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

SUBCHAPTER B. CERTIFICATE OF REGISTRATION FOR INDEPENDENT REVIEW ORGANIZATIONS
28 TAC §§12.101 - 12.106, 12.108, and 12.110

SUBCHAPTER C. GENERAL STANDARDS OF INDEPENDENT REVIEW
28 TAC §§12.201, 12.202, and 12.204 - 12.208

SUBCHAPTER D. ENFORCEMENT OF INDEPENDENT REVIEW STANDARDS
28 TAC §§12.301, 12.302, and 12.303

SUBCHAPTER E. FEES AND PAYMENT
28 TAC §§12.402 - 12.406

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

1. INTRODUCTION. The Commissioner of Insurance (Commissioner) adopts 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). Sections 12.2, 12.4, 12.5, 12.101, 12.103, 12.106, 12.108, 12.110, 12.201, 12.204 - 12.208, 12.303, 12.402, 12.404, 12.406, and 12.502 are adopted with changes to the proposed text published in the June 11, 2010 issue of the *Texas Register* (35 TexReg 4859). Sections 12.1, 12.6, 12.102, 12.104, 12.105, 12.202, 12.301, 12.302, 12.403, 12.405, and 12.501 are adopted without changes.

A correction of error notice was published in the July 2, 2010 *Texas Register* (35 TexReg 5971) to correct errors in the proposal published in the June 11, 2010 issue. The following errors were corrected:

In the Cross Reference to Statute section, the Cross Reference to Statute citation for each subchapter was incomplete as published on pages 35 TexReg 4883, 4887, 4890, 4894, 4895, and 4896. For each subchapter there were two paragraphs under the Cross Reference to Statute that were corrected. The first reference as published read, "§§12.101 – 12.106, Insurance Code §§4201.002, 4202.002, 4202.004, and 12.108, and 12.110, 4202.005." It was corrected to read, "§§12.101 – 12.106, 12.108, and 12.110 Insurance Code §§4201.002, 4202.002, 4202.004, and 4202.005." The second reference as published read, "§§12.201, 12.202, Insurance Code §1305.355 and §4202.002; and 12.204 – 12.207 Labor Code §§408.0043 – 408.0045 and 413.031." It was corrected to read, "§§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."

2. REASONED JUSTIFICATION. 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 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 certificates 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; and (v) 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. The 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. The amendment to §12.103 adds paragraph (10) to require an applicant for an initial or a renewal certificate of registration made on or after December 26, 2010 to submit as part of the application process evidence that the applicant’s primary office is located in this state. The amendment also provides that an IRO must 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. 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 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. 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) – (D) concerning prohibited activities and relationships of IROs and individuals or entities associated with IROs by adding new subsections (c) – (h). 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. 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. New §12.303 is also necessary to define the term “investigation” for purposes of the section, to clarify that a certificate of registration that is surrendered under the section is temporarily suspended while the investigation is pending, to clarify the effect of the 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 amendment to §12.502(f), relating to the random assignment of independent reviews to IROs, is also necessary to revise the subsection for clarity.

Additionally, the applicability date of December 26, 2010 in §12.4(b) gives IROs time to comply with the rules adopted to implement HB 4519 and allows time to complete the last reviews assigned to IROs under the current rules for those IROs that cannot or do not wish to comply. Specific applicability dates for certain provisions implementing HB 4519 are also included. Section 12.204(h) makes §12.204(c) – (g)

applicable only to IROs whose certificate of registration is issued or renewed on or after December 26, 2010 or to individuals or entities whose activity involves an IRO whose certificate of registration is issued or renewed on or after December 26, 2010. Section 12.103(10) requires evidence that the applicant's primary office is located in this state only for an application for a certificate or renewal of registration as an IRO in this state made on or after December 26, 2010.

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 (URA'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 to §12.5(1), (17), and (31), 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 §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 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 certificate of registration. 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 in §12.108(c) and §12.502(f)(1) provide that no assignments of an independent review will be made 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 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, amendments replace the term "screening criteria" with "review criteria" throughout Chapter 12. Specifically, the amendments to reflect this more accurate terminology appear in §§12.5(19) and (31), 12.103(1), 12.108, and 12.201(3). In addition, the Department adopts new and updated definitions in §12.5 and adopts 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 adopts an amendment to update the term "medical and scientific evidence," and adopts 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(22) 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 adopts 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 an 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.” An amendment to §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 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 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 Texas Administrative Code (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 adopted to be added in: (i) §12.4(a), concerning applicability; (ii) §12.5(22), (25), and (32), respectively, defining the terms "medical and scientific evidence," "payor," and "TDI-DWC"; and (iii) 12.502(a), concerning random assignment of independent reviews. These 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. Also, new §12.6 clarifies that 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 Title 28 TAC Chapter 12 in the same manner as reviews of utilization review decisions by health maintenance organizations. New §12.6 also clarifies that in the event of a conflict between Chapter 12 and the Labor Code or TDI-DWC rules, the Labor Code or TDI-DWC rules control. Additionally, an amendment to redesignated §12.201(3)(D) addresses the development of review criteria used to review health care delivered pursuant to the Labor Code Title 5. New §12.202(f) incorporates 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 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 certificate of registration 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, an 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 URA 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 URAs not being able to contact IROs or not having their telephone calls returned by IROs in a timely manner. To address this issue, amendments to §12.207(a) 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 an amended notification of decision. Such amended notification of decision is not specifically addressed by §12.403, so it is necessary to amend the section. An 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, an 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 to §12.404 deletes an unnecessary requirement in existing subsection (c) for an IRO to send a copy of the bill to the Department each time it bills for a review.

Finally, amendments throughout the rule text: (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.

The Department posted an informal working draft of the proposed new rules on the Department's Internet website and invited public input. The Department held a

stakeholder's meeting on September 4, 2009, to discuss implementation of HB 4290 and HB 4519 and the informal working draft with interested parties. The Department received several written comments regarding the informal working draft of the proposed new rules, and these comments were taken into consideration in preparing the proposed rules. The proposed rules were formally published in the June 11, 2010 issue of the *Texas Register* (35 TexReg 4859).

