to §12.207(a) to require IROs to be generally available by telephone.

Eighth, the Insurance Code §4202.006 provides: "The commissioner shall charge payors fees in accordance with this chapter as necessary to fund the operations of independent review organizations." Pursuant to this provision, the current §12.403 addresses fee amounts for independent review. However, at times independent review notification of decisions issued by IROs are incomplete, and it is necessary for the IRO to issue a revised notification of decision. Such revised decision notifications are not specifically addressed by §12.403, thus it is necessary to amend the section. A proposed amendment to §12.403 adds subsection (b) to establish that: (i) the expense of preparing an amended notification of decision is included in the IRO fee if the Department determines the initial notification of decision is incomplete; and (ii) the amended notification of decision is required to be filed with the Department no later than

five working days from the IRO's receipt of notice from the Department that the initial notification of decision is incomplete.

Ninth, a proposed amendment to §12.301 is necessary to conform the rule addressing the IRO complaint process to current Department procedures for addressing complaints and to provide sufficient flexibility for Department action as necessary to protect confidential information as required by law.

Tenth, an amendment is proposed to §12.404 to delete an unnecessary requirement in existing subsection (c) for an IRO to send a copy of the bill to TDI each time it bills for a review.

Finally, amendments are proposed throughout the rule text to: (i) correct typographical, grammatical, and punctuation errors in the current rule text, (ii) make changes to conform rule text to current Department drafting style, (iii) update statutory citations to conform with the non-substantive revisions to the Insurance Code, and (iv) non-substantively simplify and clarify provisions in Chapter 12.

Included in the following paragraphs is a detailed, section-by-section description of all the proposed amendments necessary to implement HB 4519 and HB 4290 and to make the other changes the Department has determined are necessary to effectively enforce the Insurance Code Chapter 4202:

Section 12.1 addresses **Statutory Basis**. The proposed amendment to §12.1 is necessary to change a statutory citation from "Texas Insurance Code, Article 21.58C" to "the Insurance Code Chapter 4202 as of September 1, 2009" to conform with non-substantive revisions to the Insurance Code.

Section 12.2 addresses **Severability Clause**. The proposed amendment to §12.2 makes changes to conform rule text to current Department drafting style.

Section 12.4 addresses **Applicability**. One proposed amendment to §12.4 is necessary to address applicability of Chapter 12 to workers' compensation health care networks and workers' compensation insurance carriers. This proposed amendment better reflects the scope of applicability of Chapter 12 in conformity with the Insurance Code §1305.355 and §4201.054. Section 1305.355, concerning workers' compensation health care networks, requires a utilization review agent to permit an employee or person acting on behalf of an employee and the employee's requesting provider whose reconsideration of an adverse determination is denied to seek review of that determination by an IRO assigned in accordance with Chapter 4202 and Commissioner rules. Section 4201.054 mandates that Chapter 4201 applies to utilization review of a health care service provided to a person eligible for workers' compensation medical benefits under Title 5, Labor Code, and further provides that the Commissioner of Workers' Compensation may adopt rules as necessary to implement the section. Title 28 Texas Administrative Code §133.308(b), one of the TDI-DWC rules implementing this requirement, provides that each IRO performing independent review of health care provided under the section is required to be certified pursuant to the Insurance Code Chapter 4202. Additionally, proposed amendments in §12.4 are necessary to divide the section into two subsections in order to address both general applicability and applicability to particular requests for independent review and to provide an applicability date for the rules as amended.

Section 12.5 addresses **Definitions**. The proposed amendments to delete existing §12.5(1), (2), and (3) are necessary because the terms defined in the paragraphs ("act," "active practice," and "administrator") are not used within Chapter 12 and are thus unnecessary as defined terms. Additional proposed amendments are necessary to redesignate the remaining paragraphs in the section both as a result of the deletion of §12.5(1) - (3) and due to other deletions and insertions that follow within the section. Proposed amendments to redesignated §12.5(1) are necessary to revise the definition for the term "adverse determination" to be consistent with the definition for the term as it is defined and used Chapter 19, Subchapter R of this title, the rules regulating utilization review agents, as well as for consistency with the definition of utilization review in the Insurance Code Chapter 4201 as amended and clarified by HB 4290. Section 12.5(5) is proposed to be redesignated as §12.5(2) due to the deletion of existing definitions. Proposed new §12.5(3) is necessary to define the term "best evidence" because it is used in the definition of the proposed term "evidence-based standards." Proposed new §12.5(4), (5), and (6) are necessary to define the terms "case-control studies," "case-series," and "cohort studies" because they are used in the definition of the proposed term "best evidence." Current §12.5(6) and (7) are proposed to be redesignated as §12.5(7) and (8). A proposed amendment is necessary to delete the current §12.5(8) because "dental plan," the term defined in the paragraph, is not used within Chapter 12 and is thus unnecessary as a defined term. The proposed amendment that adds new §12.5(10) is necessary to define the term "evidence-based medicine" because it is used to define the term "evidence-based standards." The

proposed amendment that adds new §12.5(11) is necessary to define the term "evidence-based standards." This term is necessary to define because it is used in a proposed amendment in §12.201(3)(A) in order to clarify what an IRO must take into consideration in developing review criteria. A proposed amendment is necessary to delete current §12.5(10) because "emergency care," the term defined in the paragraph, is not used within Chapter 12 and is thus unnecessary as a defined term. Proposed new §12.5(12) is necessary to define the term "expert opinion" because it is used in the definition of the proposed term "best evidence." Current §12.5(11) is proposed to be redesignated as §12.5(13). A proposed amendment to redesignated §12.5(14) is necessary to insert the words "or provider" to clarify that the term is occasionally used in lieu of the term "health care provider" within Chapter 12. Additional proposed amendments to redesignated §12.5(14) are made to conform rule text to current Department drafting style and improve clarity. The first proposed amendment to redesignated §12.5(15) is necessary to revise the definition for the term "health insurance policy" to be consistent with the definition for the term in the Insurance Code Chapter 4201.002(6), which defines the term in the context of utilization review as regulated under Chapter 4201. The second proposed amendment to redesignated §12.5(15) is necessary to revise a statutory citation from "the Insurance Code Chapter 20" to "the Insurance Code Chapter 842" to conform with the non-substantive revisions to the Insurance Code. The proposed amendment to redesignated §12.5(16) is necessary to revise the definition of the term "independent review" for consistency with the definition of utilization review in the Insurance Code §4201.002(13) as amended by

HB 4290. The first proposed amendment to redesignated §12.5(17) is necessary to insert the words “or IRO” to clarify that the term is occasionally used in lieu of the term “independent review organization” within Chapter 12. The second proposed amendment to redesignated §12.5(17) is necessary to revise a statutory citation from “Act” to “Insurance Code Chapter 4202” to conform with the non-substantive revisions to the Insurance Code. The third proposed amendment to redesignated §12.5(17) is necessary to change the word “title” to “chapter” in order to more accurately identify the location of the referenced section. The fourth proposed amendment to redesignated §12.5(17) is necessary to correct the citation to the section title of §12.402. The proposed amendment to redesignated §12.5(18) is necessary to change the term “screening criteria” to “review criteria” in order to more accurately reflect the role of independent review as a review of a utilization review determination. Proposed new §12.5(19) is necessary to add a definition for "legal holiday" because the term is used in a proposed amendment to redesignated §12.5(33), which defines “working day” and establishes a definition for the term that is consistent with TDI-DWC practices as provided in §102.3(b) of this title. Current §12.5(17) is proposed to be redesignated as §12.5(20). The proposed amendment to redesignated §12.5(21) is necessary to update the term “medical and scientific evidence” to update current sources of medical and scientific evidence and citations and to expand permitted bases of medical and scientific evidence as appropriate throughout the definition. As proposed, much of the term “medical and scientific evidence” is modeled on the term used by the National Association of Insurance Commissioners (NAIC) in its Uniform Health Carrier External

Review Model Act. A proposed amendment is necessary to delete the current §12.5(20) because “open records law,” the term defined in the paragraph, is not used within Chapter 12 and is thus unnecessary as a defined term. The proposed amendment to redesignated §12.5(22) is necessary to revise the definition for the term “nurse” for increased consistency with the definition for the term in Chapter 19, Subchapter R of this title, which provides rules regulating utilization review agents. The proposed amendment to redesignated §12.5(23) is necessary to revise the definition for the term “patient” to clarify applicability of the term with respect to persons entitled to receive workers’ compensation benefits pursuant to the Labor Code, Title 5. The proposed amendment to §12.5(24) is necessary to revise the definition for the term “payor” to clarify the applicability of the term with respect to persons or entities that provide, offer to provide, or administer workers’ compensation benefits as provided under the Insurance Code §4201.054. Current §12.5(23) and (24) are proposed to be redesignated as §12.5(25) and (26). The proposed amendment that adds new §12.5(27) is necessary to define the term “primary office” because the term is used in Chapter 12 in the implementation of HB 4519. The proposed amendment in redesignated §12.5(28), which defines “provider of record,” is necessary for consistency with current TDI rule drafting style. Proposed new §12.5(29) is necessary to define the term “randomized clinical trial” because it is used in the definition of the proposed term “evidence-based standards.” One proposed amendment to redesignated §12.5(30) is necessary to change the term “screening criteria” to “review criteria” in order to more accurately reflect the role of independent review as a review of a utilization review

determination. A second proposed amendment to redesignated §12.5(30) is necessary for consistency with the definition of "utilization review" in the Insurance Code §4201.002(13) as amended by HB 4290. Proposed new §12.5(31) adds the new defined term "TDI-DWC." This proposed amendment is necessary to introduce an abbreviated term for the Texas Department of Insurance, Division of Workers' Compensation which can be used throughout the chapter. The proposed amendment to redesignated §12.5(32) is necessary to update a statutory citation from "the Insurance Code, Article 21.58A" to "the Insurance Code Chapter 4201" to conform with a non-substantive revision to the Insurance Code. The proposed amendment to redesignated §12.5(33) establishes a definition for the term "working day" that is consistent with TDI-DWC practices as provided in §102.3(b) of this title.

Proposed new §12.6 addresses **Independent Review of Adverse Determinations of Health Care Provided Pursuant to the Labor Code Title 5 or the Insurance Code Chapter 1305**. Proposed new §12.6 is necessary to address situations where existing rules or proposed amendments to Chapter 12 conflict with the Labor Code or TDI-DWC rules when applied to independent review of adverse determinations of health care provided pursuant to the Labor Code Title 5 or the Insurance Code Chapter 1305. Pursuant to proposed new §12.6, and in accordance with the Insurance Code §4201.054, the Labor Code or TDI-DWC rules control in such an instance.

Section 12.101 addresses **Where to File Application**. One proposed amendment to §12.101 is necessary to insert a uniform term to address the certificate

that an IRO can apply for pursuant to Chapter 12. A second proposed amendment to §12.101 provides the correct mailing address to file an application for a certificate of registration as an IRO with the Department. A third proposed amendment clarifies that the section also applies to filing for renewal of the certificate of registration.

Section 12.102 addresses **Application and Renewal of Certification of Registration Form; How to Obtain Forms**. One proposed amendment to §12.102 amends the section title to better reflect the content of the section. Additional amendments are necessary to establish a uniform form and attachments for purposes of applying for both initial and renewal certificates of certification. New proposed subsection (a) is necessary to update the section to adopt by reference Form No. LHL006, the IRO Application Form for this purpose. Proposed new subsection (b) is necessary to update the section by adopting by reference Form No. FIN311, the Biographical Affidavit. IROs are required to use this form as an attachment to Form No. LHL006 (IRO Application Form). This amendment establishes the standardized form for submitting biographical information as required pursuant to the Insurance Code §4202.004(4). The amendment to redesignated §12.102(c) is necessary to provide the correct mailing address from which an applicant can obtain a form for application for a certificate of registration as an IRO.

Section 12.103 addresses **Information Required**. A proposed amendment to §12.103 amends the section title to better reflect the section content. A second proposed amendment to §12.103 amends the section to reflect that in order that the Commissioner may properly determine whether an applicant is qualified to be certified

as an IRO, the IRO must submit the information required in Form No. LHL006, including each of the data elements specified in the section. Section 12.103 also includes changes throughout for purposes of correcting grammar and conforming text to agency drafting style. A proposed amendment to §12.103(1) is necessary to change the word "title" to "chapter" in order to more accurately identify the location of the referenced section. Another proposed amendment to §12.103(1) is necessary to change "which" to "that" to correct a grammatical error. The proposed amendment to §12.103(1)(A) is necessary to change the term "screening criteria" to "review criteria" in order to more accurately reflect the role of independent review as a review of a utilization review determination. A proposed amendment adds new §12.103(1)(B) and redesignates the subparagraphs that follow it in order to address the revised definition of "utilization review" in the Insurance Code §4201.002(13) made by HB 4290 that incorporates determinations regarding the experimental or investigational nature of health care into the term. One proposed amendment to redesignated §12.103(1)(C) is necessary to change the term "screening criteria" to "review criteria" in order to more accurately reflect the role of independent review as a review of a utilization review determination. The second proposed amendment to redesignated §12.103(1)(C) is necessary to correct an internal reference by changing the word "title" to "chapter" and by deleting an unnecessary reference to a section heading. Proposed amendments to redesignated §12.103(1)(D), (2), (4), and (5) are necessary to correct internal references by changing the word "title" to "chapter." A proposed amendment to §12.103(3) is necessary to update a statutory citation from "the Act" to "Insurance Code Chapter 4202" to conform

with the non-substantive revisions to the Insurance Code. Another proposed amendment to §12.103(5) is necessary to provide the correct citation to the heading of another section. The proposed amendment to §12.103(6)(B) is necessary to revise a reference to percentage for consistency with current Department rule drafting style. The proposed amendment to §12.103(6)(D) is necessary to clarify that the chart the subparagraph requires to be submitted must show contractual arrangements of the applicant. The proposed amendment to §12.103(9) is necessary to provide guidance concerning the information required for submission with Form No. FIN311 (Biographical Affidavit). One proposed amendment to §12.103(9)(A) is necessary to correctly address the fact that the provision applies to an “applicant.” The second proposed amendment to §12.103(9)(A) is necessary to add a requirement for submission of fingerprints in compliance with §1.503 and §1.504 to more comprehensively reflect the application requirements. The third proposed amendment to §12.103(9)(A) is necessary to revise a reference to percentage for consistency with current Department rule drafting style. A last proposed amendment to §12.103(9)(A) changes the term “person” to “individual” to clarify whose total annual revenue, holdings, or investments are referenced in the subparagraph. A proposed amendment to §12.103(9)(A)(vii) is necessary to delete the word “or” so an additional entity can be added to the list for which an applicant must submit information in compliance with the subparagraph. Proposed new §12.103(9)(A)(viii) is necessary to add "independent review organization" to the list of entities for which an applicant must submit information required pursuant to §12.103(9)(A), and existing §12.103(9)(A)(viii) is redesignated as a result of this change

to proposed §12.103(9)(A)(ix). One amendment to §12.103(9)(B) is necessary to clarify that it is the applicant that must identify any relationship between the applicant and any affiliate or other organization in which an officer, director, or employee of the applicant holds a five percent or more interest. The second proposed amendment to §12.103(9)(B) is necessary to revise a reference to percentage for consistency with current Department rule drafting style. The proposed amendment to §12.103(9)(C) is necessary to clarify that it is the applicant that must submit a list of any currently outstanding loans or contracts to provide services between the applicant and any affiliates. The proposed amendment to §12.103(10) requires an applicant to submit evidence that the applicant is based in this state and that its primary office is located in this state and provides that these requirements are conditions of certification. These amendments to §12.103(10) are necessary to implement this requirement pursuant to HB 4519. A proposed amendment to §12.103(11) is necessary to add the word “and” for consistency with current Department drafting style and to correct grammar. A proposed amendment adds new §12.103(12). This new paragraph is necessary to require an applicant to disclose any enforcement actions related to the provision of medical care or conducting of medical reviews taken against a person subject to the fingerprint requirements under §1.503 and §1.504 of this title in order to assist the Department in assessing the qualifications of the applicant to conduct independent reviews.

Section 12.104 addresses **Review of Application**. The amendments to §12.104(1) and (4) are necessary to clarify the application review process that occurs

after an applicant submits its application for a certificate of registration. The amendments to §12.104(3) are necessary to correct an erroneous reference to the section by revising the phrase “this subsection” to state “this section.” An additional amendment to §12.104(3) is necessary to changed “described” to “specified” to reflect drafting style.

Section 12.105 addresses **Revisions During Review Process**. The proposed amendment to §12.105(a) is necessary to provide the correct mailing address to which revisions during the review of the application must be addressed and to delete language concerning the submission of documents that is no longer necessary due to clarifications in subsequent subsections. The proposed amendment to §12.105(b) is necessary to clarify the scope of the requirement for an applicant to submit one original and one copy of revised pages by limiting the requirement to those revised pages required by the Department under the subchapter. The proposed amendment to §12.105(c) is necessary to clarify that all copies of the revised page submitted by the applicant must contain the changed item or information “red-lined” or otherwise clearly designated and that the original revised page in an application shall be placed in the IRO’s charter file maintained by the Department. The proposed amendment to §12.105(d) is necessary to clarify which specific sections in Chapter 12 are referenced by the subsection. The collective amendments proposed throughout §12.105 are necessary to make the section more reader-friendly.

Section 12.106 addresses **Qualifying Examinations**. One proposed amendment to §12.106 is necessary to change the phrase “his or her” to “the

commissioner's" to comply with current Department rule drafting style. The second proposed amendment to §12.106 is necessary to clarify that an on-site qualifying examination may be conducted as a requirement of a renewal of certification as an IRO. The third proposed amendment to §12.106 is necessary to clarify that documents that support the application or renewal of the certificate of registration must be available for inspection. The fourth proposed amendment to §12.106 is necessary to replace the term "administrative offices" with the term "primary office" for consistency within the chapter and in order to implement HB 4519.

Section 12.108 addresses **Renewal of Certificate of Registration**. Proposed amendments to §12.108(b) are necessary to clarify that Form No. LHL006 (IRO Application for Certificate of Registration), proposed for adoption by the Commissioner in §12.102 of this subchapter, is the form that the IRO must use to apply for renewal of its certificate of registration. Amendments to §12.108(b) are also proposed to clarify that the form is available on the Department website and to provide more accurate references in the subsection. Proposed amendments to §12.108(b), (c), and (d) are necessary to change the term "screening criteria" to "review criteria" in order to more accurately reflect the role of independent review as a review of a utilization review determination. A second proposed amendment to §12.108(c) is necessary to add a provision that independent reviews will not be assigned to an IRO during the 30 days prior to the anniversary date of the issuance of the IRO's certificate of registration unless the completed renewal application form and application fee have been received by the Department in order to reduce the risk that independent reviews will be assigned

to an IRO that does not renew its application for renewal of certification. A second proposed amendment to §12.108(d) is necessary to clarify that the form referenced by the subsection is a renewal application form. The proposed amendment to §12.108(e) is necessary to update the reference to the application form referenced in the subsection. A proposed amendment adds new §12.108(h). This subsection is necessary to provide additional clarification concerning an IRO's obligations to continue to perform its duties pursuant to the Insurance Code Chapter 4202, the Labor Code Title 5, and applicable Department and TDI-DWC rules "Until the certificate of registration renewal application process is complete or the certificate of registration expires…".

Proposed new §12.110 addresses **Effect of Sale of an Independent Review Organization**. The purpose of this proposed new section is to implement HB 4519. Proposed new §12.110(a) is necessary to provide that an IRO's certificate is non-transferable, and an IRO must surrender its certificate upon sale of the IRO. Proposed new §12.110(b) is necessary to provide that an IRO that has been sold to a new owner must apply for and receive a new certificate pursuant to this subchapter before it can operate as an IRO. Proposed new §12.110(c) is necessary to require an IRO to notify the Department of an impending sale no later than 90 days prior to the date the sale will occur. The purpose of this subsection is to provide ample notice to the Department of the impending date of sale of an IRO so that the Department can ensure that all assigned independent reviews are completed before the date of the sale and that no new independent reviews are assigned at a point when the IRO is not certified, due to

the need to recertify following the sale. Proposed new subsection (c) also: (i) clarifies that the requirement to notify the Department of an impending sale is required to include the anticipated date on which the sale will be finalized and to provide a revised notification of impending sale if such date changes; and (ii) provides an address for filing the notification. Proposed new §12.110(d) is necessary to provide notice to an IRO that notification of an impending sale does not negate the IRO's continuing obligation to perform its duties pursuant to the Insurance Code Chapter 4202, the Labor Code, and Department and TDI-DWC rules. Proposed new §12.110(e) is necessary to establish that upon the sale of an IRO, the new owner is prohibited from performing the duties of an IRO prior to certification pursuant to the new ownership.

Section 12.201 addresses **Independent Review Plan**. The proposed amendment to §12.201 conforms rule text with current Department drafting style and for clarity. Proposed §12.201 provides that independent review shall be conducted in accordance with an independent review plan that is consistent with standards developed with input from appropriate health care providers and reviewed and approved by a physician. A proposed amendment to §12.201(2)(A) changes the words "addressed in" to "in accordance with" for compliance with the Department's current rule drafting style. Proposed amendments to §12.201(2)(A) and (D) changes "title" to "subchapter" in order to more accurately identify the location of the referenced section. An amendment is proposed to §12.201(2)(D) to reflect the correct title of §12.205. Five proposed amendments to §12.201(3) and the proposed amendment to §12.201(4) are necessary to change the term "screening criteria" to "review criteria" in order to more

accurately reflect the role of independent review as a review of a utilization review determination. Another proposed amendment to §12.201(3) is necessary to change the word “utilize” to “use” in order to simplify the text of the rule. Another proposed amendment to §12.201(3) is necessary to provide that the review criteria used by an IRO should be based on medical and scientific evidence, utilize evidence-based standards in addition to the current requirement that the review criteria are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers, be objective, clinically valid, compatible with established principles of health care, and flexible enough to allow deviations from the norms when justified on a case-by-case basis. This amendment is necessary to provide a more transparent framework for the independent review process. Another proposed amendment to §12.201(3) is necessary to provide that in the development of review criteria used to review health care delivered pursuant to the Labor Code Title 5, an IRO shall also consider the treatment guidelines, treatment protocols, and pharmacy closed formulary adopted by TDI-DWC. This change provides for greater conformity with existing TDI-DWC rules concerning review criteria. A proposed amendment to redesignated §12.201(3)(E) deletes a reference to “screening criteria” and makes additional nonsubstantive changes for clarity. Additional proposed amendments to §12.201(3) are necessary to change the phrase “his or her” to “the commissioner’s” to comply with current Department rule drafting style. A proposed amendment to §12.201(4) is necessary to conform the rule text to current Department rule drafting style and to make the section more reader-friendly.

Section 12.202 addresses **Personnel and Credentialing**. The proposed amendment to §12.202(b) is necessary to clarify that the purpose of maintaining complete profiles of anyone conducting independent review that include all information required by the Department in its application form and that are kept current is so that such information will be available for review by the Department and TDI-DWC upon request. The proposed amendment to §12.202(e) is necessary to provide that in addition to physicians and dentists, other persons who perform independent review whose licenses have been revoked by any state licensing agency in the United States are not eligible to direct or conduct independent review. This proposed amendment is necessary to ensure that quality personnel are engaged in the direction and conduct of independent review. An additional proposed amendment to add §12.202(f) clarifies that subsection (c) of this section does not negate the requirements for an IRO performing independent review of a health care service provided under the Labor Code Title 5 or Insurance Code Chapter 1305 to comply with licensing and professional specialty requirements for personnel performing independent review as provided by the Labor Code §§408.0043 – 408.0045, 413.031, the Insurance Code §1305.355, and Chapters 133 and 180 of this title (relating to General Medical Provisions and Monitoring and Enforcement).

Currently, §12.204 addresses **Prohibitions of Certain Activities of Independent Review Organizations**. The proposed amendment to the title of §12.204 is necessary to revise the title to be “Prohibitions of Certain Activities and Relationships of Independent Review Organizations and Individuals or Entities Associated with

Independent Review Organizations" to reflect the expanded content proposed for inclusion in the section. The proposed amendment to §12.204(a) makes nonsubstantive changes for clarification and also clarifies that the prohibition against an IRO imposing notice or review procedures that are contrary to the requirements of the health insurance policy or health benefit plan does not prohibit such practices as required by Texas law. Proposed amendments add new §12.204(c) – (h), which are necessary to implement HB 4519. Proposed new §12.204(c) is necessary to establish a prohibition that an IRO may not operate out of the same office or other facility as another IRO. Proposed new §12.204(c)(1) is necessary to clarify that the prohibition added by proposed new §12.204(c) extends to the shared use by IROs of the resources and staff that comprise an office, including: office space, telephone and fax lines, electronic equipment, supplies, and clerical staff. Proposed new §12.204(c)(2) is necessary to clarify that the prohibition added by proposed new §12.204(c) does not extend to the use of subcontractor services or personnel employed by or under contract with the IRO to perform independent review. Proposed new §12.204(d) is necessary to establish a prohibition that an individual or an entity may not own more than one IRO. Proposed new §12.204(e) is necessary to establish a prohibition that an individual may not own stock in more than one IRO. Proposed new §12.204(f) is necessary to establish a prohibition that an individual may not serve on the board of more than one IRO. Proposed new §12.204(g) is necessary to establish a prohibition that an individual who has served on the board of an IRO that has had its certification revoked for cause may not serve on the board of another IRO earlier than the fifth anniversary of the date

on which the revocation occurred. Proposed new §12.204(h) is necessary to establish a prohibition that an IRO may not employ an attorney to represent the IRO in legal proceedings if the attorney serves or has served in the past as the registered agent for the IRO.

Section 12.205 addresses **Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients**. The proposed amendment to §12.205(a) is necessary to correct a reference to an IRO's medical director by changing the word "advisor" to "director." One proposed amendment to §12.205(c) is necessary to clarify that requirements concerning timely delivery and receipt of any written narrative supplied by the patient also apply to payors requesting independent review in addition to the utilization review agent or the health insurance carrier, health maintenance organization, or managed care entity. The proposed amendment also clarifies that this obligation is additionally required pursuant to Chapters 19 and 133 of this title (relating to Agents' Licensing and General Medical Provisions, respectively). The second proposed amendment to §12.205(c) adds the word "of" to correct the omission of the word in the sentence. The third proposed amendment to §12.205(c), which adds the word "the" before the words "Insurance Code" is necessary for compliance with current TDI rule drafting style. The fourth proposed amendment to §12.205(c) is necessary to update a statutory citation from "the Insurance Code, Article 21.58A" to "the Insurance Code Chapter 4201" to conform with the non-substantive revisions to the Insurance Code. The fifth proposed amendment to §12.205(c) is necessary to delete the words "emergency or." There is not a separate

standard for emergency conditions as opposed to life-threatening conditions, making the words unnecessary. The amendment to §12.205(d) is necessary to update the section to incorporate a process concerning required notifications by the IRO to the Department that has shown to be more effective for the Department and IROs. Currently, the provision requires an IRO to notify the Department within 24 hours of the receipt of information regarding an independent review from a requesting utilization review agent, health insurance carrier, health maintenance organization, or managed care entity. However, the Department has determined that this requirement is unnecessary. As proposed, the provision only requires an IRO to notify the Department if it does not receive pertinent files containing medical and personal information from the requesting utilization review agent or the health insurance carrier, health maintenance organization, managed care entity, or other payor within three working days of receipt of the independent review assignment. One proposed amendment to §12.205(e) is necessary to clarify that the provision references documents requested by the IRO. The second proposed amendment to §12.205(e) is necessary to update a reference from the "Texas Workers' Compensation Commission" to the "TDI-DWC." The third proposed amendment to §12.205(e) is necessary to clarify that other payors are included as applicable in the requirement identifying those persons required to reimburse an IRO for the expense associated with copying records as an expense of independent review. This amendment is necessary in order to more comprehensively identify payors that may be responsible for this expense when entities other than a utilization review agent forward the request for independent review. New proposed

§12.205(f) is necessary to provide additional clarification that nothing in the section prohibits a patient, the representative of a patient, or a provider of record from submitting pertinent records to an IRO conducting independent review. Additional amendments are proposed to redesignate the subsections that follow §12.205(f), as necessary. The first proposed amendment to redesignated §12.205(g) is necessary to clarify the role an IRO has in regard to information by changing the word “collect” to “request and maintain.” The second proposed amendment to redesignated §12.205(g) is necessary to include “other payors” among the listed entities to more comprehensively identify those entities that may have requested independent review. The final two proposed amendments to redesignated §12.205(g) are necessary to reflect current Department rule drafting style by changing “and/or” to “or.” The proposed amendment to redesignated §12.205(h) revises the word “should” to “is required to” to more clearly identify sharing clinical and demographic information among divisions of the IRO to avoid duplicative requests for information from patients or providers is required of an IRO under the subsection rather than suggested.

Section 12.206 addresses **Notice of Determinations Made by Independent Review Organizations**. The proposed amendment to §12.206(b)(2) is necessary to delete a superfluous “and” and insert correct punctuation. The proposed amendment to §12.206(c) is necessary to insert the words “the notification must be” in order to clarify what the provision addresses. The proposed amendment to §12.206(d) provides a comprehensive list of the data elements that an IRO is required to include in its notification of determination. The list includes all items specified in the example

templates that are available on the Department's website and incorporates data elements identified by the Department as necessary to ensure that the review has been performed in compliance with the requirements of this chapter. Proposed required elements include: (i) a listing of all recipients of the notification that identifies such recipients by name and specifies the manner in which the IRO transmitted the notification to each recipient; (ii) the date of the original notification and any amendment thereto, if applicable; (iii) the independent review case number assigned by the Department; (iv) the name of the patient; (v) a statement of whether the type of coverage is health insurance, workers' compensation, or workers' compensation health care network; (vi) a statement of whether the context of the review is preauthorization, concurrent review, or retrospective review of health care services; (vii) the name and certification number of the IRO; (viii) a description of the services in dispute; (ix) a complete list of the information provided to the IRO for review, including dates of service and document dates where applicable; (x) a description of the qualifications of the reviewing physician or provider; (xi) a statement that the review was performed without bias for or against any party to the dispute and that the reviewing physician or provider has certified that no known conflicts of interest exist between the reviewer and any of the persons specified in subparagraphs (A) – (F); (xii) a statement that the independent review was performed by a health care provider licensed to practice in Texas if required by applicable law and of the appropriate specialty; (xiii) a statement that there is no known conflict of interest between the reviewer, IRO, and/or any officer or employee of the IRO with any of the persons specified in subparagraphs (A) – (F); (xiv) a summary

of the patient clinical history; (xv) the review outcome, clearly stating whether or not medical necessity or appropriateness exists for each of the health care services in dispute and whether the health care services in dispute are experimental or investigational, if applicable; (xvi) a determination of the prevailing party, if applicable; (xvii) the analysis and explanation of the decision, including the clinical basis, findings, and conclusions used to support the decision; (xviii) a description and the source of the review criteria that were used to make the determination; (xix) a certification by the IRO of the date that the decision was sent to all recipients in the manner specified by the IRO on the notification form; (xx) for independent review of health care services provided under Labor Code Title 5 or the Insurance Code Chapter 1305, any information required by §133.308 of this title (relating to General Medical Provisions); and (xxi) notice of applicable appeal rights under the Insurance Code Chapter 1305 and the Labor Code Title 5, and instructions concerning requesting such appeal. Requirements specified in existing §12.206(d)(1) – (4) are proposed to be incorporated into the more comprehensive listing of data elements in new §12.206(d)(i) – (xxi) and are amended as described for purposes of clarity and to change a reference to "screening" criteria to "review" criteria for accuracy of terminology. Proposed new §12.206(e) is necessary to notify IROs that example templates for the notification of determination regarding health and workers' compensation cases are available on the Department's website.

Section 12.207 addresses **Independent Review Organization Telephone Access**. The proposed amendment to the title of the section is necessary to make a

nonsubstantive change for clarity. The proposed amendments to §12.207(a) and (b) are necessary to broaden the telephone availability requirements for IROs. Currently, the section only requires an IRO to have personnel available to utilization review agents by telephone; it only requires an IRO to have a telephone system capable of accepting or recording or providing instructions to incoming calls from utilization review agents; and it only requires an IRO to respond to a call received outside of normal working hours not later than two working days from the later of the date on which the call was received or the date the details necessary to respond have been received from the caller. However, it is possible that parties other than just a utilization review agent, such as providers or patients, may need to reach an IRO. Additionally, the independent review timeframe is short in some instances, and a two day delay in response from an IRO could have an adverse impact on the party attempting to reach the IRO. Therefore, the proposed amendments to §12.207(a) and (b) remove the limitation that an IRO have personnel reasonably available to utilization review agents only, and the proposed amendments change the two working day response time to one working day.

Section 12.208 addresses **Confidentiality**. The proposed amendments to §12.208(b) are necessary to implement the Insurance Code §4202.002(c)(1)(F), enacted in HB 4519, by providing that an IRO may provide confidential information to a provider who is under contract with the IRO for the sole purpose of performing or assisting with independent review and by noting that the information provided to a provider who is under contract to perform a review shall remain confidential. A first proposed amendment to §12.208(f) is necessary to further implement the Insurance

Code §4202.002(c)(1)(F) by requiring an IRO's procedures to specify that specific information exchanged for the purpose of conducting review will be shared by the IRO with only a provider who is under contract with the IRO to perform independent review. A second proposed amendment to §12.208(f) is necessary to add the phrase "shall acknowledge" to provide additional clarity concerning the scope of the existing requirement that the IRO plan specify that the IRO agrees to abide by federal and state laws governing the issue of confidentiality. A third proposed amendment to §12.208(f) is necessary to correct a grammatical error by changing the word "which" to "that." The proposed amendments to §12.208(h) are necessary to accomplish two things. First, the provision currently requires information generated and obtained by an IRO during the course of a review only be retained "if the information relates to a case for which an adverse decision was made at any point." However, any review will have arisen from an adverse decision that was made at some point, therefore the clause addressing "an adverse decision. . . at any point" is proposed to be deleted because it is redundant. Second, it is necessary that the rule make clear that the requirement for an IRO to retain the records it has generated and obtained is an ongoing obligation that does not cease because an IRO's certificate of registration has been suspended or surrendered or due to the IRO's failure to renew the certificate. Therefore, it is proposed that a sentence be added which reflects this continuing obligation.

Section 12.301 currently addresses **Complaints and Information**. A proposed amendment is necessary to change the section title to "Complaints, Oversight, and Information" in order to accurately reflect the content that will be expanded as a result of

amendments proposed within the section. The proposed amendment to §12.301(a) is necessary to conform the rule addressing the IRO complaint process to current Department procedures for addressing complaints and to provide sufficient flexibility for Department action as necessary to protect confidential information as required by law. As amended, subsection (a) provides that complaints against an IRO shall be processed in accordance with the Department's established procedures for investigation and review of complaints. A proposed amendment adds new §12.301(b), which is necessary to address the Department's oversight of IROs by providing that as part of its oversight of IROs the Department will conduct compliance audits to ensure that IROs are in compliance with the Insurance Code Chapters 1305 and 4202 and the rules and standards in Chapter 12. A proposed amendment redesignates current §12.301(b) as §12.301(c) due to the proposed addition of proposed new §12.301(b). The additional proposed amendments to redesignated §12.301(c) make amendments for conformance with the current Department rule drafting style and to update a statutory citation from "the Insurance Code, Article 1.24" to "the Insurance Code §38.001" to conform with the non-substantive revisions to the Insurance Code. A proposed amendment also adds new §12.301(d), which is necessary to clarify that the chapter does not limit the ability of the Commissioner of Workers' Compensation or TDI-DWC to make inquiries, conduct audits, or receive and investigate complaints against IROs or personnel employed by or under contract with IROs to perform independent review to determine compliance with the Labor Code Title 5 or applicable TDI-DWC rules for violations of the Labor Code Title 5 or TDI-DWC rules.

Section 12.302 addresses **Administrative Violations**. Proposed amendments to §12.302(a), (d), (e), and (f) are necessary to update statutory citations referring to "the Act," or "Article 21.58C" to "the Insurance Code 4202" to conform with non-substantive revisions to the Insurance Code. Subsections (d) and (e) are also proposed to be amended to update references to the "Insurance Code, Article 1.10" and "the Insurance Code, Article 1.10A" with citations to "the Insurance Code Chapter 82" and "the Insurance Code Chapter 83," respectively, also to conform with nonsubstantive changes to the Insurance Code. For the same reason, a reference in subsection (e) to "the Insurance Code, Article 1.10E" is proposed to be amended to refer to "the Insurance Code Chapter 84." A proposed amendment to §12.302(a) provides notice to IROs that if the Department believes that any person conducting independent review is in violation of Insurance Code Chapters 1305 or 4202, Chapter 12 of this title, or any provision of the Labor Code Chapters 408, 409, or 413, or Chapters 19, 133, 134, 140, or 180 of this title, the department shall notify the independent review organization of the alleged violation and may compel the production of any and all documents or other information as necessary to determine whether or not such violation has taken place. The proposed amendments to §12.302(b) are necessary to provide notice to IROs and related persons and individuals that the Department or TDI-DWC may initiate appropriate proceedings under the chapter or the Labor Code Title 5 and TDI-DWC rules. The first proposed amendment to §12.302(d) is necessary to change the phrase "his or her" to "the commissioner's" in two places to comply with current Department rule drafting style. The second proposed amendment to §12.302(d) is necessary to make a

grammatical correction by changing the word “the” to “an.” The third proposed amendment to §12.302(d) is necessary to add a reference in the section to persons conducting independent review. A proposed amendment adds new §12.302(g), which is necessary to provide additional notice that if the Commissioner or the Commissioner’s designee determines that an IRO or a person conducting independent review has violated or is violating any provision of the Labor Code Title 5 or rules adopted pursuant to the Labor Code Title 5, the Commissioner or the Commissioner’s designee may impose sanctions or penalties under the Labor Code Title 5. A proposed amendment adds new §12.302(h), which is necessary to provide clarification that the chapter does not limit the ability of the Commissioner of Workers’ Compensation or TDI-DWC to take all actions permitted by the Labor Code against an IRO or personnel employed by or under contract with an IRO to perform independent review for violations of the Labor Code or rules adopted pursuant to the Labor Code Title 5 and applicable TDI-DWC rules.

A proposed amendment is necessary to add new §12.303, which addresses **Surrender of Certificate of Registration.** Proposed new §12.303 is necessary to implement the Insurance Code §4202.002(c), enacted by HB 4519. Proposed new §12.303(a) provides that upon the request of the Department, an IRO must voluntarily surrender the organization’s certificate of registration while the organization is under investigation or as part of an agreed order. Proposed new §12.303(b) is necessary to clarify that for the purposes of the section, the term “investigation” is defined as the filing of a Notice of Hearing or a Notice of Violation with the State Office of Administrative

Hearings by the Department or TDI-DWC against an IRO where such notice seeks revocation of the certification of the IRO. Proposed new §12.303(c) is necessary to provide that independent reviews shall not be assigned to an IRO during a voluntary surrender of the IRO's certificate of registration. Proposed new §12.303(d) is necessary to clarify that the voluntary surrender of an IRO's certificate of registration does not negate the requirement pursuant to §12.208(h) that an IRO retain information generated and obtained by the IRO in the course of a review for at least four years.

Section 12.402 addresses **Classification of Specialty**. The first proposed amendment to §12.402(2) is necessary to clarify that the provision regarding tier two fees is applicable to the review of "medical or surgical care" rendered in the specialties listed within the paragraph. The second proposed amendment to §12.402(2) is necessary to include chiropractic in the types of specialties addressed by the paragraph for purposes of clarifying the applicable tier for that specialty service.

Section 12.403 addresses **Fee Amounts**. The amendment to §12.403 designates the current provision in the section as subsection (a) and adds a proposed new subsection (b). An amendment is proposed to §12.403(a) to more accurately identify that other payors in addition to utilization review agents are sometimes responsible for payment of fees. Proposed new §12.403(b) is necessary to clarify that the IRO fees addressed by the section include an amended notification of decision if the Department determines the initial notification of decision is incomplete. Additionally, proposed new §12.403(b) is necessary to provide that the amended notification of decision shall be filed with the Department no later than five working days from the

IRO's receipt of notice from the Department that the initial notification of decision is incomplete.

Section 12.404 addresses **Payment of Fees**. An amendment to §12.402(b) is necessary to change the word "title" to "chapter" in order to more accurately identify the location of the referenced section. An amendment is proposed to delete §12.404(c) because the provision is unnecessary. The provision requires IROs, at the time of billing, to provide to the Department a copy of such bill for information. However, the Department generally does not need such information, so there is no reason to require that it be submitted to the Department. Additional proposed amendments redesignate the subsections that follow §12.404(c) as necessary.

Section 12.405 addresses **Failure to Pay Invoice**. An amendment to §12.405 corrects a typographical error that cites an incorrect section number. Another amendment to §12.405 is necessary to change the word "title" to "chapter" in order to more accurately identify the location of the referenced section. An additional amendment to the section is necessary to provide greater specificity concerning the scope of the violation referenced in the section.

Section 12.406 addresses **Certification and Renewal Fees**. The proposed amendment to §12.406 is necessary to change the word "certification" to the phrase "a certificate of registration" in order to utilize the term used throughout the chapter.

Section 12.501 addresses **Requests for Independent Review**. The proposed amendments to §12.501 are necessary to revise a reference to the Civil Practice and Remedies Code for consistency with the current Department rule drafting style and to

update a statutory citation from “the Insurance Code, Article 21.58A, §6” to “the Insurance Code Subchapter I” to conform with the non-substantive revisions to the Insurance Code. Additional amendments to the section are necessary to update the references addressing entities that submit requests for independent review to include Chapter 10 of this title (relating to Workers’ Compensation Health Care Networks) and Chapter 133 of this title (relating to General Medical Provisions).