The Department conducted a public hearing on the published rule proposal on July 15, 2010, under Docket Number 2714. In response to written comments on the published proposal and comments made at the hearing, the Department has made non-substantive changes to (i) proposed §12.5, adding a definition of "experimental or investigational;" (ii) proposed §12.5(21) (currently redesignated §12.5(22)), relating to the definition of "medical and scientific evidence;" (iii) proposed §12.5(23) (currently redesignated §12.5(24)), relating to the definition of "patient;" (iv) proposed §12.5(27) (currently redesignated §12.5(28)), relating to the definition of "primary office;" (v) proposed Form No. LHL006 relating to the IRO application form; (vi) proposed §12.103(10), relating to the requirement that an application for a certificate or renewal of registration as an IRO in Texas made on or after December 26, 2010 must include evidence that the applicant's primary office is located in this state; (vii) proposed §12.201(3), relating to the required use of written medically acceptable review criteria; (viii) proposed §12.207, relating to IRO telephone access; (ix) proposed §12.303, relating to the surrender of an IRO's certificate of registration while the IRO is under investigation or as part of an agreed order; (x) proposed §12.402, relating to tier two

fees for the independent review of health care services rendered in certain specialties; (xi) proposed §12.404, relating to payment of fees; and (xii) proposed §12.502, relating to random assignment. In response to written comments on the published proposal and comments made at the hearing, the Department has also (i) deleted proposed §12.204(h), relating to the requirement 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; and (ii) added new §12.204(h), relating to the applicability of §12.204(c) – (g). The Department has also made non-substantive changes to (i) proposed §12.5(32) (currently redesignated §12.5(33)), relating to the definition of "utilization review agent;" (ii) §12.2, relating to severability; (iii) §12.4, relating to applicability; (iv) §§12.101, 12.106, 12.110, 12.204, 12.206, 12.208, 12.406, and 12.502, relating to the use of the phrase "certificate of registration"; (v) §12.108, relating to renewal of certificate of registration; (vi) §12.201, relating to the independent review plan's written procedures; (vii) §12.205, relating to submission of information to the IRO; (viii) §12.206, relating to notice of determinations made by IROs; (ix) §12.502, relating to random assignment; and (x) the LHL006 Form, the IRO Application Form. None of the changes made to the proposed text or proposed form in this adoption materially alter issues raised in the proposal, introduce new subject matter, or affect persons other than those previously on notice.

As a result of a comment, the Department has added §12.5(12), which defines "experimental or investigational" as "A service or device for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the

treatment, service, or device but that is not yet broadly accepted as the prevailing standard of care." A commenter recommended that the Department add to proposed §12.201(4) language establishing the standard for determinations that health care services are "investigational or experimental." Specifically, the commenter recommended the following language for inclusion in the IRO's independent review plan: §12.201(4) "independent review determinations that: . . . (E) a health care service or treatment is investigational or experimental may only be made if the procedure, course of treatment or health care service lacks sufficient medical or scientific evidence of benefit for a particular condition. A procedure, course of treatment, or health care service is not "investigational or experimental" if it: (i) is generally accepted by the provider of record as effective and appropriate for the condition in question; or (ii) is supported by an overall balance of objective medical and scientific evidence, in which the potential risks and potential benefits are examined." The commenter asserted that adding such a definition would ensure that there is transparency and uniformity in the decision making process among IROs with regard to decisions concerning the investigational or experimental nature of a treatment and this definition would be consistent with the goals of HB 4290. The Department agrees that a definition of "experimental or investigational" would be beneficial and has added the definition in §12.5 instead of §12.402. The Department asserts that its adopted definition is consistent with the commenter's suggested definition. This change also resulted in redesignating proposed §12.5(12) – (33) to §12.5(13) – (34), respectively.

Also, as a result of a comment, the Department retained "peer-reviewed abstracts accepted for presentation at major medical association meetings" in proposed §12.5(21)(F) (currently redesignated §12.5(22)(F)) in the definition of "medical and scientific evidence." A commenter recommended that this language be retained for the following reasons: (i) the NAIC's failure to include peer-reviewed abstracts does not, per se, make the abstracts invalid as a source of medical and scientific evidence reviewable by IROs in the state of Texas; (ii) the Department previously considered the abstracts to be a valid source of medical and scientific evidence and, absent a compelling reason, should continue to do so; (iii) the fact that the abstracts are (a) peer reviewed, and (b) accepted for presentation at a major medical association meeting is sufficient indicia of reliability and acceptance in the medical community to warrant their consideration and use by IROs in their decision-making process; and (iv) to narrow the universe of acceptable material on which the aforementioned decisions are based may have the unintended result of unjustifiably restricting the consumer/patient's access to payment for health care services for which he or she contractually bargained and that he or she is, therefore, legally entitled to receive. This change also resulted in redesignating proposed §12.5(21)(F) and (G) to §12.5(21)(G) and (H), respectively.

Also, as a result of comment, the Department has revised §12.5(21)(G). First, this provision was redesignated “§12.5(22)(H)” as a result of the retention of §12.5(21)(F) and an addition of a definition in §12.5(12), as previously discussed. Secondly, the scope of subparagraph (G) was changed, although the redesignation made an actual text change unnecessary. A commenter recommended modifying

proposed subparagraph (G) (currently redesignated “(H)”) to reference other medical or scientific clinical evidence that is comparable to the sources listed in subparagraphs (A) - *(E)*, rather than (A) - *(F)*. The commenter asserted that subparagraph (F) (currently redesignated “(G)”), was limited to and specifically tailored to independent review of adverse determinations of health care provided pursuant to Labor Code Title 5 (workers' compensation decisions). Thus, it would not make sense to consider "comparable" evidence to workers' compensation treatment guidelines, treatment protocols, etc. in the context of decisions falling outside of Labor Code Title 5. The Department agrees that because proposed subparagraph (F) was limited to workers’ compensation decisions, proposed subparagraph (G) should not have referenced proposed subparagraph (F). However, because the language under the previously adopted subparagraph (F) was reinstated as a result of a separate comment, proposed subparagraphs “(F)” and “(G)” were redesignated “(G)” and “(H),” respectively. Thus, the practical effect of leaving the reference to subparagraphs “(A) – (F)” within the text in newly redesignated subparagraph (H) is to exclude the reference to proposed subparagraph (F) (since it is now “(G)”) as the commenter requested, without the need for an actual text change.

Additionally, as a result of a comment, the Department has revised §12.5(23) (currently redesignated §12.5(24)) to state, “Patient--The enrollee or an eligible dependent of the enrollee under a health benefit plan or health insurance policy, or *an injured employee* [~~a person~~] entitled to receive workers’ compensation benefits pursuant to the Labor Code Title 5.” Two commenters requested this revision to proposed §12.5(23). The commenters requested this revision because (i) injured employees are

persons who received the health care service portion of the workers' compensation medical benefit; (ii) the use of the term "injured employee" would reduce confusion; and (iii) the revision would be consistent with draft Department rules regarding URAs currently under consideration.