Section 12.502 addresses **Random Assignment**. The proposed amendment to §12.502(a) is necessary to add a reference to other payors to the subsection to more comprehensively state the entities that might submit a request for independent review. The proposed amendment to §12.502(b) is necessary to update the provision to accurately reflect the role the Department plays in screening for potential conflicts. As proposed, the amendment to §12.502(b) provides that the Department shall screen payors and utilization review agents for potential conflicts of interest with the IRO before making an assignment to the IRO. The proposed amendment to §12.502(e) is necessary to revise the subsection for clarity. Proposed new §12.502(f) is necessary to address instances in which independent reviews will not be assigned. These instances include the 30 days prior to the anniversary date of the issuance of the IRO’s certificate of registration, unless the IRO has submitted an application for renewal of its certificate of registration and application fee, and the period of time during which an IRO has voluntarily surrendered its certificate of registration pursuant to §12.303. A proposed amendment also is necessary to redesignate the current §12.502(f) as §12.502(g).

Another amendment to redesignated §12.502(g) is necessary to clarify that the list referenced in the subsection is the assignment list.

2. FISCAL NOTE. Debra Diaz-Lara, Deputy Commissioner, Health and Workers' Compensation Network Certification and Quality Assurance Division, has determined that for each year of the first five years the proposed amendments and new sections will be in effect, there will be no fiscal impact to state and local governments as a result of the enforcement or administration of the proposal. There will be no measurable effect on local employment or the local economy as a result of the proposal.

3. PUBLIC BENEFIT/COST NOTE. Ms. Diaz-Lara, Deputy Commissioner, Health and Workers' Compensation Network Certification and Quality Assurance Division, also has determined that for each year of the first five years the proposed amendments and new sections are in effect, there are several public benefits anticipated as a result of the enforcement and administration of the proposal, as well as potential costs for persons required to comply with the proposal. The Department, however, drafted the proposed rules to maximize public benefits consistent with the intent of the authorizing statutes while mitigating costs.

ANTICIPATED PUBLIC BENEFITS

The anticipated public benefits in general are the updating of existing rules regulating IROs to comply with legislation enacted by the 81st Legislature; clarification of existing rules to facilitate compliance, implementation, and enforcement of these

rules; and an improved regulatory framework for the assignment of independent reviews. Specifically, the anticipated public benefits of the proposed rules and amendments related to compliance with legislation include: (i) the establishment of a regulatory framework that supports the operation of an independent review organization (IRO) in compliance with the prohibitions and requirements mandated under House Bill (HB) 4519, 81st Legislature, Regular Session, effective September 1, 2009; this regulatory framework will provide a more diverse pool of IROs that are based in Texas and that are available to accept assignment of requests for independent review; (ii) the establishment of a regulatory framework that supports the operation of an IRO in compliance with the requirements of HB 4290, 81st Legislature, Regular Session, effective September 1, 2009, which effectively revises the definition of “adverse determination” in the Insurance Code Chapter 4201 to include retrospective reviews and determinations regarding the experimental or investigational nature of a service; these amended rules will assist health care consumers by providing for independent review of claims that could otherwise be denied without such recourse. Additionally, the anticipated public benefits of the proposed rules and amendments related to clarification of existing rules are: (i) improved transparency in the application of these rules to independent reviews of adverse determinations made by certified workers’ compensation health care networks, utilization review agents, and health insurance and workers’ compensation insurance carrier payors; (ii) increased clarity concerning the type of medical and scientific evidence, evidence-based standards, treatment guidelines, treatment protocols, and pharmacy closed formulary upon which an IRO is

required to base its review criteria; (iii) clarification concerning the transfer of rights and responsibilities of persons with respect to an IRO that is sold or anticipated to be sold; (iv) improved telephone access to IROs that will provide health care consumers with easier and more efficient access to IROs; (v) increased clarity in existing rules to assist persons applying for or renewing a certificate of registration; (vi) increased clarity concerning confidentiality requirements to better protect enrollee heath care information; (vii) enhanced oversight of IROs that will result in better compliance with requirements; and (viii) clarification concerning the payment of fees to the IROs in the event that a notice of determination is issued and subsequently amended. The anticipated public benefits also include an improved regulatory framework for the assignment of independent reviews during the various time periods in which such assignments will not be made: (i) during the 30 days prior to the anniversary date of the issuance of an IRO's certificate of registration; (ii) during the time that an IRO has voluntarily surrendered its certificate of registration pursuant to proposed §12.303 of this chapter; and (iii) during the 45 days prior to the date that a sale of an IRO is finalized.

ANTICIPATED COSTS

Ms. Diaz-Lara anticipates that there will be probable costs to persons required to comply with several of the proposed amendments and new sections during each year of the first five years that the rule will be in effect. These proposed amendments and new sections are necessary to implement HB 4519 and HB 4290 and to promulgate standards and rules, pursuant to the Commissioner's rulemaking authority in the

Insurance Code §4202.002(a)(1), for the certification, selection, and operation of IROs to perform independent review.

Anticipated Costs for Compliance with Proposed Amendments and New Sections that Implement HB 4519.

The following proposed amendments and new sections are necessary to implement HB 4519: (i) proposed §12.103(10), requiring that the IRO be based in Texas and that its primary office be located in Texas and that evidence of such be included in the application and renewal form that the applicant submits to the Department; (ii) proposed new §12.110, relating to requirements concerning the sale of an IRO; (iii) proposed new §12.204(c), relating to the prohibition of an IRO operating out of the same office or other facility as another IRO; (iv) proposed new §12.204(d), relating to the prohibition of an individual or an entity owning more than one IRO; (v) proposed new §12.204(e), relating to the prohibition of an individual owning stock in more than one IRO; (vi) proposed new §12.204(f), relating to the prohibition of an individual serving on the board of more than one IRO; (vii) proposed new §12.204(g), relating to the prohibition of an individual who has served on the board of an IRO that has had its certification revoked for cause from serving on the board of another IRO earlier than the fifth anniversary of the revocation date; (viii) proposed new §12.204(h), relating to the prohibition of an IRO employing an attorney to represent the IRO under certain specified conditions; (ix) proposed new §12.303, relating to an IRO's voluntary surrender of its certificate of registration under certain specified circumstances; and (x) proposed §12.502(f)(2), relating to an IRO that has voluntarily surrendered its certificate

of registration not receiving any assignments of independent reviews during the period of the voluntary surrender.

Proposed §12.103(10): Requirements that the IRO be based in Texas and its primary office be located in Texas. The Department anticipates that there will be costs for those IROs required to re-locate in order to comply with the requirements in proposed §12.103(10) that an IRO must be based in Texas and its primary office must be located in Texas as a condition for the IRO to be certified to conduct the business of independent review in Texas. These estimated costs are based on information provided to the Department by an IRO that has already taken steps to come into compliance with these requirements. These anticipated costs include: (i) expenses associated with establishing a new physical location; (ii) cost of new computer hardware and software; and (iii) staffing costs. The anticipated costs associated with establishing a new physical location will include: (i) the rental or lease deposit on an office location; (ii) purchase of office furniture if the IRO does not move some or all of its current furniture to the new location; (iii) deposits on utilities, such as electricity, water, and internet services; and (iv) the cost of hiring movers unless the IRO opts to purchase all new furniture and equipment. The Department recognizes that there may be an increase or decrease in rental or leasing costs as a result of re-locating to Texas. However, these increased or decreased costs will be related to the rental or leasing costs for office space available in the new location in Texas compared to the rental or leasing costs in the IRO's current location. As a result, the Department anticipates that such costs will vary for each IRO that is required to re-locate under the proposal.

However, each such IRO has access to the relevant cost information for its particular circumstances. The anticipated costs associated with establishing a new physical location is an estimated one-time cost of approximately $2,500 - $3,000. The anticipated cost of new computer hardware and software includes expenses for the purchase of: (i) a computer; (ii) a printer; (iii) a scanner; and (iv) office software, such as Paperport, Quickbooks, and Adobe Acrobat. The anticipated cost of new computer hardware and software is an estimated one-time cost of approximately $1,500 - $2,000. The anticipated staffing cost includes the cost of hiring a general office clerk to handle duties related to the re-location, including managing facility and utility contracting, equipment removal, and set-up and general office management duties for the newly established office. This anticipated staffing cost is an estimated monthly cost ranging between $1,334 and $2,176. This estimated cost is based on information concerning average salaries for general office clerks that is available on the Texas Workforce Commission website. In addition to these costs, proposed §12.103(10) also may result in persons incurring costs because of the requirement that the application for the certificate of registration provide evidence that the IRO is based in Texas and has its primary office in Texas. This requirement may result in additional costs to an out-of-state IRO because the IRO may be required to register with the Texas Secretary of State depending on the IRO's business organization type. The proposed §12.103(10) requirement, however, would not result in additional cost for an IRO choosing to form in Texas because the IRO would be subject at the time of formation to existing Texas statutory business formation requirements and fees. Business organization fees and

registration costs are specified in §§4.151 - 4.160 of the Business Organizations Code. The fee schedule is also available on the website of the Texas Secretary of State and includes: (i) assumed name certificate fee, $25; (ii) a certificate of formation fee for foreign for-profit corporations and limited liability companies, $300; (iii) a certificate of formation fee for limited partnerships, $750; and (iv) an application/registration fee for foreign limited liability partnerships, $200 for each partner in Texas, but not less than $200 nor more than $750. Fees may vary when other fees have been provided. For sole proprietorships and some types of partnerships, additional costs resulting from the proposed §12.103(10) requirement may include fees for filing an assumed name certificate with the county clerk in each county where business is conducted as required by the Business and Commerce Code §71.051. Choice of entity formation will be determined by the proprietors, partners, members and/or owners of the IRO, and those individuals have access to the information necessary to determine this cost.

Proposed new §12.110: Requirement to apply for new certification of a newly purchased IRO. One of the anticipated costs to a purchaser of a certified IRO resulting from the proposed requirement for recertification of IROs in §12.110 is $800, the fee for the original application for a certificate of registration filed with the Department. The Department anticipates that only a minimal amount of work will be required for the newly purchased IRO to update its certification application documents to reflect the new ownership. This minimal amount of work is expected to result in little or no additional cost. Additionally, updating of the certification application information is already required under the current rules in §12.105(d). As a result of this existing requirement,

the Department anticipates that the certification application documents will be substantially up-to-date, which will greatly reduce the amount of time and effort needed to prepare and submit the new application.

Proposed §12.204(c): Prohibition that an IRO may not operate out of the same office or other facility as another IRO. Probable costs for those persons required to comply with the prohibition in proposed §12.204(c) that an IRO may not operate out of the same office or other facility as another IRO will be similar to those costs for an out-of-state IRO's compliance with the §12.103(10) requirement that the IRO be based in Texas and its primary office be located in Texas. However, if the IRO business entity is currently registered with the Texas Secretary of State's Office as required under Texas law, there will not be any costs for compliance with the state's registration requirements. The estimated costs are based on information provided to the Department by an IRO that has already moved into new office space. As previously explained, the costs likely to be incurred with establishing a new physical location is a one-time cost that will likely not exceed more than approximately $2,500 - $3,000. This total estimated cost includes costs for: (i) the rental or lease deposit on an office location; (ii) purchase of office furniture if the IRO does not move some or all of its current furniture to the new location; (iii) deposits on utilities, such as electricity, water, and internet services; and (iv) the cost of hiring movers for any furniture or equipment the IRO must move to the new location. There may be an increase or decrease in rental or leasing costs as a result of an IRO being required to re-locate its office to comply with the prohibition in proposed §12.204(c) that an IRO may not operate out of the same office or other facility

as another IRO. Such costs will be related to the rental or leasing costs for the new separate office space compared to the rental or leasing costs in the IRO's current shared office space. As a result, the Department anticipates that such costs will vary for each IRO that is required to re-locate to comply with proposed §12.204(c). However, each such IRO has access to the relevant cost information for its particular circumstances. If the IRO has to purchase new computer hardware and software, the Department anticipates that such costs will range from approximately $1,500 to $2,000. This estimate includes expenses for the purchase of: (i) a computer; (ii) a printer; (iii) a scanner; and (iv) office software, such as Paperport, Quickbooks, and Adobe Acrobat. Additionally, if it is necessary for the IRO to hire additional staff to handle duties related to the relocation, the Department anticipates that such staff will be employed to perform the duties of managing facility and utility contracting, equipment removal, and set up and general office management duties for the newly established office. This anticipated staffing cost is an estimated monthly cost ranging between $1,334 and $2,176 for a general office clerk. To the extent that an IRO currently relies upon shared clerical staff, the Department further anticipates that an IRO may have to hire independent clerical staff to comply with the provision in proposed §12.204(c) that the prohibition against multiple IROs operating form the same office or other facility extends to the shared use of staff, including clerical staff. The Department anticipates that the estimated monthly cost of such clerical staff will range between $1,334 and $2,176 for a general office clerk. The monthly salary estimate for a general office clerk is based on information available on the Texas Workforce Commission website. The

Department further expects that such additional cost to an IRO for hiring clerical staff will vary for each such IRO depending upon the cost-sharing arrangements used by such IROs and the number of clerical staff employed by the IRO. Additionally, only an IRO that currently shares clerical staff with another IRO as prohibited in §12.204(c)(1) will incur the additional monthly cost for clerical staff.

Proposed §12.204(d): Prohibition that an individual or entity may not own more than one IRO. An individual, entity, or IRO that is required to comply with the prohibition in proposed §12.204(d) that an individual or entity may not own more than one IRO may incur costs related to the divestiture or merger of multiple organizations and potential loss of income associated with divestiture, if applicable. Both divestiture and merger of ownership have inherent costs that will vary based on the ownership structure for each IRO owned in excess of the maximum, but will relate to: (i) the cost of professional services determined by the individual or entity to be necessary to effectuate the divestiture or merger; (ii) the potential gain or loss to the individual or entity attributable to the divestiture or merger transaction, as well as any resulting tax consequences; and (iii) loss of any potential future gain or dividend income resulting from the divestiture or merger, particularly as a result of a sale of the ownership interest. The Department anticipates that the cost of professional services used to effectuate the divestiture or merger if determined necessary may include broker fees, attorney fees, and accountant fees. The Department expects that these fees may vary and that individuals and entities making a determination of whether to use these services will be able to determine the cost of such services on an individual basis. Similarly, the gain or loss to

an individual or entity attributable to the divestiture or merger transaction will be unique to the individual or entity, as will the resulting tax consequences from that transaction, but each individual or entity has the information necessary to determine this cost. Additionally, if divestiture amounts to closing multiple IRO operations through merger or otherwise, the individual or entity may incur additional costs due to loss of capital investment and cancelation of existing contracts, including property and equipment leases; such costs will be unique to the entity, individual, or IRO based upon the nature, scope and duration of such contracts. The amount of lost future gain or dividend income for individuals or entities that must divest themselves of ownership interests in IROs will be based on the fact that once the individual or entity has relinquished ownership the individual or entity will no longer be able to realize any potential future increase in value for the interest or dividend income. This lost potential future gain or income amount may vary greatly for any individual or entity required to comply with proposed §12.204(d). Individuals and entities who must comply with this prohibition either have this information or have access to information to enable them to determine the estimated amount of lost future gain or income. Further, this analysis presumes that the owner, whether an individual or an entity, shall determine the best means of compliance with proposed §12.204(d), including allocation of costs to the extent feasible. The Department anticipates that an individual or entity that owns more than one IRO may incur costs associated with each IRO in excess of the maximum . The Department’s estimated lost income for each IRO is based on the number of IROs owned by the individual or entity that are operating at the time of this proposal. The

Department anticipates that the current lost income for each IRO that is no longer operative and therefore, does not receive assignments for independent reviews, is approximately $3,730 for each month of no assignments minus the IRO's overhead expenses. This estimate is based on subtracting the approximate payment an IRO pays to reviewers to conduct independent review from the average income an IRO receives for assigned independent reviews. Based on Department records, an IRO receives an average of 10 independent review assignments per month. According to the records, approximately 70 percent of assigned independent reviews are tier one reviews, which require a fee of $650, and approximately 30 percent of assigned independent reviews are tier two reviews, which require a fee of $460. Therefore, an IRO earns approximately $5,930 per month from such fees. However, an IRO must pay employed or contracted reviewers to conduct the assigned independent reviews, which reduces income from the fees that the IRO receives. Based on information received from an IRO, a reviewer may receive payment of $250 to conduct a tier one review and a payment of $150 to conduct a tier two review. Based on the approximate number and type of independent reviews assigned to an IRO on a monthly basis, an IRO pays approximately $2,200 to reviewers per month. This cost, subtracted from the estimated income of $5,930, equals $3,730. This amount of lost income will be reduced even further as a result of the necessary overhead expenses of each IRO, including office space rental or leasing costs, employee salaries and benefits, and utilities. However, the overhead costs will vary for each IRO based on the IRO's business model and expenses. It is not possible to provide a more exact estimate of lost future income for

individuals or entities that must divest themselves of one or more IROs to come into compliance with the proposed §12.204(d) prohibition. The amount of lost future income is fact specific to the particular IRO or individual that is required to comply with proposed §12.204(d) and could vary greatly based on the specific situation. Relevant factors that relate to the amount of future lost income that an individual or entity will experience include the number of IROs owned that must be sold or otherwise divested, the present market value of each IRO, and the realized value if any of each divested IRO.

Proposed new §12.204(e): Prohibition that an individual may not own stock in more than one IRO. The proposed prohibition in §12.204(e) that an individual may not own stock in more than one IRO may result in an individual divesting stock, engaging in a merger, or engaging in some other stock transaction (collectively, "stock transactions") to comply with the prohibition. A stock transaction has inherent costs that will vary based on the underlying entity's ownership structure, but will relate to: (i) the cost of professional services determined by the individual to be necessary to effectuate the stock transaction; (ii) the potential gain or loss to the individual attributable to the stock transaction, as well as any resulting tax consequences; and (iii) loss of any potential future gain or dividend income resulting from the stock transaction, particularly the sale of stock. These costs and factors affecting these costs have been discussed in the previous section of this Cost Note entitled *§12.204(d): Prohibition that an individual or entity may not own more than one IRO* with regard to comparable anticipated costs that may result from that prohibition. Although the requirement in proposed new §12.204(e)

pertains to individual stock ownership rather than the more general ownership of an IRO by an individual or entity addressed in §12.204(d), the Department anticipates that the potential costs and factors related to divestiture or merger of multiple organizations will be the same for stock transactions. Individuals who must comply with this prohibition either have the information pertaining to the individual's unique situation, circumstances, and costs or have access to information to enable them to determine such costs. Similarly, the gain or loss to an individual attributable to the stock transaction will be unique to the individual, as will the resulting tax consequences from that stock transaction, but each individual has the information necessary to determine this cost. The amount of lost future gain or dividend income for individuals that must divest themselves of stock in IROs will be based on the fact that once the individual has relinquished ownership the individual will no longer be able to realize any potential future increase in value for the stock or dividend income. This lost potential future gain or income amount may vary greatly for any individual required to comply with proposed §12.204(e). As discussed with respect to divestiture of ownership interest previously in this Cost Note, if the stock transaction used by an individual divesting stock interest in multiple IROs results in closure of one or more IRO operations through merger or otherwise, the individual or IRO may additionally incur costs due to loss of capital investment and cancellation of existing contracts, including property and equipment leases; such costs will be unique to the individual or IRO based upon the nature, scope, and duration of such investments and contracts. Further, this analysis presumes that the individual stock owner shall determine the best means of compliance with proposed

§12.204(e), including allocation of costs to the extent feasible. Additionally, this proposal includes discussion of estimated lost income for each IRO that an individual or entity must divest in the previous section of this Cost Note entitled *§12.204(d): Prohibition that an individual or entity may not own more than one IRO.* Although that discussion relates to divestiture of IRO ownership generally rather than divestiture of stock in an IRO, the Department anticipates that the same analysis may be applied by an individual divesting stock to estimate lost income resulting from the prohibition in proposed §12.204(e) that an individual may not own stock in more than one IRO.

Proposed new §12.303 and §12.502(f): Provision that an IRO may not receive assignments for independent review during the proposed period of time that it has voluntarily surrendered its certificate of registration while under investigation or as part of an agreed order. Proposed §12.303(a) provides that upon the request of the Department, an IRO must voluntarily surrender its certificate of registration while the IRO is under investigation or as part of an agreed order. Proposed §12.303(c) provides that independent reviews shall not be assigned to an IRO during a voluntary surrender of the IRO's certificate of registration. The Department estimates that the anticipated lost income for an IRO that does not receive assignments for independent reviews during the period of time that it has voluntarily surrendered its certificates of registration in accordance with proposed §12.303 is approximately $3,730 dollars for each month without any assignments. This estimate is based on subtracting the approximate payment an IRO pays to reviewers to conduct independent review from the average income an IRO receives for assigned independent reviews. Based on Department

records, an IRO receives an average of 10 independent review assignments per month. According to the records, approximately 70 percent of assigned independent reviews are tier one reviews, which require a fee of $650, and approximately 30 percent of assigned independent reviews are tier two reviews, which require a fee of $460. Therefore, an IRO earns approximately $5,930 per month from such fees. However, an IRO must pay employed or contracted reviewers to conduct the assigned independent reviews, which reduces income from the fees that the IRO receives. Based on information received from an IRO, a reviewer may receive payment of $250 to conduct a tier one review and a payment of $150 to conduct a tier two review. Based on the approximate number and type of independent reviews assigned to an IRO on a monthly basis, an IRO pays approximately $2,200 to reviewers per month. This cost, subtracted from the estimated income of $5,930, equals $3,730. Additionally, during the period of the voluntary surrender of the certificate of registration, the IRO may continue to incur costs for necessary overhead expenses, including office space rental or leasing costs, employee salaries and benefits, and utilities. However, these overhead costs will vary for each IRO based on the IRO's business model and expenses. Proposed §12.502(f)(2) reiterates this same requirement for purposes of readability and ease of compliance. However, there will be no lost income in addition to the income lost by any IRO subject to the proposed §12.303 certificate of registration voluntary surrender requirement.

Anticipated Costs for Compliance with Proposed Amendments that Implement HB 4290. There will also be probable costs to persons required to comply

with several proposed amendments necessary to implement HB 4290. These proposed amendments relate to new requirements concerning retrospective utilization review and utilization review to determine the experimental or investigational nature of a health care service. These proposed amendments are: (i) the proposed redesignated §12.5(1) definition of the term "adverse determination," amended to conform the definition to the Insurance Code §4201.002(1) by adding utilization review agent (URA) determinations that health care services provided or proposed to be provided to a patient are experimental or investigational to those determinations that qualify as "adverse determinations"; (ii) the proposed redesignated §12.5(16) definition of the term "independent review," amended to expand the scope of such review to include "adverse determinations" regarding the medical necessity and appropriateness or the experimental or investigational nature of health care services; (iii) the proposed redesignated §12.5(30) definition of the term "review criteria," amended to include policies, medical protocols, previous decisions and/or guidelines used by the IRO to make decisions about the experimental or investigational nature of a health care service; and (iv) proposed new §12.103(1)(B), amended to expand the application and renewal requirements to include the submission of a summary description of review criteria and review procedures to be used to determine the experimental or investigational nature of health care as part of the summary independent review plan required for submission with the application.

Proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B): Cost of additional review criteria. The Insurance Code §4201.401

provides that a URA must allow any party whose appeal of an “adverse determination” is denied by the URA to seek review of that determination by an IRO assigned to the appeal in accordance with Chapter 4202. Consistent with the Insurance Code §4201.002(1) enacted by HB 4290, the proposed amendment to redesignated §12.5(30) expands the definition of “review criteria” to include policies, medical protocols, previous decisions and/or guidelines used by the IRO to make decisions about the experimental or investigational nature of a health care service. As a result of the enactment of HB 4290, the Department anticipates that IROs will acquire review criteria necessary to determine the experimental and investigational nature of health care because of the statutory expansion of those determinations that constitute an “adverse determination” as provided in the Insurance Code §4201.002(1). Further, for health care services or devices proposed to be provided or being provided under the Labor Code Title 5, the Labor Code §413.014(c)(6) and §134.600(p)(6) and (q)(5) of this title already impose preauthorization and concurrent review requirements related to investigational or experimental services or use of devices, and reviews of adverse determinations resulting from such review are subject to independent review pursuant to the Labor Code §413.031(d). Thus, IROs already review adverse determinations related to the experimental and investigational nature of health care services and have review criteria to enable the performance of such review. Consistent with the Insurance Code §4201.002(1) enacted by HB 4290, proposed new §12.103(1)(B) expands application and renewal requirements to include the submission of a summary description of review criteria and review procedures to be used to determine the experimental or

investigational nature of health care as part of the summary independent review plan required for submission with the application. Therefore, the Department anticipates that IROs as a part of their standard operating procedures will establish procedures for the review of the experimental and investigational nature of health care services in order to fulfill the statutorily required expanded scope of duties with respect to review of such services. Proposed new §12.103(1)(B) does not prescribe the review criteria and procedures that an IRO must use in fulfilling this statutory requirement. Rather, it requires the submission of a summary description of such criteria and review procedures as part of the initial and renewal application process for an IRO. The Department anticipates that the time and effort required to include this summary information will be minimal.

Proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B): Increased costs to URAs and payors. The Insurance Code §4201.403 requires a URA, including a payor, as applicable, to pay for an independent review conducted under Chapter 4201, Subchapter I. Section 4201.401, included in Subchapter I, requires a URA, including a payor, as applicable, to allow any party whose appeal of an adverse determination is denied by the URA to seek review of that determination by an IRO assigned to the appeal in accordance with Chapter 4202. HB 4290 clarifies applicability of independent review on a retrospective basis by amending the definition of “utilization review” to specifically include retrospective review of the medical necessity and appropriateness of health care services. HB 4290 further amends the term to include a system for prospective, concurrent, or retrospective

review to determine the experimental or investigational nature of health care services. The proposed rule amendments are consistent with the HB 4290 amendments. Both a URA's retrospective determination that health care services provided to a patient are not medically necessary or appropriate and a URA's determination that health care services are experimental or investigational are included within the scope of the term "adverse determinations." Existing §12.403 provides that fees to be paid to IROs by URAs for each independent review are either $650 for tier one reviews or $460 for tier two reviews. Although this proposal amends §12.403, the prescribed fee amount is not proposed to be changed for either type of review. Because HB 4290 amended the scope of determinations that constitute "adverse determinations," URAs, and payors, as applicable, will have to pay the appropriate fee for these types of review for both: (i) reviews of a URA's retrospective determination that health care services provided to a patient are not medically necessary or appropriate; and (ii) reviews of a URA's determination that health care services are experimental or investigational. The total cost of a URA's or payor's compliance with the fee amount prescribed in §12.403 pursuant to the statutorily expanded scope of independent review requirements will vary for each URA or payor depending upon: (i) the number of retrospective utilization review determinations that health care services are not medically necessary or appropriate; (ii) the number of utilization review determinations that health care services are experimental and investigational; (iii) the number of requests for independent review that are submitted for both new categories of adverse determination; and (iv) the applicable tier of the particular independent review

requested. Each URA and payor has baseline information upon which to estimate this cost.

Anticipated Costs for Compliance with Other Proposed Amendments.

Several other proposed amendments are not necessary to implement HB 4519 or HB 4290 but are necessary to promulgate standards and rules for the certification, selection, and operation of IROs to perform independent review pursuant to the Commissioner's rulemaking authority in the Insurance Code §4202.002(a)(1). These amendments: (i) address "best evidence" requirements; (ii) provide that an IRO will not be assigned independent reviews during the 30 days prior to the anniversary date of the issuance of the IRO's certificate of registration unless the completed renewal application form has been received by the Department; and (iii) provide that independent reviews will not be assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized.

Proposed §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3): Best evidence requirements. Collectively, proposed §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) establish the general framework within which independent review must be conducted. As part of the application and renewal process, proposed §12.103(1)(A) – (B) requires an IRO to submit a summary of its independent review plan that complies with §12.201 and that includes: (i) a summary description of review criteria and review procedures to be used to determine medical necessity or appropriateness of health care; and (ii) a summary description of review criteria and review procedures to be used to determine the experimental and

investigational nature of health care. Proposed §12.201(3) requires the independent review plan governing the performance of independent review by the IRO to include written medically acceptable review criteria that are, among other requirements, based on medical and scientific evidence and utilize evidence-based standards. Proposed §12.5(11) defines "evidence-based standards" to mean the conscientious, explicit, and judicious use of evidence-based medicine and the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients. Proposed §12.5(10) defines "evidence-based medicine" as the use of current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients. Proposed §12.5(3) defines "best evidence" by establishing a hierarchy, depending on availability of designated categories of evidence, for evidence based on randomized clinical trials, cohort studies or case-control studies, case-series, and expert opinion, in descending order of hierarchical preference. Although the Department does not prescribe the specific review criteria and procedures to be used by the IRO, the Department anticipates that IROs may have to acquire some additional review criteria in order to comply with the consideration of the best evidence hierarchy and to include such consideration as part of the independent review plan and review criteria, summaries of which must be provided to the Department pursuant to proposed §12.103(1)(A) – (B). Further, the Department anticipates that the cost of obtaining evidence-based review criteria will vary for each IRO depending upon: (i) the manner

and cost, if any, by which such evidence is available and accessible to the medical community, e.g., whether the criteria is available without charge either in the medical community or on the internet or whether it may be purchased from a third-party; and (ii) the extent to which an IRO already incorporates the best evidence hierarchy into its review criteria. It is not possible for the Department to realistically estimate the costs of such criteria for the following reasons: (i) because the Department does not prescribe the specific review criteria, IROs are free to obtain criteria from any number of sources; (ii) costs will vary from IRO to IRO and from vendor to vendor; and (iii) the Department has no way of knowing which criteria each IRO currently has and which criteria it would need to purchase. Currently certified IROs should already have criteria available and may have most or part of the criteria needed to comply with the new requirements. As a result, all IROs will obtain varying degrees of what is needed to complete its set of criteria. The cost of obtaining such criteria may already be absorbed by the IRO in accordance with its existing independent review plan, but to the extent that the independent review plan does not address best evidence standards, such plans will require amendment. The Department anticipates that the cost of summarizing such criteria will be minimal. Each IRO has information to enable the IRO to estimate any additional costs necessary to comply with these proposed requirements.

Proposed amendments to §12.108(c) and proposed new §12.502(f)(1): Prohibition of assignment of independent reviews during certain specified time. The Department also anticipates that there will be probable costs to persons required to comply with a proposed amendment to §12.108(c) and proposed new §12.502(f)(1),

prohibiting an IRO from being assigned independent reviews during the 30 days prior to the anniversary date of the issuance of the IRO's certificate of registration unless the completed renewal application form has been received by the Department.

The Department estimates that the anticipated lost income for an IRO subject to the proposed §12.108(c) prohibition will be approximately $3,730 dollars for a full 30-day period without any assignments. This estimate is based on subtracting the approximate payment an IRO pays to reviewers to conduct independent review from the average income an IRO receives for assigned independent reviews. Based on Department records, an IRO receives an average of 10 independent review assignments per month. According to the records, approximately 70 percent of assigned independent reviews are tier one reviews, which require a fee of $650, and approximately 30 percent of assigned independent reviews are tier two reviews, which require a fee of $460. Therefore, an IRO earns approximately $5,930 per month from such fees. However, an IRO must pay employed or contracted reviewers to conduct the assigned independent reviews, which reduces income from the fees that the IRO receives. Based on information received from an IRO, a reviewer may receive payment of $250 to conduct a tier one review and a payment of $150 to conduct a tier two review. Based on the approximate number and type of independent reviews assigned to an IRO on a monthly basis, an IRO pays approximately $2,200 to reviewers per month. This cost, subtracted from the estimated income of $5,930, equals $3,730. Additionally, during these 30 days, the IRO will likely continue to incur costs for necessary overhead expenses, including office space rental or leasing costs, employee

salaries and benefits, and utilities. However, these overhead costs will vary for each IRO based on the IRO's business model and expenses. Proposed §12.502(f)(1) reiterates this same requirement for purposes of readability and ease of compliance. However, there will be no lost income in addition to the income lost by any IRO subject to the proposed §12.108(c) prohibition.

Proposed new §12.110(d): Provision that independent reviews will not be assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized. Proposed §12.110(d) provides that independent reviews will not be assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized. The Department estimates that the anticipated lost income to an IRO that does not receive assignments for independent reviews during the 45 days prior to the date that the sale of the IRO is finalized is approximately $5,595 for the 45 day-period. This estimate is based on subtracting the approximate payment an IRO pays to reviewers to conduct independent review from the average income an IRO receives for assigned independent reviews. Based on Department records, an IRO receives an average of 10 independent review assignments per month or 15 assignments per 45-day period. According to the records, approximately 70 percent of assigned independent reviews are tier one reviews, which require a fee of $650, and approximately 30 percent of assigned independent reviews are tier two reviews, which require a fee of $460. Therefore, an IRO earns approximately $8,895 per 45-day period from such fees. However, an IRO must pay employed or contracted reviewers to conduct the assigned independent reviews, which reduces income from the fees that the IRO receives. Based on

information received from an IRO, a reviewer may receive payment of $250 to conduct a tier one review and a payment of $150 to conduct a tier two review. Based on the approximate number and type of independent reviews assigned to an IRO on a 45-day basis, an IRO pays approximately $3,300 to reviewers per 45 day period. This cost, subtracted from the estimated income of $8,895, equals $5,595. Additionally, during the 45-day period, the IRO may continue to incur costs for necessary overhead expenses, including office space rental or leasing costs, employee salaries and benefits, and utilities. However, these overhead costs will vary for each IRO based on the IRO's business model and expenses.

All Other Costs Result of Legislative Enactment of HB 4290

HB 4290 amends the definition of "adverse determination" to mean a determination by a utilization review agent that health care services provided or proposed to be provided to a patient are not medically necessary or are experimental or investigational. HB 4290 also amends the Insurance Code §4201.002(13), which defines "utilization review" to include "retrospective review" and "a system for prospective, concurrent, or retrospective review to determine the experimental or investigational nature of health care services." These proposed rules are consistent with these definitional changes. The costs that will be required of persons as a result of these proposed provisions are addressed in this proposal. However, all other costs required to comply with HB 4290 are the result of the legislative enactment of HB 4290 and not as a result of the adoption, enforcement, or administration of this proposal.

4. ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO BUSINESSES. The Government Code §2006.002(c) requires that if a proposed rule may have an adverse economic impact on small businesses, state agencies must prepare as part of the rulemaking process an economic impact statement that assesses the potential impact of the proposed rule on small businesses and a regulatory flexibility analysis that considers alternative methods of achieving the purpose of the rule. The Government Code §2006.001(2) defines "small business" as a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has fewer than 100 employees or less than $6 million in annual gross receipts. The Government Code §2006.001(1) defines "micro business" similarly to "small business" but specifies that such a business may not have more than 20 employees. The Government Code §2006.002(f) requires a state agency to adopt provisions concerning micro businesses that are uniform with those provisions outlined in the Government Code §2006.002(b) – (d) for small businesses.

Analysis of Economic Impact

The Department has determined that this proposal contains eight requirements that may have an adverse economic effect on approximately 35 small or micro business IROs and that must be analyzed in order to determine costs to small and micro business IROs required to comply with this proposal. The proposal also contains one requirement that may have an adverse economic effect on approximately 43 attorneys whose practice may qualify as small or micro businesses, one requirement that may

have an adverse economic impact on approximately 154 certified or registered small and micro business utilization review agents and 315 – 325 payors, and one requirement that may have an adverse impact on small and micro business entities, if any, that currently own more than one IRO.

Impact on IROs

In accordance with the Government Code §2006.002(c), the Department has determined that there are several proposed amendments and new sections that may have an adverse economic impact on approximately 35 IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) and that are required to comply with the proposed rules. This estimate is based on the Department's review of information relating to the amount of gross receipts for the 43 IROs currently licensed in Texas. The Department determined that 8 of these 43 IROs are subsidiaries of larger holding companies, and therefore do not qualify as small or micro businesses under the Government Code §2006.001(1) and (2) while the remaining 35 do qualify based on the amount of gross receipts. The Department's cost analysis and resulting estimated costs, as detailed in the Public Benefit/Cost Note part of this proposal, are equally applicable to small or micro business IROs.

Impact of Proposed §12.103(10) on IROs: Requirements that the IRO be based in Texas and its primary office be located in Texas. Proposed §12.103(10) provides that as a condition of being certified to conduct the business of independent review in this state, an IRO must be based in this state and must locate its primary office in this state. The Department has determined that this requirement may result in costs that will

have an adverse economic impact on small or micro business IROs. In summary, these anticipated costs include: (i) an estimated one-time cost of approximately $2,500 - $3,000 to establish a new physical location; (ii) an estimated one-time cost of approximately $1,500 - $2,000 for new computer hardware and software; and (iii) estimated monthly cost ranging between $1,334 and $2,176 for a general office clerk to handle duties related to re-location. Additionally, there may be an increase in monthly rental or leasing costs as a result of re-locating to Texas. Whether there will be such an increase or a decrease will be related to the rental or leasing costs for office space available in the new location in Texas compared to the rental or leasing costs in the IRO's current location. Proposed §12.103(10) also may result in Texas Secretary of State registration costs for small and micro IROs that are located out-of-state and are required to re-locate to Texas. Proposed §12.103(10) requires that an application for the certificate of registration provide evidence that the IRO is based in Texas and has its primary office in Texas. The registration fee amount is dependent on the small or micro IRO's business organization type. The fees, which range from an initial one-time cost of $25 to $750, are detailed in the Public Benefit/Cost Note part of this proposal under the subheading "Proposed §12.103(10): Requirements that the IRO be based in Texas and its primary office be located in Texas." The proposed §12.103(10) requirement, however, would not result in additional cost for a small or micro IRO choosing to form in Texas because the IRO would be subject at the time of formation to existing Texas statutory business formation requirements and fees. The Insurance Code §4202.002(c) enacted by HB 4519 requires the Commissioner to adopt standards and rules that

require an IRO to be based and certified in Texas and to locate its primary offices in Texas.

Impact of Proposed new §12.110(b): Requirement to apply for new certification of a newly purchased IRO. Under proposed new §12.110(b), an IRO that has been sold to a new owner must apply for and receive a new certificate before it can operate in Texas as an IRO. Pursuant to §12.406, the fee for the original application for a certificate of registration filed with the Department is $800. While this fee requirement may have an adverse economic impact on small or micro business IROs, the Department anticipates that the updating of the certification application documents to reflect the new ownership will not have an adverse economic impact for the following reasons. The Department anticipates that only a minimal amount of work will be required for the newly purchased IRO to update its certification application documents to reflect the new ownership. This minimal amount of work is expected to result in little or no additional cost. Additionally, updating of the certification application information is already required under the current rules in §12.105(d). As a result of this existing requirement, the Department anticipates that the certification application documents will be substantially up-to-date, which will greatly reduce the amount of time and effort needed to prepare and submit the new application. The Insurance Code §4202.002(c) enacted by HB 4519 requires the Commissioner to adopt standards and rules that require an IRO to apply for and receive a new certification after the organization is sold to a new owner.

Impact of Proposed §12.204(c) on IROs: Prohibition that an IRO may not operate out of the same office or other facility as another IRO. Under proposed §12.204(c), an IRO may not operate out of the same office or other facility as another IRO. Probable costs for small and micro businesses required to comply with the prohibition in proposed §12.204(c) that an IRO may not operate out of the same office or other facility as another IRO will be similar to those costs for a small or micro out-of-state IRO's compliance with the §12.103(10) requirement that the IRO be based in Texas and its primary office be located in Texas. However, if the small or micro IRO business entity is currently registered with the Texas Secretary of State's Office as required under Texas law, there will not be any costs for compliance with the state's registration requirements. As previously explained in the section of this Economic Impact Statement entitled, "*Impact of proposed §12.103(10) on IROs: Requirements that the IRO be based in Texas and its primary office be located in Texas*," in summary, these anticipated costs include: (i) an estimated one-time cost of approximately $2,500 - $3,000 to establish a new physical location; (ii) an estimated one-time cost of approximately $1,500 - $2,000 for new computer hardware and software; and (iii) estimated monthly cost ranging between $1,334 and $2,176 for a general office clerk to handle duties related to re-location. Additionally, there may be an increase in monthly rental or leasing costs as a result of re-locating to Texas. Whether there will be such an increase or a decrease will be related to the rental or leasing costs for office space available in the new location in Texas compared to the rental or leasing costs in the IRO's current location. To the extent that an IRO currently relies upon shared clerical

staff, the Department further anticipates that an IRO may have to hire independent clerical staff to comply with the provision in proposed §12.204(c) that the prohibition against multiple IROs operating form the same office or other facility extends to the shared use of staff, including clerical staff. The Department anticipates that the estimated monthly cost of such clerical staff will range between **$**1,334 and $2,176 for a general office clerk. The monthly salary estimate for a general office clerk is based on information available on the Texas Workforce Commission website. The Department further expects that such additional cost to an IRO for hiring clerical staff will vary for each such IRO depending upon the cost-sharing arrangements used by such IROs and the number of clerical staff employed by the IRO. Additionally, only an IRO that currently shares clerical staff with another IRO as prohibited in §12.204(c)(1) will incur the additional monthly cost for clerical staff.

The Insurance Code §4202.002(c) enacted by HB 4519 requires the Commissioner to adopt standards and rules that prohibit more than one IRO from operating out of the same office or other facility.

Impact of Proposed new §12.303 and §12.502(f) on IROs: Provision that an IRO may not receive assignments for independent review during the proposed period of time that it has voluntarily surrendered its certificate of registration while under investigation or as part of an agreed order. Proposed §12.303(a) provides that upon the request of the Department, an IRO must voluntarily surrender its certificate of registration while the IRO is under investigation or as part of an agreed order. Proposed §12.303(c) provides that independent reviews shall not be assigned to an IRO during a voluntary surrender

of the IRO's certificate of registration. The Department has determined that this requirement may result in costs that will have an adverse economic impact on small or micro business IROs. In summary, the Department estimates that the anticipated lost income for an IRO, including a small or micro business IRO, that does not receive assignments for independent reviews during the period of time that it has voluntarily surrendered its certificates of registration in accordance with proposed §12.303, is approximately $3,730 dollars for each month without any assignments. Proposed §12.502(f)(2) reiterates the same requirement as §12.303 for purposes of readability and ease of compliance. However, there will be no lost income that is in addition to the income lost by any IRO subject to the proposed §12.303 certificate of registration voluntary surrender requirement. The Insurance Code §4202.002(c) enacted by HB 4519 requires the Commissioner to adopt standards and rules to require an IRO to voluntarily surrender its certification while the organization is under investigation or as part of an agreed order.