Additionally, as a result of comment, the Department has amended §12.5(27) (currently redesignated §12.5(28)) to define "primary office" as "the place where, based upon the totality of the business activities related to independent review performed under this chapter, an independent review organization's books and records pertaining to independent reviews assigned by the Department are stored." The Department has also revised §12.103(10) to state, "(10) for an application for a certificate or renewal of registration as an independent review organization in this state made on or after December 26, 2010, evidence that the applicant's primary office is located in this state. As a condition of being certified to conduct the business of independent review in this state, an independent review organization must locate its primary office in this state." The Department has made a conforming change to Form No. LHL006 (relating to IRO Application Form), which previously stated, "Provide evidence that the applicant is based in the state and that its primary office is located in this state." The Department has revised this requirement in Form No. LHL006 to state, "Provide evidence that the applicant's primary office is located in this state." Three commenters stated that the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas is in violation of the Commerce Clause of the U.S. Constitution. Three other

commenters opposed the provision as unnecessary. A seventh commenter requested adding new language to §12.103.

The first commenter asserted that although a State's power to regulate the business of insurance is broadened by the McCarran-Ferguson Act, this extended power does not grant the Department the power to restrict all out-of-state IROs from engaging in business in Texas. The commenter further noted that there has been no evidence that out-of-state IROs pose any problems within the regulatory confines of this state. If the matter is not deemed unconstitutional, the commenter recommended removing "is based" in §12.103(10) and amending §12.103 to read as follows: “(10) Evidence of (sic) the IRO has a primary office physically located in this State, and that this is reported and declared as the Business Office of the IRO in the IRO's Application for Certification, and in annual renewal statements, and that at any time that this address is changed, that TDI be notified 10 days prior to the change of such Business Address. The primary office of an IRO shall be the physical Business Address of the IRO that is declared in the Application for Certification as an IRO, must be where the management of the processes of independent review occur, and the location where corporate records case files, and files containing information on the medical and reviewers of the IRO are maintained. With regard to credentialing and case files, IROs must maintain at the primary office documents that demonstrate that all reviewers on the IRO's medical review panel are licensed to practice in the State of Texas, and that, on a case by case basis, the IRO has assigned fully credentialed reviewers to each case, and that reviewer has signed no conflict of interest statements.” Further, the

commenter suggested that entities that were certified prior to the new Code shall have a grace period of 120 days to comply with the new law. During this grace period, an IRO will have the option of opening a primary office for independent review in Texas, or of selling the IRO to an owner in Texas who agrees to open a primary office, as defined above. During this grace period, which would begin on the date of the adoption of the new rules, the IRO would continue to be required to follow rules currently in effect, not the new proposed rules. The commenter asserted that the proposed language offered for implementing the requirement in the Insurance Code §4202.002(c)(2)(A) does not provide sufficient guidance to operating IROs and that the current language suggests that the actual medical reviews take place at the primary office, which is a practical impossibility.

The second commenter stated that if we eliminate the out-of-state IROs, we are going to lose their knowledge. These IROs were involved in drafting federal legislation. The small out-of-state IROs cannot afford to move to Texas. The large IROs are not going to move either, because the IRO business in Texas is not lucrative enough. This portion of the law is unnecessary. The first two levels of review are by URAs, who are located all over the country. The federal legislation is going to change the game completely. The out-of-state IROs were not involved in the stakeholder meetings. Some IROs did not know that the law had been passed.

The third commenter stated the following reasons that the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas should be deleted: (i) the commenter's out-of-state IRO consistently receives 100% on

its report card issued by the Department; (ii) the commenter's IRO has done nothing unscrupulous and can be trusted; (iii) the IRO has learned and abided by all of the rules and regulations of the Department that govern the IRO business and, to the commenter's knowledge, has never had a complaint filed against it; (iv) there is no public purpose for this new law; (v) the law was written by another IRO owner who was trying to increase his own business by putting out-of-state IROs out of business; and (vi) this regulation does nothing to help the patients of Texas get fairness in the health care process, which is what we should be spending time and energy discussing.

The fourth commenter stated that if the number of IRO cases is going to increase, now is not a good time to eliminate IROs. Some of the out-of-state IROs are big IROs that conduct business nationally, and the commenter asserts that they are good companies. The commenter further stated that there is no indication that out-of-state IROs posed a problem.

The fifth commenter stated the following reasons for deleting the requirement that the IRO be based in Texas and have its primary office in Texas: (i) the commenter's IRO received a 100% score in Department rankings; (ii) the IRO has never had a complaint filed against it by a patient, provider, insurance company, or URA; (iii) working with the Department is a pleasure under current rules; (iv) URAs that are similarly regulated by the Department are located all over the country; (v) one IRO owner is trying to manipulate the system for his own personal gain; (vi) there are numerous other out-of-state IROs that will be forced to relocate under this provision in order to keep their IRO business in Texas; (vii) for the commenter's family to relocate, it

would cost tens of thousands of dollars and the commenter's wife would not be able to keep her job; therefore, the commenter would be forced to sell his IRO; and (viii) the effect of this regulation would be to eliminate 20% of the IROs certified in Texas, bringing less competition and less independence to the system; with the new federal legislation, Texas will need more IROs, not less, to deal with the expanding system.

A sixth commenter cited the following reasons for deleting this requirement: (i) forcing a company to move its office to Texas puts an unnecessary financial strain on the company; (ii) people working for these companies will undoubtedly lose their jobs as a result of this provision, further worsening the economy; and (iii) many of the top rated IROs will no longer find it financially feasible to do Texas independent reviews and the Department will lose these quality reviewers.

A seventh commenter suggested adding the following subparagraph to §12.103: "(11) information related to out-of-state licensure of legal process. All applicants must furnish a copy of the Certificate of Registration or other licensing document from the domiciled state's licensing authority. As a condition of being certified to conduct the business of independent reviews in this State, an Independent Review Organization must locate its primary office in this State."

Although the Department disagrees that the case law on which the first commenter relies supports the proposition that an IRO's activity is not considered the "business of insurance" or that the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas violates the Commerce Clause of the U.S. Constitution, the Department's revisions narrow the definition of "primary office" and

impose the requirement that the primary office be located in Texas only to applicants for a new license or renewal on or after December 26, 2010. This revision to §12.103(10) also removes the requirement that Form No. LHL006 include evidence that the applicant *is based* in Texas, as the first commenter requested. Being based in Texas is no longer a condition of being certified to conduct the business of independent review. Additionally, the revision imposes the requirement that the primary office be located in Texas only on applicants for a new license or renewal on or after December 26, 2010. Thus, any potential applicant will be aware of the primary office requirement set forth in §12.103(10) before deciding whether to apply for licensure or renewal. Although in some instances this applicability date may result in a shorter time period than the 120 day grace period the first commenter suggested, in other cases it may create a longer time period with which to comply. This revision to the definition of "primary office" addresses the first commenter's request that books and records should be maintained at the primary office. This revision should also alleviate the first commenter's concern that the rule requires actual medical reviews take place at the primary office which is a practical impossibility, which was not the Department's intent.