Impact of Proposed §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) on IROs: Best evidence requirements. Proposed §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) address the best evidence requirements for independent review. Collectively, these provisions establish the general framework within which independent review must be conducted. As part of the application and renewal process, proposed §12.103(1)(A) – (B) requires an IRO to submit a summary of its independent review plan that complies with §12.201 and that includes: (i) a summary description of review criteria and review procedures to be used to determine

medical necessity or appropriateness of health care; and (ii) a summary description of review criteria and review procedures to be used to determine the experimental and investigational nature of health care. Proposed §12.201(3) requires the independent review plan governing the performance of independent review by the IRO to include written medically acceptable review criteria that are, among other requirements, based on medical and scientific evidence and utilize evidence-based standards. Proposed §12.5(11) defines “evidence-based standards” to mean the conscientious, explicit, and judicious use of evidence-based medicine and the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients. Proposed §12.5(10) defines “evidence-based medicine” as the use of current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients. Proposed §12.5(3) defines “best evidence” by establishing a hierarchy, depending on availability of designated categories of evidence, for evidence based on randomized clinical trials, cohort studies or case-control studies, case-series, and expert opinion, in descending order of hierarchical preference. Although the proposed rules do not prescribe the specific review criteria and procedures to be used by the IRO, the Department anticipates that IROs may have to acquire some additional review criteria in order to comply with the consideration of the best evidence hierarchy and to include such consideration as part of the independent review plan and review criteria, summaries of which must be provided to the Department pursuant to proposed

§12.103(1)(A) – (B). The Department has determined that this requirement may result in costs to obtain evidence-based review criteria that may have an adverse economic impact on small or micro business IROs. However, these costs of obtaining evidence-based review criteria will vary for each IRO, including a small or micro business IRO, depending upon: (i) the manner and cost, if any, by which such evidence is available and accessible to the medical community, e.g., whether the criteria is available without charge either in the medical community or on the internet or whether it may be purchased from a third-party; and (ii) the extent to which an IRO already incorporates the best evidence hierarchy into its review criteria. It is not possible for the Department to realistically estimate the costs of such criteria for the following reasons: (i) because the Department does not prescribe the specific review criteria, IROs are free to obtain criteria from any number of sources; (ii) costs will vary from IRO to IRO and from vendor to vendor; and (iii) the Department has no way of knowing which criteria each IRO currently has and which criteria it would need to purchase. Currently certified IROs should already have criteria available and may have most or part of the criteria needed to comply with the new requirements. As a result, all IROs will obtain varying degrees of what is needed to complete its set of criteria. The cost of obtaining such criteria may already be absorbed by the IRO in accordance with its existing independent review plan, but to the extent that the independent review plan does not address best evidence standards, such plans will require amendment. The Department anticipates that the cost of summarizing such criteria will be minimal. Each IRO has information to enable the IRO to estimate any additional costs necessary to comply with these proposed

requirements. These proposed requirements are necessary to promulgate standards and rules for the certification, selection, and operation of IROs to perform independent review pursuant to the Commissioner's rulemaking authority in the Insurance Code §4202.002(a)(1).

Impact of proposed amendments to §12.108(c) and proposed new §12.502(f)(1) on IROs: Prohibition of assignment of independent reviews during certain specified time. Proposed amendments to §12.108(c) prohibit an IRO from being assigned independent reviews during the 30 days prior to the anniversary date of the issuance of the IRO's certificate of registration unless the completed renewal application form has been received by the Department. The Department has determined that this requirement may result in costs that will have an adverse economic impact on small or micro business IROs. In summary, the Department estimates that the anticipated lost income for an IRO, including a small or micro business IRO, subject to the proposed §12.108(c) prohibition will be approximately $3,730 dollars for a full 30-day period without any assignments. Proposed §12.502(f)(1) reiterates this same requirement for purposes of readability and ease of compliance. However, there will be no lost income that is in addition to the income lost by any IRO subject to the proposed §12.108(c) prohibition. These proposed requirements are necessary to promulgate standards and rules for the certification, selection, and operation of IROs to perform independent review pursuant to the Commissioner's rulemaking authority in the Insurance Code §4202.002(a)(1).

Impact of proposed new §12.110(d) on IROs: Provision that independent reviews will not be assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized. Proposed new §12.110(d) prohibits independent reviews from being assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized. The Department has determined that this requirement may result in costs that will have an adverse economic impact on small or micro business IROs. In summary, the Department estimates that the anticipated lost income to an IRO, including a small or micro business IRO that does not receive assignments for independent reviews during the 45 days prior to the date that the sale of the IRO is finalized is approximately $5,595 for the 45 day-period. These proposed requirements are necessary to promulgate standards and rules for the certification, selection, and operation of IROs to perform independent review pursuant to the Commissioner's rulemaking authority in the Insurance Code §4202.002(a)(1).

Impact on URAs and Payors

Impact of proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B) on URAs: Increased costs to URAs and Payors. A cost applicable to URAs and payors, including small and micro business URAs and payors, results from proposed §12.5(1), (16), and (30) and proposed new §12.103(1)(B). The Insurance Code §4201.403 requires a URA, including a payor, as applicable, to pay for an independent review conducted under Chapter 4201, Subchapter I. Section 4201.401, included in Subchapter I, requires a URA, including a payor, as applicable, to allow any party whose appeal of an adverse determination is denied by the URA to seek review of

that determination by an IRO assigned to the appeal in accordance with Chapter 4202. HB 4290 clarifies applicability of independent review on a retrospective basis by amending the definition of “utilization review” to specifically include retrospective review of the medical necessity and appropriateness of health care services. HB 4290 further amends the term to include a system for prospective, concurrent, or retrospective review to determine the experimental or investigational nature of health care services. The proposed rule amendments are consistent with the HB 4290 amendments. Both a URA’s retrospective determination that health care services provided to a patient are not medically necessary or appropriate and a URA’s determination that health care services are experimental or investigational are included within the scope of the term “adverse determinations.” Existing §12.403 provides that fees to be paid to IROs by URAs for each independent review are either $650 for tier one reviews or $460 for tier two reviews. Although this proposal amends §12.403, the prescribed fee amount is not proposed to be changed for either type of review. Because HB 4290 amended the scope of determinations that constitute “adverse determinations,” URAs, and payors, as applicable, will have to pay the appropriate fee for these types of review for both: (i) reviews of a URA’s retrospective determination that health care services provided to a patient are not medically necessary or appropriate; and (ii) reviews of a URA’s determination that health care services are experimental or investigational.

However, this fee may already be in effect for some URAs and payors. Retrospective reviews of medical necessity for workers’ compensation claims are already submitted to an IRO pursuant to Labor Code §413.031 and 28 TAC §133.305

and §133.308. Thus, to the extent that a workers' compensation insurance carrier payor or URA is already required to pay such fees for retrospective reviews under existing statutes and regulations, proposed amendments to §12.5(1) and (16) would not impose an additional cost on these entities. Additionally, pursuant to 28 TAC §133.308, the IRO fee is paid by the non-prevailing party in workers' compensation retrospective reviews. Thus, in some instances, the IRO fee could be paid by the provider and not the URA or payor. Finally, pursuant to Labor Code §413.014(c)(6), preauthorization is required for experimental or investigational health care services in the workers' compensation system. Therefore, these preauthorization disputes are already handled by IROs in the workers' compensation system and proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B) would not impose any additional costs for such disputes.

To the extent that existing statutes or regulations do not already impose a fee on a URA or payor, and proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B) impose additional costs when read together with the existing fees required under §12.403, the Department has determined that proposed §12.5(1), (16), and (30) and proposed new §12.103(1)(B) may have an adverse economic impact on approximately 154 URAs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) and that are required to comply with the proposed rules. There are currently 184 certified URAs and 15 registered URAs in Texas. However, 45 of those 184 certified URAs are certified as URAs for workers' compensation claims only, and therefore, because these URAs are already required to

pay such fees for retrospective reviews under existing statutes and regulations, these entities will not incur additional costs as a result of proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B). Thus, these 45 have been excluded from the adverse economic impact analysis. Additionally, not all of the remaining 154 certified or registered URAs necessarily meet the definition of small or micro business. Thus, the number of small or micro business URAs is no more than 154 certified or registered URAs.

The Department has determined that proposed §12.5(1), (16), and (30) and proposed new §12.103(1)(B) may have an adverse economic impact on approximately 315 - 325 payors that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) and that are required to comply with the proposed rules. This estimate is based on an estimated 30 – 40 health insurers and HMOs that qualify as small or micro businesses and another 285 third party administrators that qualify as small or micro businesses.

The Department's cost analysis and resulting estimated costs for URAs and payors in the Public Benefit/Cost Note portion of this proposal are equally applicable to small or micro business URAs and payors. In summary, the total cost of a URA's or payor's compliance with the fee amount prescribed in §12.403 pursuant to the statutorily expanded scope of independent review requirements will vary for each URA or payor depending upon: (i) the number of retrospective utilization review determinations that health care services are not medically necessary or appropriate; (ii) the number of utilization review determinations that health care services are experimental and

investigational; (iii) the number of requests for independent review that are submitted for both new categories of adverse determination; and (iv) the applicable tier of the particular independent review requested. Each URA and payor has baseline information upon which to estimate this cost. These proposed requirements are necessary to implement Chapter 4201 of the Insurance Code, including amendments to Chapter 4201 under HB 4290, pursuant to the Commissioner's rulemaking authority in the Insurance Code §4201.003(a).

Impact on entities owning more than one IRO

Impact of proposed §12.204(d) on entity owners: Prohibition that an entity may not own more than one IRO. Proposed §12.204(d) prohibits an individual or an entity from owning more than one IRO. The Government Code §2006.002 does not apply to individuals. Sections 2006.001(1) and (2) define a micro business and a small business as being "a legal entity." Therefore, proposed rules that impose requirements that may have an adverse impact on an individual are not subject to an economic impact analysis under §2006.002(c)(1) or the regulatory flexibility provisions of §2006.002(c)(2). An entity or IRO that is required to comply with this prohibition will incur costs related to the divestiture or merger of multiple organizations and potential loss of income. The Department has determined that this requirement may result in costs that will have an adverse economic impact on small or micro business entities or IROs required to comply with this prohibition. The Department does not have any information regarding which entities currently own more than one IRO. However, there may be such entities.

Both divestiture and merger of ownership have inherent costs that will vary based on the ownership structure for each IRO owned in excess of the maximum, but will relate to: (i) the cost of professional services determined by the entity to be necessary to effectuate the divestiture or merger; (ii) the potential gain or loss to the entity attributable to the divestiture or merger transaction, as well as any resulting tax consequences; and (iii) loss of any potential future gain or dividend income resulting from the divestiture or merger, particularly as a result of a sale of the ownership interest. The Department anticipates that the cost of professional services used to effectuate the divestiture or merger if determined necessary may include broker fees, attorney fees, and accountant fees. The Department expects that these fees may vary and that entities making a determination of whether to use these services will be able to determine the cost of such services on an individual basis. Similarly, the gain or loss to an entity attributable to the divestiture or merger transaction will be unique to the entity, as will the resulting tax consequences from that transaction, but each entity has the information necessary to determine this cost. Additionally, if divestiture amounts to closing multiple IRO operations through merger or otherwise, the entity may incur additional costs due to loss of capital investment and cancelation of existing contracts, including property and equipment leases; such costs will be unique to the entity or IRO based upon the nature, scope and duration of such contracts. The amount of lost future gain or dividend income for entities that must divest themselves of ownership interests in IROs will be based on the fact that once the entity has relinquished ownership the entity will no longer be able to realize any potential future increase in value for the

interest or dividend income. This lost potential future gain or income amount may vary greatly for any entity required to comply with proposed §12.204(d). Entities who must comply with this prohibition either have this information or have access to information to enable them to determine the estimated amount of lost future gain or income. Further, this analysis presumes that the entity shall determine the best means of compliance with proposed §12.204(d), including allocation of costs to the extent feasible. The Department anticipates that an entity that owns more than one IRO may incur costs associated with each IRO in excess of the maximum.

Impact on Attorneys and IROs

Impact of Proposed new §12.204(h): Prohibition that an IRO may not employ an attorney to represent the IRO in legal proceedings if the attorney serves or has served in the past as the registered agent for the IRO. Proposed §12.204(h) provides that an IRO may not employ an attorney to represent the IRO in legal proceedings if the attorney serves or has served in the past as the registered agent for the IRO. The Department has determined that proposed §12.204(h) may have an adverse economic impact on approximately 43 attorneys that may qualify as small or micro businesses under the Government Code §2006.001(1) and (2) and that are required to comply with the proposed rules. According to the State Bar of Texas, Department of Research and Analysis' "State Bar of Texas Membership: Attorney Statistical Profile (2008-09)" report, there were approximately 16,170 in-state Texas bar members who were solo practitioners as of December 31, 2008. Based on this figure, the Department estimates that the total pool of attorneys who may be affected by proposed §12.204(h) is an

estimated 16,171 attorneys. Pursuant to the definitions of “small business” and “micro business” under the Government Code §2001.001(1) and (2), the Department is only required to consider the economic impact of proposed rules on legal entities, not on individuals. Thus, only solo practitioners acting in a capacity as a legal entity are subject to analysis in this economic impact statement, e.g., an attorney who has formed a corporation and is the sole owner. The Department did not consider the economic impact on small or micro business law firms with more than one attorney, because proposed §12.204(h) does not prohibit an IRO from using one attorney from a law firm as its registered agent and another attorney from the same law firm to represent the IRO in its legal proceedings. Additionally, there are only 43 IROs certified in the state of Texas. Assuming each IRO has used an average of one attorney as its licensed registered agent, at most there would be 43 attorneys affected by proposed §12.204(h). Based on the Government Code’s definitions of “small business” and “micro business,” it is likely that proposed §12.204(h) affects even fewer attorneys than the Department’s estimated number of 43 attorneys, because only a subset will likely meet the definition of a “legal entity.” To the extent that an attorney is acting only in his or her individual capacity and not as a legal entity, the Department is not required to address potential adverse economic impacts to such individuals. The Government Code §2006.002 does not apply to individuals. Sections 2006.001(1) and (2) define a micro business and a small business as being “a legal entity.” Therefore, proposed rules that impose requirements that may have an adverse impact on an individual are not subject to an

economic impact analysis under §2006.002(c)(1) or the regulatory flexibility provisions of §2006.002(c)(2).

The Department's cost analysis and resulting estimated costs for attorneys in the Public Benefit/Cost Note portion of this proposal are equally applicable to small or micro business attorneys. In summary, the prohibition in §12.204(h) will result in potential lost future income to any attorney that would otherwise have been eligible to represent the IRO in legal proceedings. The amount of this potential lost future income will be based on the number of legal proceedings for which the attorney would have been employed and the amount of the attorney's fees for each such legal proceeding. Each attorney affected by this prohibition has the necessary information to estimate the potential amount of lost income.

Proposed §12.204(h) may also have an adverse impact on the approximately 35 IROs that qualify as small or micro business IROs under the Government Code §2006.001(1) and (2) and that are required to comply with the proposed rule. If each of the 35 small or micro business IROs currently use an attorney as its registered agent, each IRO may incur additional costs for having to hire an additional attorney or attorneys to represent the IRO in legal proceedings. The cost of employing this additional attorney or attorneys will vary based on the costs, if any, in finding the additional attorney or attorneys and the charges for representation. To the extent that the additional attorney fees exceed the amount that would have been charged by the attorney who is the IRO's registered agent, that excess amount may result in an adverse impact to the small or micro business IRO. Each small or micro business IRO

will have the information available to determine the costs and the extent of the adverse economic impact if any. The Insurance Code §4202.002(c) enacted by HB 4519 requires the Commissioner to adopt standards and rules that prohibit an attorney who is, or has in the past served as, the registered agent for an IRO from representing the IRO in legal proceedings.

REGULATORY FLEXIBILITY ANALYSIS

Proposed amendments and new sections that implement HB 4519. There are six proposed amendments and new sections that are necessary to implement HB 4519 and that may also have an adverse economic impact on small or micro business IROs.

Pursuant to the Government Code §2006.002(c-1), an agency must “consider, if consistent with the health, safety, and environmental and economic welfare of the state, using regulatory methods that will accomplish the objectives of applicable rules while minimizing adverse impacts on small businesses.” An agency is not required to consider alternatives that while possibly minimizing adverse impacts on small businesses would not be protective of the health, safety, and environmental and economic welfare of the state. The Final Guidelines (Guidelines) issued by the Office of the Texas Attorney General (April 2008) providing guidance for compliance with the Government Code §2006.002(c-1) state that under §2006.002(c-1), an agency must "consider, if consistent with the health, safety, and environmental and economic welfare of the state, using regulatory methods that will accomplish the objectives of applicable rules while minimizing adverse impacts on small business." The Guidelines further

state that an agency is not required to consider alternatives that, while possibly minimizing adverse impacts on small businesses would not be protective of the health, safety and environmental and economic welfare of the state. According to the Guidelines, one common example appears to fit within this exception. This example is when agencies are required "to adopt as rules specific fees or specific standards and procedures under a legislative or federal mandate." In these situations, "the mandated language may be considered *per se* consistent with the health, safety, or environmental and economic welfare of the state and the agency need not consider other regulatory methods."

HB 4519 mandates that the Commissioner adopt specified standards and rules. HB 4519 amends the Insurance Code §4202.002 to add a new section (c) to read: "In addition to the standards described by Subsection(b) [of the Insurance Code §4202.002], the commissioner shall adopt standards and rules that (1) prohibit: (A) more than one independent review organization from operating out of the same office or other facility; (B) an individual or entity from owning more than one independent review organization; (C) an individual from owning stock in or serving on the board of more than one independent review organization; (D) an individual who has served on the board of an independent review organization whose certification was revoked for cause from serving on the board of another independent review organization before the fifth anniversary of the date on which the revocation occurred; (E) an attorney who is, or has in the past served as, the registered agent for an independent review organization from representing the independent review organization in legal proceedings; and (F) an

independent review organization from disclosing confidential patient information, except to a provider who is under contract to perform the review; and (2) require: (A) an independent review organization to be based and certified in this state and to locate the organization's primary offices in this state; (B) an independent review organization to voluntarily surrender the organization's certification while the organization is under investigation or as part of an agreed order; and (C) an independent review organization to apply for and receive a new certification after the organization is sold to a new owner."

As previously stated, six of the proposed amendments and new sections necessary to implement HB 4519, which may have an adverse economic impact on small or micro business IROs, attorneys, or entities owning more than one IRO, reflect the mandated standards and rules of a legislative mandate, i.e., the Insurance Code §4202.002(c). As a result, in accordance with the Guidelines, "the mandated language may be considered *per se* consistent with the health, safety, or environmental and economic welfare of the state and the agency need not consider other regulatory methods." These six proposed amendments and new sections are: (i) proposed §12.103(10), requiring that the IRO be based in Texas and that its primary office be located in Texas and that evidence of such be included in the application and renewal form that the applicant submits to the Department; (ii) proposed new §12.110(b), requiring the new owner to apply for new certification of a newly purchased IRO; (iii) proposed new §12.204(c), prohibiting an IRO from operating out of the same office or other facility as another IRO; (iv) proposed new §12.204(d), relating to the prohibition of

an entity owning more than one IRO; (v) proposed new §12.204(h), relating to the prohibition of an IRO employing an attorney to represent the IRO under certain specified conditions; (vi) proposed new §12.303 and §12.502(f)(2), providing that an IRO may not receive assignments for independent review during the proposed period of time that it has voluntarily surrendered its certificate of registration while under investigation or as part of an agreed order.

Because these proposed amendments and new sections would constitute rules that adopt specific standards under the legislative mandate in HB 4519, they may be considered *per se* consistent with the health, safety, and environmental and economic welfare of the state, and the Department is not required to consider other regulatory methods. Therefore, pursuant to the Government Code §2006.002(c-1) a regulatory flexibility analysis is not required for these proposed amendments and new sections that implement HB 4519.

Proposed amendments and new sections that implement HB 4290

HB 4290 amends current law relating to retrospective utilization review and utilization review to determine the experimental or investigational nature of a health care service. The legislative intent of HB 4290 is specified in the Senate Committee on State Affairs Bill Analysis for HB 4290. According to this analysis, a study by a national association of health plans found that a majority of states currently have independent review programs that cover either all adverse determinations or all adverse determinations involving medical necessity or services deemed to be experimental. The analysis points out that Texas is the only state with limitations on retrospective reviews

of denials based on medical necessity and the only state with an independent review law that does not extend to retrospective reviews of at least emergency and urgent care. The purpose of the law is (i) to respond to the numerous consumer complaints that have been filed with the Department regarding these issues; (ii) to ensure that carriers have consistent standards for what is considered experimental and investigational. TEXAS SENATE STATE AFFAIRS COMMITTEE, BILL ANALYSIS (Committee Report, Substituted), C.S.H.B. 4290, 81st Leg., R.S. (May 12, 2009).