The revision of §12.103(10) is also consistent with some of the fourth commenter's suggested language. However, the Department does not intend on accepting a copy of a foreign Certificate of Registration as the only other required criterion for an IRO to conduct business in Texas.

Also, as a result of comment, the Department has revised §12.201(3)(A) to state, "based on medical and scientific evidence and utilize evidence-based standards, *or if*

evidence is not available, generally accepted standards of medical practice recognized in the medical community." A commenter recommended that proposed §12.201(3)(A) be modified to read as follows: "(3) required use of written medically acceptable review criteria that are: (A) established with consideration, as appropriate, given to [~~based on~~] medical and scientific evidence and [~~utilize~~] evidence-based standards;. . . ." The commenter cited the following reasons for the suggested change: (i) this language will ensure that the purpose of the HB 4290 is fulfilled; (ii) proposed §12.201(3)(A) will be consistent with 12.201(3)(B), which requires the review criteria to 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;" (iii) under current §12.201, the components of the independent review plan are somewhat broadly-defined (presumably in order to provide flexibility in their application); (iv) under the current regulations, the independent review plan must be developed with input from appropriate health care providers and reviewed and approved by physician, which is similar to the statutory requirement for utilization review plans under Texas Insurance Code §4201.151; (v) the Department's proposed modifications to §12.201 provide an extra layer of detail and, unfortunately, inflexibility to the independent review plan by requiring that the plan use written medically acceptable review criteria that are "based on medical and scientific evidence and utilize evidence-based standards;" (vi) as proposed, the standards established by §12.201(3)(A) may be too rigid to account for varying circumstances and emerging science in the practice of medicine; (vii) although the commenter supports the consideration and use of appropriately tested and peer-

reviewed evidence in making independent review determinations, given that the practice of medicine is an art as well as a science, it is critical that the proposed rules not be overly prescriptive in the use of so called "best evidence" to the detriment of payment for the provision of sound patient care; (viii) to require a strict adherence to the evidence-based standards would sacrifice legitimate determinations concerning medical necessity and the investigational/experimental nature of a particular treatment or drug in favor of uniform (if, sometimes, inaccurate) decisions using so-called "evidence based standards;" (ix) the Department must be mindful that what is the "best evidence" today may be outdated tomorrow and that which is the cutting edge today may be the state of the art and then the standard practice tomorrow; (x) the rules must be flexible enough to acknowledge a wide array of treatments and services that have been proven to be beneficial to patients; (xi) without providing for adequate flexibility in the rule, the review criteria required under the rule may be so stringent that many appropriate and beneficial health care services will be inaccurately classified as investigational or experimental, while HB 4290 was designed to ensure that those health care services that insurers deemed "investigational" or "experimental" were properly reviewed by an IRO; (xii) this modification would be consistent with the NAIC Model Act's focus on reviewing guidelines, as appropriate, when making the independent review determination; and (xiii) modification would be consistent with subparagraph (E) which requires the review criteria to be used only as a tool in the review process (and not determinative of the ultimate decision). The Department agrees with the commenter that proposed §12.201(3)(A) was too rigid, since evidence-based medicine may not be available in

every situation and thus cannot always be relied upon. However, the Department asserts that evidence-based standards should be used when available.

Additionally, as a result of comment, the Department has deleted proposed §12.204(h) from the adopted rules. Two commenters argued that §12.204(h) appeared to be in violation of the U.S. Constitution. Both commenters noted that it was clearly unconstitutional unless the State could articulate a *compelling* reason for denying IROs the right to choose its own counsel. According to the first commenter, who has acted as a registered agent for two IROs, since there did not seem to be a valid reason for §12.204(h), it is possible that §12.204(h) was specifically included in the bill to harm him personally because of past dealings with an individual who was involved in drafting the legislation. This provision, when enacted, will require the commenter to end representation of current IRO clients and to deny his clients the right to choose him as their attorney. A registered agent simply accepts service for his or her client. Registered agents include attorneys, entity officers, professional services and others. There is a trust that has been built up and will be lost. It is also a long tradition that an individual should be able to select his own lawyer. Both commenters also noted that there is no reference to what this regulation is intended to remedy.

The Department has considered §12.204(h) further and has determined that the provision governs the practice of law by limiting the conduct of certain licensed attorneys in the state of Texas. Because the Department's regulatory authority does not extend to the practice of law, the Department has deleted this provision.

Also, as a result of comment, the Department has revised §12.204 by adding a new subsection (h), which states, *"Notwithstanding §12.4(b) of this chapter (relating to Applicability), the prohibitions in subsections (c) – (g) of this section apply only to: (1) an independent review organization that: (A) is licensed on or after December 26, 2010; or (B) has its certificate of registration renewed in this state on or after December 26, 2010; and (2) an individual or entity whose activity involves an independent review organization that: (A) is licensed on or after December 26, 2010; or (B) has its certificate of registration renewed in this state on or after December 26, 2010."* This change makes §12.204(c) – (g) applicable only to IROs whose certificate of registration is issued or renewed on or after December 26, 2010 or to individuals or entities whose activity involves an IRO whose certificate of registration is issued or renewed on or after December 26, 2010. This change was in response to the general comment that legal action may be taken to challenge the constitutionality of the rules once adopted. The Department's revision clarifies that the requirements in §12.204(c) – (g) only apply to IROs that are licensed or whose certificates of registration are renewed on or after December 26, 2010 or to individuals or entities whose activity involves an IRO that is licensed or whose certificates of registration is renewed on or after December 26, 2010. This revision avoids disruption of any expectations, rights, or privileges under or related to a current certificate of registration that has already been issued and has not yet expired.

Also, as a result of comment, the Department has revised §12.207(b) to state, "An independent review organization must have a telephone system capable of

accepting or recording or providing instructions to incoming calls *related to utilization review* during other than normal business hours and shall respond to such calls not later than one working day from the date the call was received." A commenter opposed the amendments to §12.207 for the following reasons: (i) the new rule requires that IROs should be "generally (sic) available by telephone" to parties other than URAs; while this appears to make no substantive change to broaden the telephone availability requirements for IROs, in effect it would require IROs to communicate with anyone and everyone; (ii) under amended §12.207, an IRO would be compelled to discuss details of individual cases with persons other than URAs, which hinders both the patient privacy and the independence of the process; (iii) this open access creates an economic burden on IROs, which was not present in prior rules; (iv) previously, the IRO had to return calls "to URAs" in 2 working days, which allowed plenty of time to address any issue during the 20-day review process; (v) amended §12.207 significantly increases costs to the IROs, by encouraging patients to directly contact them; (vi) the proposed rule change jeopardizes the independent status of the IROs; and (vii) any change that increases the workload of the IROs should also have a corresponding fee increase. The Department's revision narrows the scope of §12.207(b) to calls *related to utilization review*.

Additionally, as a result of comment, the Department has revised §12.303 by (i) removing the terms "voluntary" and "voluntarily"; (ii) adding subsection (c) to state, "A certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending;" and (iii) adding subsection (f) to state,

“Notwithstanding §12.4(b) of this chapter (relating to Applicability), this section only applies to an independent review organization that: (1) is licensed on or after December 26, 2010; or (2) has its certificate of registration renewed in this state on or after December 26, 2010.” The Department has also removed the term “voluntarily” from §12.502(f)(2).

Two commenters asserted that §12.303 contains no due process of law. One commenter recommended removing the reference to a voluntary surrender of certificate and suggests referencing a surrender of certificate only after an IRO has been provided due process on the issue. This commenter further stated that the provision requiring a "voluntary suspension of a license" is neither voluntary nor legally permissible as it eliminates a vested right to continue to operate without any due process. According to the commenter, when the state vests a right to do business to a company, certain due process standards must be afforded prior to suspension of their ability to continue to do business.

The commenter further asserts that the Department is subject to Chapters 2001 and 2002 of the Texas Government Code. These chapters have been deemed by Texas courts to require agencies to assure fairness to affected persons and to assure that the public and affected persons are heard on matters that involve their interests and affairs. A *mandatory voluntary* surrender of the certificate runs afoul with the rules that govern Texas agencies because it hinders an IRO's ability to be heard and provided due process before the certificate is required to be surrendered.

The Department has removed the terms “voluntary” and “voluntarily” to clarify that the surrender is required and to avoid confusion as to whether the surrender is mandatory or voluntary. Additionally, the Department has provided that a certificate of registration that is surrendered under §12.303 is temporarily suspended while the investigation is pending, clarifying that the certificate of registration is not permanently revoked without due process of law. The addition of subsection (f) makes this provision only applicable to IROs newly licensed on or after December 26, 2010 or to existing IROs upon renewal of their certificates of registration on or after December 26, 2010. Thus, any potential applicant will be aware of the surrender process set forth in §12.303 before deciding whether to apply for licensure or renewal. Finally, the Department has also removed the term “voluntarily” from §12.502(f)(2) as a conforming change, since this section refers to §12.303.

Additionally, as a result of comment, the Department has revised §12.402(2) to state, “(2) Tier two fees will be for the independent review *of health care services* 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.” A commenter strongly recommended that the Department replace the reference to "medical or surgical care" with "health care services" in §12.402(2). The commenter objected to the Department's proposed reference to "medical or surgical care" rendered by the specialties listed in proposed §12.402(2); the specialties listed in proposed §12.402(2)

are not M.D.s or D.O.s and, therefore, are not statutorily authorized to practice medicine or to provide general medical or surgical care; rather, they are authorized only to provide the limited health care services consistent with and within the scope of their respective enabling statutes. The commenter asserted that the suggested revision makes the proposed language of §12.402(2) consistent with Texas law. The Department has made the requested revision.

Finally, as a result of comment, the Department has revised §12.404(c) by adding a second sentence that states, “For workers’ compensation network and non-network disputes, the independent review organization fees shall be paid in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).” A commenter recommended that §12.404 regarding payment of fees be amended to address the following concerns: (i) IROs should not be allowed to submit an invoice to a URA or payor until their services have been rendered; in workers' compensation many deadlines for payment of a bill are based on receipt of the invoice, and requests for a review may be withdrawn prior to the review being performed; and (ii) the rule should be clarified to reference the Division of Workers' Compensation rules, which have different payment timelines for workers' compensation URAs.

The Department has revised §12.2 to state, “If a court of competent jurisdiction holds that any provision of this chapter or its application to any person or circumstance is invalid for any reason, the invalidity does not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.” The Department has made this

clarifying change to proposed §12.2 for consistency with the Government Code §312.013(a).

The Department has also changed proposed §12.4(b) to state, "*Except as otherwise provided*, this chapter is applicable to all requests for independent review filed with the department on or after *December 26, 2010*. All independent reviews filed with the department prior to *December 26, 2010* shall be subject to the rules in effect at the time the independent review was filed with the department." The addition of the language "Except as otherwise provided" was to reflect that more specific applicability dates were added to §§12.103(10), 12.204(h), and 12.303(f) as a result of other comments. The "December 26, 2010" change was necessary for compliance with the effective date requirements in the Government Code §2001.036. Section 2001.036 provides that a rule takes effect 20 days after the date on which it is filed in the Office of the Secretary of State unless certain other statutorily specified conditions are met. The change is also necessary to avoid any retroactive effect of the rule.

The Department has revised redesignated §12.5(33) to define "utilization review agent" as "A person holding a certificate under the Insurance Code Chapter 4201," removing the reference to "of registration" for clarification because some URAs are certified and some are registered.

The Department has revised §§12.101, 12.106, 12.110, 12.204, 12.206, 12.208, 12.406, and 12.502, replacing the term "certification." The term "certification" refers to an issuance of the certificate of registration. For consistency of terminology throughout the rule text, the Department has removed references to "certification," instead referring

to a “certificate of registration.” As a conforming change, the Department has also changed the title of Subchapter B from “Certification of Independent Review Organizations” to “Certificate of Registration for Independent Review Organizations.” The Department has revised the first sentence of §12.101 to state, “An application for a certificate of registration and for renewal of a certificate of registration as an independent review organization and *application for a certificate of registration* or renewal fee must be filed with the Texas Department of Insurance at the following address:…,” deleting the term “certification” and replacing it with the phrase “application for a certificate of registration.”

The Department has revised the first sentence of §12.106 to state, “The commissioner or the commissioner’s designee may conduct an on-site qualifying examination of an applicant as a requirement of *applying for a certificate of registration or renewing a certificate of registration* as an independent review organization.” This sentence previously stated, “The commissioner or the commissioner’s 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.” The Department has revised the phrase “certification or a renewal of certification” to “applying for a certificate of registration or renewing a certificate of registration.” The Department has also revised §12.110(e), stating “…and applicable department and TDI-DWC rules prior to *issuance of the certificate of registration* to the independent review organization pursuant to its new ownership,” replacing the phrase “certification of” with the phrase “issuance of the certificate of registration.”

The Department has revised §12.204(g) to state, “An individual who has served on the board of an independent review organization that has had its *certificate of registration* 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.” The Department has replaced the term “certification” with the phrase “certificate of registration.”

The Department has revised §12.206(d)(7) to state, “the name and *certificate* number of the independent review organization,” replacing the word “certification” with the word “certificate.”

The Department has also revised §12.208(e) to refer to a “certificate number” instead of a “certification number.”

The Department has revised the title of §12.406 from “Certification and Renewal Fees” to “Certificate of Registration and Renewal Fees.”

Finally, the Department has also revised §12.502(c) to refer to the “date of issuance of the certificate of registration” instead of the “date of certification.”