Proposed amendments to §12.5(1), (16), and (30) and proposed new §12.103(1)(B): Increased costs to URAs and Payors. The Insurance Code §4201.403 requires a URA, including a payor, as applicable, to pay for an independent review conducted under Chapter 4201, Subchapter I. Section 4201.401, included in Subchapter I, requires a URA, including a payor, as applicable, to allow any party whose appeal of an adverse determination is denied by the URA to seek review of that determination by an IRO assigned to the appeal in accordance with Chapter 4202. HB 4290 clarifies applicability of independent review on a retrospective basis by amending the definition of "utilization review" to specifically include retrospective review of the medical necessity and appropriateness of health care services. HB 4290 further amends the term to include a system for prospective, concurrent, or retrospective review to determine the experimental or investigational nature of health care services. The proposed rule amendments are consistent with the HB 4290 amendments. Both a URA's retrospective determination that health care services provided to a patient are not medically necessary or appropriate and a URA's determination that health care

services are experimental or investigational are included within the scope of the term "adverse determinations." Existing §12.403 provides that fees to be paid to IROs by URAs for each independent review are either $650 for tier one reviews or $460 for tier two reviews. Although this proposal amends §12.403, the prescribed fee amount is not proposed to be changed for either type of review. Because HB 4290 amended the scope of determinations that constitute "adverse determinations," URAs and payors, as applicable, will have to pay the appropriate fee for these types of review for both: (i) reviews of a URA's retrospective determination that health care services provided to a patient are not medically necessary or appropriate; and (ii) reviews of a URA's determination that health care services are experimental or investigational.

The other regulatory methods considered by the Department to accomplish the objectives of the statute and the proposal and to minimize any adverse impact on IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) include: (i) lowering fees for small or micro business URAs and payors; and (ii) not adopting proposed §§12.5(1), (16), and (30) and proposed new §12.103(1)(B).

(i) Lowering fees for small or micro business URAs and payors. The Department considered lowering fees for small or micro business URAs and payors. However, as these fees are paid to IROs, including small or micro business IROs, lowering the fees could have an adverse economic impact on the small or micro business IROs. Thus, the Department has determined that such a requirement would be contrary to the purpose of regulatory flexibility under the Government Code §2006.002(b) and (c)(2).

(ii) Not adopting proposed §12.5(1), (16), and (30) and proposed new §12.103(1)(B). If the proposed amendments in §§12.5(1), (16), and (30) and proposed new §12.103(1)(B) are not adopted, the fees would still apply. The effect of this option would be that our rules would be inconsistent with the statute, but the Department's declining to adopt these rules would not affect the statutory requirements for additional types of independent reviews, and the current fees in §12.403 would still apply. Because HB 4290 amended the scope of determinations that constitute "adverse determinations," URAs, and payors would still have to pay the appropriate fee for these types of review for both: (i) reviews of a URA's retrospective determination that health care services provided to a patient are not medically necessary or appropriate; and (ii) reviews of a URA's determination that health care services are experimental or investigational. The Department, therefore, rejected this approach.

Proposed amendments under the general rulemaking authority in the Insurance Code §4202.002(a)(1).

Proposed §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3): Best evidence requirements.

Collectively, proposed §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) establish the general framework within which independent review must be conducted. As part of the application and renewal process, proposed §12.103(1)(A) – (B) requires an IRO to submit a summary of its independent review plan that complies with §12.201 and that includes: (i) a summary description of review criteria and review procedures to be used to determine medical necessity or appropriateness of health

care; and (ii) a summary description of review criteria and review procedures to be used to determine the experimental and investigational nature of health care. Proposed §12.201(3) requires the independent review plan governing the performance of independent review by the IRO to include written medically acceptable review criteria that are, among other requirements, based on medical and scientific evidence and utilize evidence-based standards. Proposed §12.5(11) defines "evidence-based standards" to mean the conscientious, explicit, and judicious use of evidence-based medicine and the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients. Proposed §12.5(10) defines "evidence-based medicine" as the use of current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients. Proposed §12.5(3) defines "best evidence" by establishing a hierarchy, depending on availability of designated categories of evidence, for evidence based on randomized clinical trials, cohort studies or case-control studies, case-series, and expert opinion, in descending order of hierarchical preference. Although the rules do not prescribe the specific review criteria and procedures to be used by the IRO, the Department anticipates that IROs may have to acquire some additional review criteria in order to comply with the consideration of the best evidence hierarchy and to include such consideration as part of the independent review plan and review criteria, summaries of which must be provided to the Department pursuant to proposed §12.103(1)(A) – (B).

The other regulatory methods considered by the Department to accomplish the objectives of the statute and the proposal and to minimize any adverse impact on IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) include: (i) not adopting the proposed regulations; and (ii) not requiring compliance with the proposed regulations for the estimated 35 IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2).

(i) Not adopting the proposed amendments in §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) that contain best evidence requirements. If the proposed amendments in §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) were not adopted, IROs, including IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2), would not have to acquire additional review criteria in order to comply with the consideration of the best evidence hierarchy and to include such consideration as part of the independent review plan and review criteria. The effect of this option would be that those IROs that would otherwise have to incur costs to purchase the review criteria would not have to incur such costs. However, the Department has determined that requiring all IROs to follow this review criteria is important and necessary because (1) it promotes valid and sound decisions when credible and scientific guidelines are utilized. In addition, the use of credible and scientific guidelines promotes confidence in the IRO's decisions because the IRO can support and substantiate its decisions; and (2) it promotes and ensures consistent decisions among all IROs regarding specific health care treatments and services. Proposing the amendments to apply to all IROs, regardless of size, will result

in consistent application of review criteria for all consumers involved in the IRO process. The Department, therefore, determined that the approach of not adopting the proposed amendments is not viable.

(ii) Implementing different requirements or standards for IROs that qualify as small and micro businesses. If the proposed amendments in §§12.5(3), 12.5(10), 12.5(11), 12.103(1)(A) – (B), and 12.201(3) were not made applicable to IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2), the proposal would not result in an adverse economic effect on the small or micro business IROs. However, of the 43 IROs that are currently certified it is estimated that approximately 35 IROs qualify as small or micro businesses under the Government Code §2006.001(1) and (2). Making the rule inapplicable to such a large number of IROs would effectively negate the provision. In addition, requiring only a small number of IROs to comply with these requirements results in an unfair competitive market for a few IROs. The result will be inconsistent application of review criteria for consumers involved in the IRO process. Those consumers who are involved with IROs that are not required to acquire additional review criteria in order to comply with the consideration of the best evidence hierarchy will be subject to a lesser quality of review. Therefore, the Department has determined that this approach is not viable.

Proposed amendments to §12.108(c) and proposed new §12.502(f)(1): Prohibition of assignment of independent reviews during certain specified time. The Insurance Code §4202.002(a) requires the Commissioner to adopt “standards and rules for. . . the certification, selection, and operation of independent review organizations.”

To implement these requirements, current rules at §§12.101 - 12.109 require a certified IRO to annually submit an application for renewal of certificate of registration. If the application for renewal of certificate of registration is not submitted, the IRO will lose its certification. Additionally, current rules at §12.502 establish a process of random assignment of independent reviews to IROs. However, the process establishing random assignment of independent reviews can result in an independent review being assigned to an IRO that needs to complete its annual renewal of certificate of registration, and the current rules do not address what should be done if the IRO is assigned an independent review but then fails to have its certificate of registration renewed before it completes the assigned review. To address this issue, amendments are proposed in §12.108 and §12.502 that prohibit assignment of an independent review to an IRO within the 30 days before the IRO is required to submit its completed annual renewal of certificate of registration.

The other regulatory methods considered by the Department to accomplish the objectives of the statute and the proposal and to minimize any adverse impact on IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) include: (i) not adopting the proposed amendment; and (ii) not requiring compliance with the proposed amendment for the estimated 35 IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2).

(i) Not adopting the proposed amendments in §12.108 and §12.502. If the proposed amendments in §12.108 and §12.502 were not adopted, IROs, including IROs that qualify as small or micro businesses under the Government Code §2006.001(1)

and (2), could be assigned independent reviews within the 30 days before they are required to submit their annual certification renewal and therefore, would not have a loss of income during the 30-day period. However, this alternative approach could also result in situations in which an IRO is assigned an independent review but then fails to have its certificate of registration renewed before it completes the assigned review. The assigning of reviews to an IRO that either does not complete its renewal application or fails to have its certification renewed results in reviews being performed by IROs that do not have statutory authority to perform such reviews. A decision by an unlicensed IRO would not be valid and the review would have to be assigned to a new IRO. This means that there would be delays in issuing decisions, which could result in delaying medically necessary health care services to patients. The Department, therefore, determined that this alternative approach is not viable.

(ii) Not requiring small and micro business IROs to comply with the proposed amendments in §12.108 and §12.502. If the proposal exempted small and micro business IROs from the proposed amendments in §12.108 and §12.502, 35 of the 43 certified IROs could be assigned independent reviews within the 30 days before they are required to submit their annual certification renewal and therefore, would not have a loss of income during the 30-day period. Therefore, the proposal would not have an adverse economic impact on the small and micro business IROs. However, making the rule inapplicable to such a large number of IROs would effectively negate the provision. Therefore, the rule could result in many situations in which an IRO is assigned an independent review but then fails to have its certificate renewed before it completes the

assigned review. The assigning of reviews to an IRO that either does not complete its renewal application or fails to have its certification renewed results in reviews being performed by IROs that do not have statutory authority to perform such reviews. A decision by an unlicensed IRO would not be valid and the review would have to be assigned to a new IRO. This means that there would be delays in issuing decisions, which could result in delaying medically necessary health care services to patients. The Department, therefore, determined that this alternative approach is not viable.

Proposed new §12.110(d): Provision that independent reviews will not be assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized. Proposed new §12.110(d) requires that independent reviews will not be assigned to the IRO during the 45 days prior to the date that the sale of the IRO is finalized. The other regulatory methods considered by the Department to accomplish the objectives of the statute and the proposal and to minimize any adverse impact on IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) include: (i) not adopting proposed new §12.110(d); (ii) adopting a shorter time period of 30 days; and (iii) implementing different requirements for small or micro business IROs.

(i) Not adopting proposed new §12.110(d). If the proposed new §12.110(d) were not adopted, IROs, including IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2), could be assigned independent reviews within the 45 days prior to the date that the sale of the IRO is finalized. The effect of this option would be that those IROs would not have a loss of income during the 45 days

prior to the date the sale of the IRO is finalized. However, another effect of this option would be that the rule would not prevent situations in which an IRO is assigned an independent review but then no longer holds a certificate of registration to conduct independent reviews. Also, the Department would not have sufficient time to consider the details of the sale to ensure that the IRO is not being sold to a "payor," which is prohibited by Chapter 4201. The Department, therefore, rejected this approach.

(ii) Adopting a shorter time period of 30 days. The Department also considered providing that independent reviews will not be assigned to the IRO during the 30 days prior to the date that the sale of the IRO is finalized. The effect of this option would be that the IROs would only have a loss of income for 30 days, instead of the longer 45-day period. However, due to the shorter time period, this approach would more likely result in an IRO being assigned an independent review which could not be completed before the sale of the IRO. The Department, therefore, rejected this approach.

(iii) Implementing different requirements or standards for small or micro business IROs. If the proposed new §12.110(d) was not made applicable to IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2), the proposal would not result in an adverse economic effect on the small or micro business IROs. However, of the 43 IROs that are currently certified it is estimated that approximately 35 IROs qualify as small or micro businesses under the Government Code §2006.001(1) and (2). Making the rule inapplicable to such a large number of IROs would effectively negate the provision, and in most cases the rule would not serve its intended purpose of preventing situations in which an IRO is assigned an

independent review but then no longer holds a certificate of registration to conduct independent reviews. In addition, requiring only a small number of IROs to comply with these requirements results in an unfair competitive market and unfair loss of income for a few IROs. The Department, therefore, rejected this approach.

5. TAKINGS IMPACT ASSESSMENT. The Department has determined that no private real property interests are affected by this proposal and that this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking or require a takings impact assessment under the Government Code §2007.043.

6. REQUEST FOR PUBLIC COMMENT. To be considered, written comments on the proposal must be submitted no later than 5:00 p.m. on July 12, 2010 to Gene C. Jarmon, General Counsel and Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P. O. Box 149104, Austin, Texas 78714-9104. An additional copy of the comment must be simultaneously submitted to Debra Diaz-Lara, Deputy Commissioner, Health and Workers' Compensation Network Certification and Quality Assurance Division, Mail Code 103-6A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104.

The Commissioner will consider the adoption of the proposed amendments and new sections in a public hearing under Docket No. 2714 scheduled for July 15, 2010 at 9:30 a.m. in Room 100 of the William P. Hobby, Jr. State Office Building, 333

Guadalupe Street, Austin, Texas. Written and oral comments presented at the hearing will be considered.

7. STATUTORY AUTHORITY. The amendments and new sections are proposed pursuant to the Insurance Code §4201.003 and §4202.002, the Labor Code §402.00111(b) and §413.031, and the Insurance Code §36.001. The Insurance Code §4201.003 provides that the Commissioner may adopt rules to implement the Insurance Code Chapter 4201. The Insurance Code §4202.002(a) provides that the Commissioner shall promulgate standards and rules for the certification, selection, and operation of IROs to perform independent review. The Insurance Code §4202.002(c) provides that the Commissioner shall adopt standards and rules that prohibit: (i) more than one IRO from operating out of the same office or other facility; (ii) an individual or entity from owning more than one IRO; (iii) an individual from owning stock in or serving on the board of more than one IRO; (iv) an individual who has served on the board of an IRO whose certification was revoked for cause from serving on the board of another IRO before the fifth anniversary of the date on which the revocation occurred; (v) an attorney who is, or has in the past served as, the registered agent for an IRO from representing the IRO in legal proceedings; and (vi) an IRO from disclosing confidential patient information, except to a provider who is under contract to perform the review. The Insurance Code §4202.002(c) also states that the Commissioner shall adopt standards and rules that require: (i) an IRO to be based and certified in this state and to locate the organization's primary offices in this state; (ii) an IRO to voluntarily

surrender the organization's certification while the organization is under investigation or as part of an agreed order; and (iii) an IRO to apply for and receive a new certification after the organization is sold to a new owner. The Labor Code §402.00111(b) provides that the Commissioner of Insurance may delegate to the Commissioner of Workers' Compensation or to that person's designee and may redact any delegation, and the Commissioner of Workers' Compensation may delegate to the Commissioner of Insurance or to that person's designee, any power or duty regarding workers' compensation imposed on the Commissioner of Insurance or the Commissioner of Workers' Compensation under the Labor Code Title 5, including the authority to make final orders or decisions. The Labor Code §413.031 provides that a review of the medical necessity of a health care service requiring preauthorization under §413.014 or commissioner rules under that section or §413.011(g) shall be conducted by an IRO under Chapter 4202, Insurance Code, in the same manner as reviews of utilization review decisions by health maintenance organizations. The Insurance Code §36.001 provides that the Commissioner of Insurance may adopt any rules necessary and appropriate to implement the powers and duties of the Texas Department of Insurance under the Insurance Code and other laws of this state.

8. CROSS REFERENCE TO STATUTE. The following statutes are affected by this proposal:

Rule	Statute
§12.1	Insurance Code §§4202.001 – 4202.010

§12.2	Insurance Code §4202.002
§12.4	Insurance Code §§1305.355; 4201.054; and 4202.001 – 4202.010; Labor Code §402.00111 and §413.031
§12.5	Insurance Code §4201.002
§12.6	Insurance Code §4202.002, §4201.054, and Chapter 1305; Labor Code §402.00111 and Chapters 408 and 413
§§12.101 – 12.106, 12.108, and 12.110	Insurance Code §§4201.002, 4202.002, 4202.004, and 4202.005
§§12.201, 12.202, and 12.204 – 12.207	Insurance Code §1305.355 and §4202.002; Labor Code §§408.0043 – 408.0045 and 413.031
§12.208	Insurance Code §4202.002 and §4202.009
§§12.301 – 12.303	Insurance Code §4202.002, §4202.007, and Chapters 1305 and 4202; Labor Code §402.00111 and Chapters 408, 409, and 413
§§12.402 – 12.406	Insurance Code §4202.002 and §4202.006
§§12.501 – 12.502	Insurance Code §4202.002

9. TEXT.

SUBCHAPTER A. GENERAL PROVISIONS

§12.1. Statutory Basis. This chapter implements the [~~provisions of~~] Insurance Code Chapter 4202 as of September 1, 2009 [~~Senate Bill 386 enacted by Acts 1997, 75th~~

~~Legislature, Regular Session, codified as the Texas Insurance Code, Article 21.58C, effective September 1, 1997~~].

§12.2. Severability Clause. If [~~Where any terms or sections of this chapter are determined by~~] a court of competent jurisdiction holds that any provision of this chapter is inconsistent with any statutes of this state, is unconstitutional, or is invalid for any reason, [~~to be inconsistent with any statutes of this state or these United States, or to be unconstitutional,~~] the remaining [~~terms and~~] provisions of this chapter shall remain in effect.

§12.4. Applicability.

(a) All independent review organizations performing independent reviews of adverse determinations made [~~in Texas as requested~~] by utilization review agents, health insurance carriers, health maintenance organizations, and managed care entities, [~~regardless of where the independent review activities are physically based,~~] must comply with this chapter. Independent review organizations performing independent reviews of adverse determinations made by certified workers' compensation health care networks and workers' compensation insurance carriers must comply with this chapter, subject to §12.6 of this subchapter (relating to Independent Review of Adverse Determinations of Health Care Provided Pursuant to the Labor Code Title 5, or the Insurance Code Chapter 1305).

(b) This chapter is applicable to all requests for independent review filed with the department on or after October 16, 2010. All independent reviews filed with the department prior to October 16, 2010 shall be subject to the rules in effect at the time the independent review was filed with the department.

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

[~~(1) Act--Insurance Code, Article 21.58C, entitled Standards for Independent Review Organizations.~~]

[~~(2) Active practice--20 hours per week in the examination, diagnosis, and/or treatment of patients.~~]

[~~(3) Administrator--A person holding a certificate of authority under the Insurance Code , Article 21.07-6.~~]

(1)[~~(4)~~] Adverse determination--A determination by a utilization review agent made on behalf of any payor that the health care services provided [~~furnished~~] or proposed to be provided [~~furnished~~] to a patient are not medically necessary or [~~not~~] appropriate, or are experimental or investigational.

(2)[~~(5)~~] Affiliate--A person who directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the person specified.

(3) Best evidence--Evidence based on:

(A) randomized clinical trials;

(B) if randomized clinical trials are not available, cohort studies or case-control studies;

(C) if subparagraphs (A) and (B) are not available, case-series; or

(D) if subparagraphs (A), (B) and (C) are not available, expert opinion.

(4) Case-control studies--A retrospective evaluation of two groups of patients with different outcomes to determine which specific interventions the patients received.

(5) Case-series--An evaluation of a series of patients with a particular outcome, without the use of a control group.

(6) Cohort studies--A prospective evaluation of two groups of patients with only one group of patients receiving a specific intervention(s).

(7)[~~(6)~~] Commissioner--The Commissioner of Insurance.

(8)[~~(7)~~] Department--Texas Department of Insurance.

[~~(8) Dental plan--An insurance policy or health benefit plan, including a policy written by a company subject to the Insurance Code Chapter 842 [20], that provides coverage for expenses for dental services.~~]

(9) Dentist--A licensed doctor of dentistry holding either a D.D.S. or a D.M.D. degree.

(10) Evidence-based medicine--The use of current best quality scientific and medical evidence formulated from credible scientific studies, including peer-

reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients.

(11) Evidence-based standards--The conscientious, explicit, and judicious use of evidence-based medicine and the current best evidence based on the overall systematic review of the research in making decisions about the care of individual patients.

[~~(10) Emergency care--Health care services provided in a hospital emergency facility or comparable facility to evaluate and stabilize medical conditions of a recent onset and severity, including but not limited to severe pain, that would lead a prudent layperson possessing an average knowledge of medicine and health to believe that his or her condition, sickness, or injury is of such a nature that failure to get immediate medical care could result in:~~]

[~~(A) placing the patient's health in serious jeopardy;~~]

[~~(B) serious impairment to bodily functions;~~]

[~~(C) serious dysfunction of any bodily organ or part;~~]

[~~(D) serious disfigurement; or~~]

[~~(E) in the case of a pregnant woman, serious jeopardy to the health of the fetus.~~]

(12) Expert opinion--A belief or an interpretation by specialists with experience in a specific area about the scientific evidence pertaining to a particular service, intervention, or therapy.

(13)[~~(11)~~] Health benefit plan--A plan of benefits that defines the coverage provisions for health care offered or provided by any organization, public or private, other than health insurance.

(14)[~~(12)~~] Health care provider or provider--A [~~Any~~] person, corporation, facility, or institution that is:[~~,~~]

(A) licensed by a state to provide or otherwise lawfully providing health care services; and [~~, that is~~]

(B) eligible for independent reimbursement for those services.

(15)[~~(13)~~] Health insurance policy--An insurance policy, including a policy written by a corporation subject to the Insurance Code[~~,~~] Chapter 842 [~~20~~], that provides coverage for medical or surgical expenses incurred as a result of accident or sickness.

(16)[~~(14)~~] Independent review--A system for final administrative review by a designated independent review organization of an adverse determination regarding the medical necessity and appropriateness or the experimental or investigational nature of health care services [~~being provided or proposed to be provided to an individual who resides within the state by a designated independent review organization~~].

(17)[~~(15)~~] Independent review organization or IRO--An entity that is certified by the commissioner to conduct independent review under the authority of the Insurance Code Chapter 4202 [~~Act~~]. Such entity must have the capacity for independent review of all specialty classifications and subspecialties thereof contained in the two tiered structure of specialty classifications set forth in §12.402 of this chapter [~~title~~] (relating to Classification [~~Classifications~~] of Specialty).