The Department also made a clarifying change to §12.108(b), revising the text to state, “Form No. LHL006 (IRO Application *Form*),” instead of “Form No. LHL006 (IRO Application *for Certification*.” This change is for consistency with §12.102, which adopts by reference “Form No. LHL006 (IRO Application Form).”

Also, in addition to the revision to §12.201 made as a result of comment, the Department has also revised §12.201(2)(A) to state, “notification of the independent review organization’s determinations provided to the patient or a *representative* of the

patient, the patient's provider of record, and the utilization review agent, in accordance with §12.206 of this subchapter (relating to Notice of Determinations Made by Independent Review Organizations)." The Department changed the phrase "person acting on behalf" to "representative" for consistency throughout the text. As a conforming change, the Department has also revised §12.205(c), 12.206(a), and §12.502(a), again replacing "person acting on behalf" with "representative."

The Department has also revised §12.205(c) to correct a typographical error, adding a parenthesis after "(relating to Agents' Licensing and General Medical Provisions."

Additionally, the Department has made several non-substantive revisions to §12.206(d) for clarification. First, the Department has revised §12.206(d)(6) to state, "a statement of whether the context of the review is preauthorization, concurrent *utilization* review, or retrospective *utilization* review of health care services." The Department added the term "utilization" for clarification. Second, the Department has revised §12.206(d)(12) to state, "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 *professional* specialty." The Department added "professional" for clarification and for consistency with §12.202(f), which refers to a "professional specialty." Third, the Department has also revised §12.206(d)(13)(B) and (C), replacing the term "physician" with the term "provider." This change was also made for consistency throughout the rule text. Fourth, the Department revised §12.206(d)(14) to

state, “a summary of the patient’s clinical history;” changing the word “patient’” to “patient’s” for ease of readability.

Finally, in addition to the conforming change made as a result of comments to Form No. LHL006, the IRO Application Form, in which the Department revised the form to state, “Provide evidence that the applicant’s primary office is located in this state,” the Department determined that it was also necessary to make two clarifying changes. First, the Department revised the title of the form to “Independent Review Organization (IRO) Application Form.” Proposed §12.102 adopts by reference Form No. LHL006, the “IRO Application Form.” The proposed form had the title “Independent Review Organization (IRO) Application *for Certification*.” The Department’s revision corrects the title for consistency with §12.102. Second, the Department revised Form No. LHL006 to properly reference the biographical affidavit addendum, stating, “Biographical affidavits addendum (form #LHL652).” The proposed form stated, “Biographical affidavits addendum (form #I_____),” so it was necessary to correct the incomplete reference.

Section 12.1 addresses **Statutory Basis**. The 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 amendment to §12.2 makes changes to conform rule text to current Department drafting style, consistent with the Government Code §312.013(a).

Section 12.4 addresses **Applicability**. One amendment to §12.4 is necessary to address applicability of Chapter 12 to workers' compensation health care networks and workers' compensation insurance carriers. This 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 URA 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 TAC §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, amendments to §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 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 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. 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 in Chapter 19, Subchapters R and U of this title, the rules regulating URAs, 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 redesignated as §12.5(2) due to the deletion of existing definitions. New §12.5(3) is necessary to define the term “best evidence” because it is used in the definition of the adopted term “evidence-based standards.” 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 adopted term “best evidence.” Current §12.5(6) and (7) are adopted to be redesignated as §12.5(7) and (8). An 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 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 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 the adopted amendment in §12.201(3)(A) in order to clarify what an IRO must take into consideration in developing review criteria. The 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. New §12.5(12) is necessary to define the term "experimental or investigational," as requested by a commenter and for clarification. New §12.5(13) is necessary to define the term "expert opinion" because it is used in the definition of the adopted term "best evidence." Current §12.5(11) is redesignated as §12.5(14). An amendment to redesignated §12.5(15) 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 amendments to redesignated §12.5(15) are made to conform rule text to current Department drafting style and improve clarity. The first amendment to redesignated §12.5(16) 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 §4201.002(6), which defines the term in the context of utilization review as regulated under Chapter 4201. The second amendment to redesignated §12.5(16) 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 amendment to redesignated §12.5(17) 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 amendment to redesignated §12.5(18) 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 amendment to redesignated §12.5(18) 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 amendment to redesignated §12.5(18) is necessary to change the word “title” to “chapter” in order to more accurately identify the location of the referenced section. The fourth amendment to redesignated §12.5(18) is necessary to correct the citation to the section title of §12.402. The amendment to redesignated §12.5(19) 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. New §12.5(20) is necessary to add a definition for "legal holiday" because the term is used in an adopted amendment to redesignated §12.5(34), 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 redesignated as §12.5(21). The amendment to redesignated §12.5(22) 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 adopted, 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. An 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 amendment to redesignated §12.5(23) is necessary to revise the definition for the term “nurse” for increased consistency with the definition for the term in Chapter 19, Subchapters R and U of this title, which provides

rules regulating URAs. The amendment to redesignated §12.5(24) 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 amendment to §12.5(25) 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 redesignated as §12.5(26) and (27). The amendment that adds new §12.5(28) is necessary to define the term “primary office” because the term is used in Chapter 12 in the implementation of HB 4519. The amendment in redesignated §12.5(29), which defines “provider of record,” is necessary for consistency with current Department rule drafting style. New §12.5(30) is necessary to define the term “randomized clinical trial” because it is used in the definition of the term “evidence-based standards.” One amendment to redesignated §12.5(31) 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 amendment to redesignated §12.5(31) is necessary for consistency with the definition of “utilization review” in the Insurance Code §4201.002(13) as amended by HB 4290. New §12.5(32) adds the new defined term “TDI-DWC.” This 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 amendment to redesignated §12.5(33) 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 amendment to redesignated §12.5(34) establishes a definition for the term "working day" that is consistent with TDI-DWC practices as provided in §102.3(b) of this title.

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**. New §12.6 is necessary to address situations where existing rules or adopted 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 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 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 adopted 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 adopted amendment clarifies that the section also applies to filing for renewal of the certificate of registration.

Section 12.102 addresses **Application and Renewal of Certificate of Registration Form; How to Obtain Forms**. One 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 registration. New subsection (a) is necessary to

update the section to adopt by reference Form No. LHL006, the IRO Application Form for this purpose. 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 amendments to redesignated §12.102(c) are necessary to provide the correct web address and 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 in Application and Renewal Form**. An amendment to §12.103 amends the section title to better reflect the section content. A second 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. An 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 amendment to §12.103(1) is necessary to change “which” to “that” to correct a grammatical error. The 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. An

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 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 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. Adopted amendments to redesignated §12.103(D) are necessary to correct internal references by changing the word “title” to “subchapter.” Amendments to redesignated §12.103(1)(D), (2), (4), and (5) are necessary to correct internal references by changing the word “title” to “chapter.” An 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 amendment to §12.103(5) is necessary to provide the correct citation to the heading of another section. The amendment to §12.103(6)(B) is necessary to revise a reference to percentage for consistency with current Department rule drafting style. The 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 amendment to §12.103(9) is necessary to provide guidance concerning the information required for submission with Form No. FIN311 (Biographical Affidavit). One amendment to

§12.103(9)(A) is necessary to correctly address the fact that the provision applies to an "applicant." The second 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 amendment to §12.103(9)(A) is necessary to revise a reference to percentage for consistency with current Department rule drafting style. A last 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. An 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. 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 §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 amendment to §12.103(9)(B) is necessary to revise a reference to percentage for consistency with current Department rule drafting style. The 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 amendment to §12.103(10) requires, for an application for a certificate or renewal of registration as an IRO in this

state made on or after December 26, 2010, an applicant to submit evidence that the applicant's primary office is located in this state and provides that this requirement is a condition of applying for a certificate of registration. These amendments to §12.103(10) are necessary to implement this requirement pursuant to HB 4519. It is also important that the Department have the ability to conduct on-site examinations of IRO's records that relate to independent reviews conducted in Texas. If the IRO's primary office is located outside of Texas, it is more costly to conduct on-site examinations and also may cause unnecessary delay in situations where immediate on-site auditing may be necessary. An amendment to §12.103(11) is necessary to add the word "and" for consistency with current Department drafting style and to correct grammar. An 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 change "described" to "specified" to reflect drafting style.

Section 12.105 addresses **Revisions During Review Process**. The 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 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 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 amendment to §12.105(d) is necessary to clarify which specific sections in Chapter 12 are referenced by the subsection. The collective amendments throughout §12.105 are necessary to make the section more reader-friendly.

Section 12.106 addresses **Qualifying Examinations**. One 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 amendment to §12.106 is necessary to clarify that an on-site qualifying examination may be conducted as a requirement of applying for or renewing a certificate of registration as an IRO. The third 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 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**. Amendments to §12.108(b) are necessary to clarify that Form No. LHL006 (IRO Application Form), adopted 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) also clarify that the form is available on the Department website and to provide more accurate references in the subsection. 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 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 submit its application for renewal of its certificate of registration. A second amendment to §12.108(d) is necessary to clarify that the form referenced by the subsection is a renewal application form. The amendment to §12.108(e) is necessary to update the reference to the application form referenced in the subsection. An 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…”.

New §12.110 addresses **Effect of Sale of an Independent Review Organization**. The purpose of this new section is to implement HB 4519. 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. 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. 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. 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. 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. 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 obtaining its certificate of registration pursuant to the new ownership.

Section 12.201 addresses **Independent Review Plan**. The amendment to §12.201 conforms rule text with current Department drafting style and for clarity. Section 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. An 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. A second amendment to §12.201(2)(A) changes the words “person acting on behalf” to “representative,” for consistency throughout the rule text. 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 to §12.201(2)(D) reflects the correct title of §12.205. Five amendments to §12.201(3) and the 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 amendment to §12.201(3) is necessary to change the word “utilize” to “use” in order to simplify the text of the rule. Another 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 and utilize evidence-based standards, or if evidence is not available, generally accepted standards of medical practice recognized in the medical community, 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 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. An amendment to redesignated §12.201(3)(E) deletes a reference to "screening criteria" and makes additional nonsubstantive changes for clarity. Additional 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. An 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 amendment to §12.202(b) is necessary to clarify that the purpose of maintaining complete profiles of anyone conducting independent review is so that such information will be available for review by the Department and TDI-DWC upon request. The 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 amendment is necessary to ensure that quality personnel are engaged in the direction and conduct of independent review. An additional 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).

Section 12.204 addresses **Prohibitions of Certain Activities and Relationships of Independent Review Organizations and Individuals or Entities Associated with Independent Review Organizations**. The amendment to the title of §12.204 is necessary to reflect the expanded content included in the section. The 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. Amendments add new §12.204(c) – (h), which are necessary to implement HB 4519. 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. New §12.204(c)(1) is necessary to clarify that the

prohibition added by 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. New §12.204(c)(2) is necessary to clarify that the prohibition added by 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. New §12.204(d) is necessary to establish a prohibition that an individual or an entity may not own more than one IRO. New §12.204(e) is necessary to establish a prohibition that an individual may not own stock in more than one IRO. New §12.204(f) is necessary to establish a prohibition that an individual may not serve on the board of more than one IRO. 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 certificate of registration 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. New §12.204(h) is necessary to establish specific applicability provisions for §12.204(c) – (g), stating that the prohibitions in subsections (c) – (g) apply only to (i) an IRO that is licensed or has its certificate of registration renewed in Texas on or after December 26, 2010; or (ii) an individual or entity whose activity involves an IRO that is licensed or has its certificate of registration renewed in Texas on or December 26, 2010.

Section 12.205 addresses **Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients**. The 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 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 URA or the health insurance carrier, health maintenance organization, or managed care entity. The 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 amendment to §12.205(c) adds the word "of" to correct the omission of the word in the sentence. The third amendment to §12.205(c), which adds the word "the" before the words "Insurance Code" is necessary for compliance with current Department rule drafting style. The fourth 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 amendment to §12.205(c) inserts a parenthesis after "(relating to Agents' Licensing and General Medical Provisions" to correct a typographical error. The sixth 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 seventh amendment to §12.205(c) replaces the words "person acting on behalf" with the word "representative" for consistency throughout the rule text. 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 URA, health insurance carrier, health maintenance organization, or managed care entity. However, the Department has determined that this requirement is unnecessary. As adopted, 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 URA 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 amendment to §12.205(e) is necessary to clarify that the provision references documents requested by the IRO. The second amendment to §12.205(e) is necessary to update a reference from the "Texas Workers' Compensation Commission" to the "TDI-DWC." The third 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 URA forward the request for independent review. New §12.205(f) is necessary to provide additional clarification that nothing in the section prohibits a patient, representative of a patient, or a provider of record from submitting pertinent records to an IRO conducting independent review. Additional amendments redesignate the subsections that follow §12.205(f), as necessary. The first 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 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 amendments to redesignated §12.205(g) are necessary to reflect current Department rule drafting style by changing “and/or” to “or.” The 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 amendment to §12.206(a) is necessary to replace the phrase “person acting on behalf” with the term “representative” for consistency throughout the rule text. §12.206(b)(2) is necessary to delete a superfluous “and” and insert correct punctuation. The amendment to §12.206(c) is necessary to insert the words “the notification must be” in order to clarify what the provision addresses. The 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. 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 utilization review, or retrospective utilization review of health care services; (vii) the name and certificate 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 professional 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's 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 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. 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 amendment to the title of the section is necessary to make a nonsubstantive change for clarity. The 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 URAs by telephone; it only requires an IRO to have a telephone system capable of accepting or recording or providing instructions to incoming calls from URAs; 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 URA, 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 amendments to §12.207(a) and (b) remove the limitation that an IRO have personnel reasonably available to URAs only, and the adopted amendments change the two working day response time to one working day. Additionally, an amendment to §12.207(b) states that the IRO has to respond to calls "related to utilization review," clarifying that the IRO does not have to respond to calls that are unrelated to utilization review.