(18)[~~(16)~~] Independent review plan--The review [~~screening~~] criteria and review procedures of an independent review organization.

(19) Legal holiday-- A holiday:

(A) as provided in the Government Code §662.003(a), including New Year's Day; Martin Luther King, Jr. Day; Presidents' Day; Memorial Day; Independence Day; Labor Day; Veterans Day; Thanksgiving Day; and Christmas Day; and

(B) as provided in §102.3(b) of this title, (relating to Computation of Time), the Friday after Thanksgiving Day; December 24th; and December 26th.

(20)[~~(17)~~] Life-threatening condition--A disease or condition for which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(21)[~~(18)~~] Medical and scientific evidence--Evidence found in [~~derived from~~] the following sources:

(A) peer-reviewed[~~Peer reviewed~~] scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;[~~.~~]

(B) peer-reviewed medical[~~Peer reviewed~~] literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus

(Medline) and Elsevier Science Ltd. for indexing in[~~,~~] Excerpt--Medicus (EMBASE);[~~, Medline, and MEDLARS database Health Services Technology Assessment Research (HSTAR).~~]

(C) medical[~~Medical~~] journals recognized by the Secretary of Health and Human Services, pursuant to [~~under~~] Section 1861(t)(2) [~~1961(t)(2)~~] of the federal Social Security Act;[~~,~~]

(D) the[~~The~~] following standard reference compendia:

(i) the American Hospital Formulary Service Drug Information;[~~,~~]

(ii) Drug Facts and Comparisons, current edition as published by Lippincott Williams & Wilkins;[~~the American Medical Association Drug Evaluation,~~]

(iii) the American Dental Association Accepted Dental Therapeutics;[~~,~~] and

(iv) the United States Pharmacopoeia--Drug Information;[~~,~~]

(E) findings[~~Findings~~], studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including:

(i) the Federal Agency for Healthcare Research and Quality;[~~Health Care Policy and Research,~~]

(ii) the National Institutes of Health;[,]

(iii) the National Cancer Institute;[,]

(iv) the National Academy of Sciences;[~~,Health Care Financing Administration, Congressional Office of Technology Assessment,~~]

(v) the Centers for Medicare & Medicaid Services;

(vi) the federal Food and Drug Administration; and

(vii) any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services;[~~.~~]

(F) for independent review of adverse determinations of health care provided pursuant to the Labor Code Title 5, the treatment guidelines, treatment protocols, and pharmacy closed formulary as provided in applicable orders issued or rules adopted by the TDI-DWC pursuant to the Labor Code §408.028 and §413.011, including Chapter 134 of this title (relating to Benefits—Guidelines for Medical Services, Charges, and Payments) and Chapter 137 of this title (relating to Disability Management); or [~~Peer reviewed abstracts accepted for presentation at major medical association meetings.~~]

(G) any other medical or scientific evidence that is comparable to the sources listed in subparagraphs (A) - (F) of this paragraph.

(22)[~~(19)~~] Nurse--A [~~professional or~~] registered or professional nurse, a licensed vocational nurse, or a licensed practical nurse.

[~~(20) Open records law--Chapter 552, Government Code.~~]

(23)[~~(21)~~] Patient--The enrollee or an eligible dependent of the enrollee under [~~A person covered by~~] a health benefit plan or health insurance policy, or a person entitled to receive workers' compensation benefits pursuant to the Labor Code

Title 5. [~~or health benefit plan on whose behalf independent review is sought. This term includes a person who is covered as an eligible dependent of another person.~~]

(24)[~~(22)~~] Payor--

(A) an [~~An~~] insurer that writes [~~writing~~] health insurance policies;

(B) a preferred provider organization, [~~any~~] health maintenance organization, or self-insurance plan;[~~,~~] or

(C) any other person or entity that [~~which~~] provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits, including workers' compensation benefits as provided under the Insurance Code §4201.054, to persons treated by a health care provider in this state under a [~~pursuant to any~~] policy, plan, or contract.

(25)[~~(23)~~] Person--An individual, corporation, partnership, association, joint stock company, trust, unincorporated organization, any similar entity, or any combination of the foregoing acting in concert.

(26)[~~(24)~~] Physician--A licensed doctor of medicine or a doctor of osteopathy.

(27) Primary office--The headquarters of an independent review organization and the place where, based upon the totality of the business activities related to independent review performed under this chapter, the principal business affairs and essential business functions of the independent review organization occur, including the following:

(A) bookkeeping and other recordkeeping;

(B) payroll maintenance;

(C) receipt of business telephone calls;

(D) receipt of correspondence;

(E) storing of books and records; and

(F) directing, controlling, and coordinating activities and policies by officers, principals, and managers.

(28)[~~(25)~~] Provider of record--The physician or other health care provider that has primary responsibility for the care, treatment, and services rendered or requested on behalf of the patient;[~~,~~] or the physician or health care provider that has rendered or has been requested to provide the care, treatment, or [~~and/or~~] services to the patient. This definition includes any health care facility where treatment is rendered on an inpatient or outpatient basis.

(29) Randomized clinical trial--A controlled, prospective study of patients that have been randomized into an experimental group and a control group at the beginning of the study with only the experimental group of patients receiving a specific intervention, which includes study of the groups for variables and anticipated outcomes over time.

(30)[~~(26)~~] Review [~~Screening~~] criteria--The written policies, medical protocols, previous decisions and/or guidelines used by the independent review organization to make [~~preliminary~~] decisions about the medical necessity or [~~and~~] appropriateness of a treatment, procedure, or service or the experimental or investigational nature of a treatment, procedure, or service.

(31) TDI-DWC--The Texas Department of Insurance, Division of Workers' Compensation.

(32)[~~(27)~~] Utilization review agent--A person holding a certificate of registration under the Insurance Code Chapter 4201[~~, Article 21.58A~~].

(33)[~~(28)~~] Working day--A weekday that is not a legal holiday.[~~, excluding New Years Day, Memorial Day, Fourth of July, Labor Day, Thanksgiving Day, and Christmas Day.~~]

§12.6. Independent Review of Adverse Determinations of Health Care Provided Pursuant to the Labor Code Title 5, or the Insurance Code Chapter 1305.

(a) Review of the medical necessity or appropriateness of a health care service provided under the Labor Code Chapter 408 or Chapter 413 shall be conducted under this chapter in the same manner as reviews of utilization review decisions by health maintenance organizations.

(b) Notwithstanding subsection (a) of this section, for independent review of adverse determinations of health care provided pursuant to the Labor Code Title 5 or the Insurance Code Chapter 1305:

(1) independent review organizations and personnel conducting independent review must comply with the Labor Code Title 5 and applicable TDI-DWC rules;

(2) in the event of a conflict between this chapter and the Labor Code, the Labor Code controls; and

(3) in the event of a conflict between this chapter and TDI-DWC rules, TDI-DWC rules control.

SUBCHAPTER B. CERTIFICATION OF INDEPENDENT REVIEW ORGANIZATIONS

§12.101. Where to File Application. An application for a certificate of registration and for renewal of a certificate of registration as [~~certification of~~] an independent review organization and certification or renewal fee must be filed with the Texas Department of Insurance at the following address: Texas Department of Insurance, Mail Code 103-6A [~~108-6A~~], P.O. Box 149104, Austin, Texas 78714-9104.

§12.102. Application and Renewal of Certificate of Registration Form; How to Obtain Forms.

(a) The commissioner adopts by reference Form No. LHL006 (IRO Application Form) to be used for application for a certificate of registration and for renewal of a certificate of registration as an independent review organization in this state.

(b) The commissioner adopts by reference Form No. FIN311 (Biographical Affidavit) to be used as an attachment to Form No. LHL006 (IRO Application Form), the application for the certificate of registration and for renewal of a certificate of registration as an independent review organization in this state.

(c) The forms are available at http://www.tdi.state.tx.us/forms. The [~~application~~] forms may also [~~must be submitted on a form which can~~] be obtained from the Texas

Department of Insurance, Mail Code 103-6A [~~108-6A~~], 333 Guadalupe, P.O. Box 149104, Austin, Texas 78714-9104.

§12.103. Information Required in Application and Renewal Form. Form No. LHL006 requires information necessary for the commissioner to properly determine whether an applicant is qualified to be certified as an independent review organization pursuant to the Insurance Code §4202.004, including: [~~The applicant must provide information required by the commissioner, which includes, but is not limited to, the following:~~]

(1) a summary of the independent review plan that [~~which~~] meets the requirements of §12.201 of this chapter [~~title~~] (relating to Independent Review Plan) and must include:

(A) a summary description of review [~~screening~~] criteria and review procedures to be used to determine medical necessity or [~~and~~] appropriateness of health care;

(B) a summary description of review criteria and review procedures to be used to determine the experimental or investigational nature of health care;

(C)[~~(B)~~] a certification signed by an authorized representative that such review [~~screening~~] criteria and review procedures to be applied in review determinations are established with input from appropriate health care providers and approved by physicians in accordance with §12.201(3) of this chapter [~~title (relating to Independent Review Plans)~~]; and

(D)[~~(C)~~] procedures ensuring that the information regarding the reviewing physicians and providers is updated in accordance with §12.105(d) of this subchapter [~~title~~] (relating to Revisions During Review Process) and §12.108(e) of this subchapter [~~title~~] (relating to Renewal of Certificate of Registration) to ensure the independence of each health care provider or physician making review determinations.

(2) copies of policies and procedures which ensure that all applicable state and federal laws to protect the confidentiality of medical records and personal information are followed. These procedures must comply with §12.208 of this chapter [~~title~~] (relating to Confidentiality);

(3) a certification signed by an authorized representative that the independent review organization will comply with the [~~provisions of the~~] Insurance Code Chapter 4202 [~~Act~~].

(4) a description of personnel and credentialing, and a completed profile for each physician and provider, both as described in §12.202 of this chapter [~~title~~] (relating to Personnel and Credentialing);

(5) a description of hours of operation and how the independent review organization may be contacted after hours, during weekends and holidays, as set forth in §12.207 of this chapter [~~title~~] (relating to Independent Review Organization [~~Organization's~~] Telephone Access);

(6) the organizational information, documents and all amendments, including:

(A) (No change.)

(B) for an applicant that is publicly held, the name of each stockholder or owner of more than five percent [~~5.0 %~~] of any stock or options;

(C) (No change.)

(D) a chart showing contractual arrangements of the applicant [~~independent review system~~].

(7) - (8) (No change.)

(9) biographical information about officers, directors, and executives, including information requested in Form No. FIN311 (Biographical Affidavit) as required in §12.102(b) of this subchapter (relating to Application and Renewal of Certificate of Registration Form; How to Obtain Forms):

(A) the applicant [~~independent review organization~~] must submit the name, [~~and~~] biographical information, and, in compliance with §1.503 and §1.504 of this title (relating to Application of Fingerprint Requirement and Fingerprint Requirement), a complete set of fingerprints for each director, officer, and executive of the applicant, any entity listed under paragraph (8) of this section, and a description of any relationship the named individual has which represents revenue equal to or greater than five percent [~~5.0 %~~] of that individual's [~~person's~~] total annual revenue or which represents a holding or investment worth $100,000 or more in any of the following entities:

(i) - (vi) (No change.)

(vii) a health care provider; [~~or~~]

(viii) another independent review organization; or

(ix) a group representing any of the entities described by clauses (i) - (viii) of this subparagraph.

(B) the applicant must identify any relationship between the applicant [~~independent review organization~~] and any affiliate or other organization in which an officer, director, or employee of the applicant [~~independent review organization~~] holds a five percent [~~5.0 %~~] or more interest;

(C) the applicant must submit a list of any currently outstanding loans or contracts to provide services between the applicant and any [~~the~~] affiliates;

(10) evidence that the applicant is based in this state and that its primary office is located in this state. [~~information related to out-of-state licensure and service of legal process. All applicants must furnish a copy of the certificate of registration or other licensing document from the domiciliary state's licensing authority.~~] As a condition of being certified to conduct the business of independent review in this state, an independent review organization must be based in this state and must locate its primary office in this state [~~that maintains its principal offices or any portion of its books, records, or accounts outside this state must appoint and maintain a person in this state as attorney for service of process on whom all judicial and administrative process, notices, or demands may be served, and must notify the department of any change of appointment or appointee's address immediately~~];

(11) the percentage of the applicant's revenues that are anticipated to be derived from independent reviews conducted; and[~~.~~]

(12) a disclosure of any enforcement actions related to the provision of medical care or conducting of medical reviews taken against a person subject to the fingerprint requirements under §1.503 and §1.504 of this title.

§12.104. Review of Application. The application process is as follows:

(1) After review, the department shall [either] certify the application, provide the applicant written notice of any omissions or deficiencies noted as a result of the review conducted pursuant to this section, or deny the application[, and give the applicant written notice of any omission or deficiencies noted as a result of the review conducted pursuant to this section].

(2) (No change.)

(3) The applicant may waive any of the time limits specified [described] in this section [subsection], except as set forth in paragraph (2) of this section. The applicant may waive the time limit in paragraph (2) of this section [subsection] only with the consent of the department.

(4) Department staff shall notify the applicant of any omission or deficiencies noted during its review[,] and inform the applicant that the application will [shall] be denied, absent corrections. If the time required for the revisions will exceed 30 days, the applicant must request additional time within which to make the revisions. In the request, the [The] applicant must specifically set out the length of time requested, not to exceed 90 days,[.] and must include [Additional delays may be requested. The request for any additional delays must set out the need for the additional delay in]

sufficient detail for the commissioner or the commissioner's [~~his or her~~] designee to determine whether good cause for such extension [~~delay~~] exists. [~~The department must review all revisions within 60 days of receipt.~~] The commissioner or the commissioner's [~~his or her~~] designee may grant or deny any request for an extension of time at the [~~his or her~~] discretion of the commissioner or the commissioner's designee. The department shall review all revisions and take action as provided in paragraph (1) of this section.

(5) (No change.)

§12.105. Revisions During Review Process.

(a) Revisions during the review of the application must be addressed to: Texas Department of Insurance, Mail Code 103-6A [~~108-6A~~], 333 Guadalupe, P.O. Box 149104, Austin, Texas 78714-9104. [~~The applicant must include an original and one copy of the transmittal letter, plus the original and one copy of any revision required by this subchapter.~~]

(b) The applicant must submit an original plus one copy of any revised page required by the department pursuant to this subchapter. Each revision to the organizational document or bylaws must be accompanied by the notarized certification of an officer or authorized representative of the applicant that the item submitted is true, accurate, and complete, and, if the item is a copy, by a notarized certification that the copy is a true, accurate, and complete copy of the original.

(c) If a page is to be revised, all copies of the revised page submitted by the applicant must [~~a complete new page~~] contain [~~must be submitted with~~] the changed

item or information "red-lined" or otherwise clearly designated. [~~on all copies except the~~] The original revised page required to be submitted under subsection (b) of this section[~~, which~~] shall be placed in the charter file maintained by the department.

(d) The independent review organization shall report any material changes in the information in the application required by §12.102 of this subchapter (relating to Application and Renewal of Certificate of Registration Form; How to Obtain Forms) or renewal form required by §12.108 of this subchapter (relating to Renewal of Certificate of Registration) [~~referred to in this chapter~~] not later than the 30th day before the date on which the change takes effect.

(e) – (f) (No change.)

§12.106. Qualifying Examinations. The commissioner or the commissioner's [~~his or her~~] designee may conduct an on-site qualifying examination of an applicant as a requirement of certification or a renewal of certification as an independent review organization. Documents that support the application for the certificate of registration or renewal of the certificate of registration must be available for inspection at the time of such qualifying examination at the primary office [~~administrative offices~~] of the independent review organization.

§12.108. Renewal of Certificate of Registration.

(a) (No change.)

(b) An independent review organization must apply for renewal of its certificate of registration every year, not later than the anniversary date of the issuance of the registration. Form No. LHL006 (IRO Application for Certificate of Registration), adopted by reference in §12.102 of this subchapter (relating to Application and Renewal of Certificate of Registration Form; How To Obtain Forms), [~~A renewal form~~] must be used for this purpose. Form No. LHL006 [~~The renewal form~~] can be obtained from the website and from the address listed in §12.102 of this subchapter [~~title (relating to How to Obtain Forms)~~]. The completed renewal form, a summary of the current review [~~screening~~] criteria, renewal fee, and a certification that no material changes exist that have not already been filed with the department must be submitted to the department at the address listed in §12.101 of this subchapter [~~title~~] (relating to Where To File Application). Material changes shall include changes relating to physicians or providers performing independent review.

(c) An independent review organization may continue to operate under its certificate of registration after a completed renewal application form, application fee, and a summary of the current review [~~screening~~] criteria have [~~has~~] been [~~timely~~] received by the department until the renewal is finally denied or issued by the department. However, independent reviews will not be assigned to an independent review organization during the 30 days prior to the anniversary date of the issuance of the independent review organization's certificate of registration unless a completed renewal application form and the application fee have been received by the department.

(d) If a completed renewal application form and a summary of the review [~~screening~~] criteria are [~~is~~] not received prior to the anniversary date of the year in which the certificate of registration must be renewed, the certificate of registration will automatically expire and the independent review organization must complete and submit a new application for certificate of registration.

(e) The independent review organization shall report any material changes in the information required in Form No. LHL006 [~~the application or renewal form referred to in this chapter~~], including changes relating to physicians and providers performing independent review, not later than the 30th day before the date on which the change takes effect.

(f) - (g) (No change.)

(h) Until the certificate of registration renewal application process is complete or the certificate of registration expires, an independent review organization must:

(1) continue to perform its duties pursuant to the Insurance Code Chapter 4202, the Labor Code, and department and TDI-DWC rules, including maintenance and retention of medical records and patient-specific information pursuant to §12.208 of this chapter (relating to Confidentiality); and

(2) in regard to reviews of the medical necessity of a health care service provided under the Labor Code Title 5 or Insurance Code Chapter 1305, make responses to requests for letters of clarification pursuant to §133.308 of this title (relating to MDR by Independent Review Organizations).

§12.110. Effect of Sale of an Independent Review Organization.

(a) Non-transferability of Certificate. An independent review organization's certificate is non-transferable, and an independent review organization must surrender its certificate upon sale of the independent review organization.

(b) Effect of Sale. An independent review organization that has been sold to a new owner must apply for and receive a new certificate pursuant to this subchapter before it can operate as an independent review organization.

(c) Notification of Sale. An independent review organization must notify the department of an impending sale in writing at least 90 days prior to the date the sale will be finalized. The notification must include the date on which the sale is anticipated to be finalized, and the independent review organization must provide a revised notification of impending sale if the anticipated date for finalization of the sale changes. The notification must be filed with the Texas Department of Insurance at the following address: Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104.

(d) Obligation to Continue Performing Duties Prior to Sale. An independent review organization must continue to perform all duties prior to the date that the sale of the independent review organization is finalized. Independent reviews will not be assigned to the independent review organization during the 45 days prior to the date that the sale of the independent review organization is finalized. Notification of the impending sale of an independent review organization does not negate the independent review organization's obligation to continue to perform its duties pursuant to the

Insurance Code Chapters 1305 and 4202, the Labor Code Title 5, and applicable department and TDI-DWC rules.

(e) Activities Following a Sale. Upon the sale of an independent review organization, the new owner is prohibited from performing the duties of an independent review organization specified in this chapter, the Insurance Code Chapters 1305 and 4202, the Labor Code Title 5, and applicable department and TDI-DWC rules prior to certification of the independent review organization pursuant to its new ownership.

SUBCHAPTER C. GENERAL STANDARDS OF INDEPENDENT REVIEW

§12.201. Independent Review Plan. Independent review shall be conducted in accordance with an [~~The~~] independent review plan that is consistent [~~shall be conducted in accordance~~] with standards developed with input from appropriate health care providers, and reviewed and approved by a physician. The independent review plan shall include the following components:

(1) (No change.)

(2) written procedures for:

(A) notification of the independent review organization's determinations provided to the patient or a person acting on behalf of the patient, the patient's provider of record, and the utilization review agent, in accordance with [~~as addressed in~~] §12.206 of this subchapter [~~title~~] (relating to Notice of Determinations Made by Independent Review Organizations);

(B) - (C) (No change.)

(D) contacting and receiving information from health care providers in accordance with §12.205 of this subchapter [~~title~~] (relating to Independent Review Organization [~~Organization's~~] Contact with and Receipt of Information from Health Care Providers and Patients);

(3) [~~screening criteria. Each independent review organization shall~~] required use of [~~utilize~~] written medically acceptable review [~~screening~~] criteria that [~~which~~] are:

(A) based on medical and scientific evidence and utilize evidence-based standards;

(B) established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers; [~~. Such screening criteria must be~~]

(C) objective, clinically valid, compatible with established principles of health care, and flexible enough to allow deviations from the norms when justified on a case-by-case basis;[~~.~~]

(D) developed based on consideration of the treatment guidelines, treatment protocols, and pharmacy closed formulary as provided in orders issued or rules adopted by TDI-DWC, including Chapter 134 of this title (relating to Benefits--Guidelines for Medical Services, Charges, and Payments) and Chapter 137 of this title (relating to Disability Management) for health care provided pursuant to the Labor Code Title 5;

(E) [~~Screening criteria must~~] used only [~~be used~~] as a tool in the review process; and[~~.~~]

(F) [~~Such written screening criteria and review procedures shall be~~] available for review, [~~and~~] inspection, and copying as necessary by the commissioner or the commissioner's [~~his or her~~] designated representative in order for the commissioner to carry out the commissioner's [~~his or her~~] lawful duties under the Insurance Code;

(4) independent review determinations that:[~~.~~]

(A) [~~Each independent review organization shall~~] utilize review procedures that [~~which~~] are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers;[~~.~~]

(B) [~~Independent review determinations shall be~~] are made in accordance with medically accepted review [~~screening~~] criteria, taking into account the special circumstances of each case that may require a deviation from the norm; and [~~.~~]

(C) [~~All independent review determinations shall be~~] are made by physicians, dentists, or other health care providers, as appropriate.

§12.202. Personnel and Credentialing.

(a) (No change.)

(b) The independent review organization is required to provide to the commissioner the number, type, and minimum qualifications of the personnel either employed or under contract to perform the independent review. Independent review

organizations are [~~shall be~~] required to adopt written procedures used to determine whether physicians or other health care providers utilized by the independent review organization are licensed, qualified, in good standing, and appropriately trained, and [~~must~~] maintain records on such. In addition, the independent review organization is required to [~~must~~] maintain complete profiles of anyone conducting independent review. Such profiles are required to [~~must~~] include all information required by the department in its application form[~~,~~] and [~~must~~] to be kept current and made available for review by the department and TDI-DWC upon request.

(c) - (d) (No change.)

(e) Notwithstanding subsections (c) and (d) of this section, a physician, [~~or~~] dentist, or other person who performs independent review whose license has been revoked by any state licensing agency in the United States is not eligible to direct or conduct independent review.

(f) Notwithstanding subsection (c) of this section, an independent review organization that performs independent review of a health care service provided under the Labor Code Title 5 or the Insurance Code Chapter 1305 shall comply with the licensing and professional specialty requirements for personnel performing independent review as provided by the Labor Code §§408.0043 - 408.0045 and 413.031; the Insurance Code §1305.355; and Chapters 133 and 180 of this title (relating to General Medical Provisions and Monitoring and Enforcement).

§12.204. Prohibitions of Certain Activities and Relationships of Independent Review Organizations and Individuals or Entities Associated with Independent Review Organizations.

(a) An independent review organization shall not set or impose any notice or other review procedures that are contrary to the requirements of the health insurance policy or health benefit plan unless those requirements are [~~other than those~~] set forth in this chapter or Texas law.

(b) (No change.)

(c) An independent review organization may not operate out of the same office or other facility as another independent review organization.

(1) This prohibition extends to the shared use by independent review organizations of the resources and staff that comprise an office, including: office space, telephone and fax lines, electronic equipment, supplies, and clerical staff.

(2) This prohibition does not extend to the use of subcontractor services or personnel employed by or under contract with the independent review organization to perform independent review.

(d) An individual or an entity may not own more than one independent review organization.

(e) An individual may not own stock in more than one independent review organization.

(f) An individual may not serve on the board of more than one independent review organization.

(g) An individual who has served on the board of an independent review organization that has had its certification revoked for cause may not serve on the board of another independent review organization earlier than the fifth anniversary of the date on which the revocation occurred.

(h) An independent review organization may not employ an attorney to represent the independent review organization in legal proceedings if the attorney serves or has served in the past as the registered agent for the independent review organization.

§12.205. Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients.

(a) A health care provider may designate one or more individuals as the initial contact or contacts for independent review organizations seeking routine information or data. In no event shall the designation of such an individual or individuals preclude an independent review organization or medical director [~~advisor~~] from contacting a health care provider or others in his or her employ where a review might otherwise be unreasonably delayed or where the designated individual is unable to provide the necessary information or data requested by the independent review organization.

(b) (No change.)

(c) In addition to pertinent files containing medical and personal information, the utilization review agent[~~,~~] or the health insurance carrier, health maintenance organization, [~~or~~] managed care entity, or other payor requesting the independent review shall be responsible for timely delivering to and ensuring receipt by the

independent review organization of any written narrative supplied by the patient pursuant to the Insurance Code Chapter 4201 and Chapters 19 and 133 of this title (relating to Agents' Licensing and General Medical Provisions [~~, Article 21.58A~~]. However, in instances of [~~emergency or~~] life-threatening condition, the independent review organization shall contact the patient or person acting on behalf of the patient, and provider directly.

(d) An independent review organization shall notify the department if, within three working days [~~24 hours~~] of receipt of the independent review assignment, the independent review organization has not received the pertinent files containing medical and personal information [~~information regarding an independent review~~] from the requesting utilization review agent[~~,~~] or the health insurance carrier, health maintenance organization, [~~or~~] managed care entity, or other payor. [~~that such documents have been delivered and the date of such delivery.~~]

(e) An independent review organization shall reimburse health care providers for the reasonable costs of providing medical information in writing, including copying and transmitting any [~~requested~~] patient records or other documents requested by the independent review organization. A health care provider's charge for providing medical information to an independent review organization shall not exceed the cost of copying set by rules of TDI-DWC at §134.120 of this title (relating to Reimbursement for Medical Documentation) [~~the Texas Workers' Compensation Commission~~] for records and may not include any costs that are otherwise recouped as a part of the charge for health care. Such expense shall be reimbursed by the utilization review agent, health

insurance carrier, health maintenance organization, [~~or~~] managed care entity, or other payor requesting the review as an expense of independent review.

(f) Nothing in this section prohibits a patient, the representative of a patient, or a provider of record from submitting pertinent records to an independent review organization conducting independent review.

(g)[~~(f)~~] When conducting independent review, the independent review organization shall request and maintain [~~collect~~] any information necessary to review the adverse determination not already provided by the utilization review agent, health insurance carrier, health maintenance organization, [~~or~~] managed care entity, or other payor. This information may include identifying information about the patient, the benefit plan, the treating health care provider, or [~~and/or~~] facilities rendering care. It may also include clinical information regarding the diagnoses of the patient and the medical history of the patient relevant to the diagnoses; the patient's prognosis; or [~~and/or~~] the treatment plan prescribed by the treating health care provider along with the provider's justification for the treatment plan.

(h)[~~(g)~~] The independent review organization is required to [~~should~~] share all clinical and demographic information on individual patients among its various divisions to avoid duplication of requests for information from patients or providers.

§12.206. Notice of Determinations Made by Independent Review Organizations.

(a) (No change.)

(b) The notification required by this section must be mailed or otherwise transmitted not later than the earlier of:

(1) (No change.)

(2) the 20th day after the date the independent review organization receives the request for the independent review.[~~; and~~]

(c) In the case of a life-threatening condition, the notification must be by telephone to be followed by facsimile, electronic mail, or other method of transmission not later than the earlier of:

(1) – (2) (No change.)

(d) Notification of determination by the independent review organization is required to [~~must~~] include at a minimum:

(1) a listing of all recipients of the notification of determination as described in subsection (a) of this section, identifying for each:

(A) the name; and

(B) as applicable to the manner of transmission used to issue the notification of determination to the recipient:

(i) mailing address;

(ii) facsimile number; or

(iii) electronic mail address;

(2) the date of the original notice of the decision, and if amended for any reason, the date of the amended notification of decision;

(3) the independent review case number assigned by the department;

(4) the name of the patient;

(5) a statement of whether the type of coverage is health insurance, workers' compensation, or workers' compensation health care network;

(6) a statement of whether the context of the review is preauthorization, concurrent review, or retrospective review of health care services;

(7) the name and certification number of the independent review organization;

(8) a description of the services in dispute;

(9) a complete list of the information provided to the independent review organization for review, including dates of service and document dates where applicable;

(10) a description of the qualifications of the reviewing physician or provider;

(11) a statement that the review was performed without bias for or against any party to the dispute and that the reviewing physician or provider has certified that no known conflicts of interest exist between the reviewer and:

(A) the patient;

(B) the patient's employer, if applicable;

(C) the insurer;

(D) the utilization review agent;

(E) any of the treating physicians or providers; or

(F) any of the physicians or providers who reviewed the case for determination prior to referral to the independent review organization, and that the review was performed without bias for or against any party to the dispute;

(12) a statement that the independent review was performed by a health care provider licensed to practice in Texas if required by applicable law and of the appropriate specialty;

(13) a statement that there is no known conflict of interest between the reviewer, the IRO, and/or any officer or employee of the IRO with:

(A) the patient;

(B) the physician requesting independent review;

(C) the physician of record;

(D) the utilization review agent;

(E) the payor; and

(F) the certified workers' compensation health care network, if applicable;

(14) a summary of the patient clinical history;

(15) the review outcome, clearly stating whether or not medical necessity or appropriateness exists for each of the health care services in dispute and whether the health care services in dispute are experimental or investigational, as applicable;

(16) a determination of the prevailing party if applicable;

(17) the analysis and explanation of the decision, including the clinical bases, findings and conclusions used to support the decision [~~(1) the specific reasons, including the clinical basis, for the determination~~];

(18)[~~(2)~~] a description and the source of the review [~~screening~~] criteria that were utilized to make the determination;

(19) a certification by the independent review organization of the date that the decision was sent to all of the recipients of the notification of determination as required in subsection (a) of this section via U.S. Postal Service or otherwise transmitted in the manner indicated on the form; and

(20) for independent reviews of health care services provided under the Labor Code Title 5 or the Insurance Code Chapter 1305, any information required by §133.308 of this title (relating to MDR by Independent Review Organizations); and

(21) notice of applicable appeal rights under the Insurance Code Chapter 1305 and the Labor Code Title 5, and instructions concerning requesting such appeal.

[~~(3) a description of the qualifications of the reviewing physician or provider; and~~]

[~~(4) a certification by the independent review organization that the reviewing physician or provider has certified that no known conflicts of interest exist between him or her and any of the treating physicians or providers or any of the physicians or providers who reviewed the case for determination prior to referral to the independent review organization.~~]

(e) Example templates for the notification of determination regarding health and workers' compensation cases may be found on the department's website at http://www.tdi.state.tx.us/forms.

§12.207. Independent Review Organization [~~Organizations'~~] Telephone Access.

(a) An independent review organization shall have appropriate personnel reasonably available [~~to utilization review agents~~] by telephone at least 40 hours per week during normal business hours[~~,~~] in both time zones in Texas[~~, if applicable, to discuss patients' care and allow response to telephone review questions~~].

(b) An independent review organization must have a telephone system capable of accepting or recording or providing instructions to incoming calls [~~from utilization review agents~~] during other than normal business hours and shall respond to such calls not later than one working day from [~~two working days of the later of~~] the date [~~on which~~] the call was received [~~or the date the details necessary to respond have been received from the caller~~].

§12.208. Confidentiality.

(a) (No change.)

(b) An independent review organization may not disclose or publish individual medical records or other confidential information about a patient without the prior written consent of the patient or as otherwise provided [~~required~~] by law. An independent review organization may provide confidential information to a provider who is [~~third~~

~~party~~] under contract [~~or affiliated~~] with the independent review organization for the sole purpose of performing or assisting with independent review. Information provided to a provider who is under contract to perform a review [~~third parties~~] shall remain confidential.

(c) – (e) (No change.)

(f) The independent review organization's procedures shall specify that specific information exchanged for the purpose of conducting review will be considered confidential, be used by the independent review organization solely for the purposes of independent review, and be shared by the independent review organization with only a provider who is under contract with the independent review organization to perform independent review [~~those third parties who have authority to receive such information~~]. The independent review organization's plan shall specify the procedures that are in place to assure confidentiality and shall acknowledge that the independent review organization agrees to abide by any federal and state laws governing the issue of confidentiality. Summary data that [~~which~~] does not provide sufficient information to allow identification of individual patients, providers, payors or utilization review agents need not be considered confidential.

(g) (No change.)

(h) Information generated and obtained by the independent review organization in the course of the review shall be retained for at least four years. This requirement is not negated by the suspension or surrender of the independent review organization's

certificate of registration or the failure to renew the certificate of registration[~~if the information relates to a case for which an adverse decision was made at any point~~].

(i) (No change.)

SUBCHAPTER D. ENFORCEMENT OF INDEPENDENT REVIEW STANDARDS

§12.301. Complaints, Oversight, and Information.

(a) Complaints against an independent review organization shall be processed in accordance with the department's established procedures for investigation and resolution of complaints. [~~Complaints to the department. Within a reasonable time period, upon receipt of a written complaint alleging a violation of this chapter or the Act by an independent review organization from a patient's health care provider, a person acting on behalf of the patient, the patient, the payor, or a utilization review agent, the department shall investigate the complaint and furnish a written response to the complainant and the independent review organization named.~~]

(b) As part of its oversight of independent review organizations, the department will conduct compliance audits to ensure that independent review organizations are in compliance with the Insurance Code Chapters 1305 and 4202 and the rules and standards in this chapter.

(c) [~~(b) Authority of the department to make inquiries.~~] The department may use the authority of the Insurance Code §38.001[~~, Article 1.24,~~] to make inquiries of any independent review organization.

(d) This chapter does not limit the ability of the Commissioner of Workers' Compensation or TDI-DWC to make inquiries, conduct audits, or receive and investigate complaints against independent review organizations or personnel employed by or under contract with independent review organizations to perform independent review to determine compliance with or violations of the Labor Code Title 5 or applicable TDI-DWC rules.

§12.302. Administrative Violations.

(a) If the department believes that any person conducting independent review is in violation of the Insurance Code Chapters 1305 or 4202 [~~Act~~] or this chapter, or any provision of the Labor Code Chapters 408, 409, or 413, or Chapters 19, 133, 134, 140, or 180 of this title (relating to Agents' Licensing; General Medical Provisions; Benefits--Guidelines for Medical Services, Charges, and Payments; Dispute Resolution – General Provisions and Monitoring and Enforcement, respectively, the department shall notify the independent review organization of the alleged violation and may compel the production of any and all documents or other information as necessary to determine whether or not such violation has taken place.

(b) The department or TDI-DWC may initiate appropriate proceedings under this chapter or the Labor Code Title 5 and TDI-DWC rules.

(c) (No change.)

(d) If the commissioner or the commissioner's [~~his or her~~] designee determines that an [~~the~~] independent review organization or a person conducting independent

review has violated or is violating any provision of the Insurance Code Chapter 4202 [~~Act~~] or this chapter, the commissioner or the commissioner's [~~his or her~~] designee may:

(1) impose sanctions under the Insurance Code Chapter 82[~~, Article 1.10~~];

(2) issue a cease and desist order under the Insurance Code Chapter 83[~~, Article 1.10A~~]; and/or

(3) assess administrative penalties under the Insurance Code Chapter 84[~~, Article 1.10E~~].

(e) If the independent review organization has violated or is violating any provisions of the Insurance Code other than Chapter 4202 [~~the Act~~], or applicable rules of the department, sanctions may be imposed under the Insurance Code Chapters 82, 83, or 84[~~, Articles 1.10, 1.10A, or 1.10E~~].

(f) The commission of fraudulent or deceptive acts or omissions in obtaining, attempting to obtain, or use of certification or designation as an independent organization shall be a violation of the Insurance Code Chapter 4202 [~~Act~~].

(g) If the commissioner or the commissioner's designee determines that an independent review organization or a person conducting independent review has violated or is violating any provision of the Labor Code Title 5 or rules adopted pursuant to the Labor Code Title 5, the commissioner or the commissioner's designee may impose sanctions or penalties under the Labor Code Title 5.

(h) This chapter does not limit the ability of the Commissioner of Workers' Compensation or TDI-DWC to make inquiries, conduct audits, receive and investigate complaints, and take all actions permitted by the Labor Code against an independent

review organization or personnel employed by or under contract with an independent review organization to perform independent review to determine compliance with the Labor Code Title 5 and applicable TDI-DWC rules.

§12.303. Surrender of Certificate of Registration.

(a) Pursuant to the Insurance Code §4202.002(c)(2)(B), upon the request of the department, an independent review organization must voluntarily surrender the organization's certificate of registration while the organization is under investigation or as part of an agreed order.

(b) For the purposes of this section, the term "investigation" is defined as the filing of a Notice of Hearing or a Notice of Violation with the State Office of Administrative Hearings by the department or TDI-DWC against an independent review organization where such notice seeks revocation of the certificate of registration of the independent review organization.

(c) Independent reviews shall not be assigned to an independent review organization during a voluntary surrender of the independent review organization's certificate of registration.

(d) Voluntary surrender of an independent review organization's certificate of registration does not negate the requirement in §12.208(h) of this chapter (relating to Confidentiality) that an independent review organization retain information generated and obtained by the independent review organization in the course of a review for at least four years or the obligation to complete all independent reviews assigned to the

independent review organization prior to the voluntary surrender of the certificate of registration.

SUBCHAPTER E. FEES AND PAYMENT

§12.402. Classification of Specialty. Fees for independent review shall be based on a two tiered structure of specialty classifications as follows:

(1) (No change.)

(2) Tier two fees will be for the independent review of medical or surgical care rendered in the specialties of podiatry, optometry, dental, audiology, speech-language pathology, master social work, dietetics, professional counseling, psychology, occupational therapy, physical therapy, marriage and family therapy, chiropractic, and chemical dependency counseling, and any subspecialties thereof.

§12.403. Fee Amounts.

(a) Fees to be paid to independent review organizations by utilization review agents, and other payors, for each independent review are as follows:

(1) tier one: $650; and

(2) tier two: $460.

(b) The IRO fees specified in subsection (a) of this section include an amended notification of decision if the department determines the initial notification of decision is incomplete. The amended notification of decision shall be filed with the department no

later than five working days from the independent review organization's receipt of notice from the department that the initial notification of decision is incomplete.

§12.404. Payment of Fees.

(a) (No change.)

(b) Independent review organizations may also bill utilization review agents or payors, as appropriate, for copy expenses related to review as set forth in §12.205 of this chapter [~~title~~] (relating to Independent Review Organization Contact with and Receipt of Information from Heath Care Providers and Patients).

(c) [~~At the time of billing, independent review organizations shall provide to the department a copy of such bill for information.~~]

[~~(d)~~] Utilization review agents or payors, as appropriate, shall pay independent review organizations directly within 30 days of receipt of invoice.

(d)[~~(e)~~] Utilization review agents may recover from the payors the costs associated with the independent review.

§12.405. Failure to Pay Invoice. Failure by utilization review agents or payors, as appropriate, to pay invoices from an independent review organization within 30 days of receipt shall constitute a violation of §12.404(c) of this subchapter (relating to Payment of Fees) and shall be subject to enforcement action and penalty in accordance with [~~under~~] §12.302 [~~§12.303~~] of this chapter [~~title~~] (relating to Administrative Violations).

§12.406. Certification and Renewal Fees. Fees to be paid to the department for the original application for a certificate of registration [~~certification~~] as an independent review organization is $800. The fee for renewal of a certificate of registration [~~certification~~] is $200.

SUBCHAPTER F. RANDOM ASSIGNMENT OF INDEPENDENT REVIEW ORGANIZATIONS

§12.501. Requests for Independent Review. Requests for independent review shall be made to the department on behalf of the patient by the utilization review agent pursuant to the Insurance Code Subchapter I [~~, Article 21.58A, §6A~~] and Chapter 19, Subchapter R of this title (relating to Utilization Review Agents), Chapter 10 of this title (relating to Workers' Compensation Health Care Networks), Chapter 133 of this title (relating to General Medical Provisions), or by a health insurance carrier, health maintenance organization, or managed care entity pursuant to the Civil Practice and Remedies Code[~~,~~] §88.003(c).

§12.502. Random Assignment.

(a) The department shall randomly assign each request for independent review to an independent review organization[~~,~~] and shall notify the utilization review agent and the health insurance carrier, health maintenance organization, [~~or~~] managed care entity, or other payor requesting the independent review, the independent review organization,

the patient or a person acting on behalf of the patient, and the provider of record of such assignment.

(b) The department shall screen [~~treating physicians, other providers, and~~] payors and utilization review agents [~~against the independent review organization~~] for potential conflicts of interest with the independent review organization before making an assignment to the independent review organization. The independent review organization shall screen its physicians and other providers conducting independent review for potential conflicts of interest. The department shall have the discretion to determine whether conflicts exist.

(c) – (d) (No change.)

(e) Assignment of an independent review to an [~~An~~] independent review organization [~~assigned an independent review~~] moves the independent review organization receiving the assignment to the bottom of the assignment list.

(f) Independent reviews will not be assigned:

(1) to an independent review organization during the 30 days prior to the anniversary date of the issuance of the independent review organization's certificate of registration unless the completed application for renewal of its certificate of registration and the application fee have been received by the department; or

(2) during the time that an independent review organization has voluntarily surrendered its certificate of registration pursuant to §12.303 of this chapter (relating to Surrender of Certificate of Registration) and the Insurance Code §4202.002(c)(2)(B).

(g)[~~(f)~~] Nonselection for presence of conflicts of interest does not move the independent review organization to the bottom of the assignment list. Such independent review organization retains its chronological position until selected for independent review.

10. CERTIFICATION. This agency hereby certifies that the proposal has been reviewed by legal counsel and found to be within the agency's authority to adopt.

Issued at Austin, Texas, on May 28, 2010.