Section 12.208 addresses **Confidentiality**. The 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 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 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 amendment to §12.208(f) is necessary to correct a grammatical error by changing the word “which” to “that.” The 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” 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, a sentence is added which reflects this continuing obligation.

Section 12.301 currently addresses **Complaints, Oversight, and Information**. An 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 adopted within the section. The 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. An 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. An amendment redesignates current §12.301(b) as §12.301(c) due to the addition of adopted new §12.301(b). The additional 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. An 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**. 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 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 amended to refer to “the Insurance Code Chapter 84.” An 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 IRO 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 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 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 amendment to §12.302(d) is necessary to make a grammatical correction by changing the word “the” to “an.” The third amendment to §12.302(d) is necessary to add a reference in the section to persons conducting independent review. An 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. An 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.

An amendment is necessary to add new §12.303, which addresses **Surrender of Certificate of Registration.** New §12.303 is necessary to implement the Insurance Code §4202.002(c), enacted by HB 4519. New §12.303(a) provides that upon the request of the Department, an IRO must surrender the organization's certificate of registration while the organization is under investigation or as part of an agreed order. 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 certificate of the IRO. New §12.303(c) is necessary to clarify that a certificate of registration that is surrendered under §12.303 is temporarily suspended while the investigation is pending. New §12.303(d) is necessary to provide that independent reviews shall not be assigned to an IRO during a surrender of the IRO's certificate of registration. New §12.303(e) is necessary to clarify that the 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. New §12.303(f) is necessary to set

forth applicability dates for §12.303. Under subsection (f), §12.303 applies to an IRO that is licensed on or after December 26, 2010; or has its certificate of registration renewed in this state on or after December 26, 2010.

Section 12.402 addresses **Classification of Specialty**. The first amendment to §12.402(2) is necessary to clarify that the provision regarding tier two fees is applicable to the review of "health care services" rendered in the specialties listed within the paragraph. The second 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 new subsection (b). Section 12.403(a) is amended to more accurately identify that other payors in addition to URAs are sometimes responsible for payment of fees. 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, 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 deletes §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 amendments redesignate the subsections that follow §12.404(c) as necessary. An amendment to redesignated §12.404(c) is necessary to reference 28 TAC §133.308 (relating to MDR by Independent Review Organizations).

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 **Certificate of Registration and Renewal Fees**. The 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. A conforming change is also made to the title of this section.

Section 12.501 addresses **Requests for Independent Review**. The 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 first 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 second amendment to §12.502(a) replaces the words "person acting on behalf" with the word "representative" for consistency throughout the text. The 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 adopted, the amendment to §12.502(b) provides that the Department shall screen payors and URAs for potential conflicts of interest with the IRO before making an assignment to the IRO. The amendment to §12.502(e) is necessary to revise the subsection for clarity. 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 surrendered its certificate of registration pursuant to §12.303. An 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.

3. HOW THE SECTIONS WILL FUNCTION.

§12.1. Statutory basis. Section 12.1 sets forth the statutory basis for this chapter, stating that it implements the Insurance Code Chapter 4202 as of September 1, 2009.

§12.2. Severability Clause. Section 12.2 provides for severability of terms or sections of this chapter under certain circumstances. It provides that if a court of competent jurisdiction holds that any provision of 28 TAC Chapter 12 or its application to any person or circumstance is invalid for any reason, the invalidity does not affect other provisions or applications of 28 TAC Chapter 12 that can be given effect without the invalid provision or application, and to this end the provisions of the chapter are severable.

§12.4. Applicability. Section 12.4 sets forth the applicability of this chapter.

§12.5. Definitions. Section 12.5 contains definitions for words and terms when used in the chapter.

§12.6. Independent Review of Adverse Determinations of Health Care Provided Pursuant to the Labor Code Title 5, or the Insurance Code Chapter 1305. Section 12.6 addresses (i) how review of the medical necessity or appropriateness of a health care service provided under the Labor Code Chapter 408 or Chapter 413 should be conducted; and (ii) how independent review of adverse determinations of health care provided pursuant to the Labor Code Title 5 or the Insurance Code Chapter 1305

should be conducted, including how conflicts between 28 TAC Chapter 12 and either the Labor Code or TDI-DWC rules should be resolved.

§12.101. Where to File Application. Section 12.101 provides information on where to file an application and fees for a certificate of registration and a renewal of a certificate of registration as an IRO.

§12.102. Application and Renewal of Certificate of Registration Form; How to Obtain Forms. Section 12.102 adopts by reference Form No. LHL006 (IRO Application Form) and Form No. FIN311 (Biographical Affidavit) and provides information on how these forms may be obtained.

§12.103. Information Required in Application and Renewal Form. Section 12.103 states that Form No. LHL006 requires information necessary for the commissioner to properly determine whether an applicant is qualified to be certified as an IRO and includes a list of the information that is necessary.

§12.104. Review of Application. Section 12.104 sets forth the applicable timeframes and the duties of the applicant and the Department during the application process.

§12.105. Revisions During Review Process. Section 12.105 contains the requirements for filing revisions to the application during the review process.

§12.106. Qualifying Examinations. Section 12.106 allows the commissioner or the commissioner's designee to conduct on-site qualifying examinations as a requirement of applying for or renewing a certificate of registration.

§12.108. Renewal of Certificate of Registration. Section 12.108 provides that an IRO must apply for renewal of its certificate of registration each year and sets forth the renewal requirements and procedures. It provides that Form No. LHL006 must be used for this purpose.

§12.110. Effect of Sale of an Independent Review Organization. Section 12.110 sets forth certain requirements related to the sale of an IRO, including provisions on non-transferability of an IRO certificate of registration, the effect of the sale of an IRO, notification requirements prior to the sale, obligations to continue performing duties prior to the sale, and activities following a sale.

§12.201. Independent Review Plan. Section 12.201 describes the independent review plan, which must be filed by IROs, and lists the components that must be included in the plan.

§12.202. Personnel and Credentialing. Section 12.202 sets forth personnel and credentialing requirements for IROs.

§12.204. Prohibitions of Certain Activities and Relationships of Independent Review Organizations and Individuals or Entities Associated with Independent Review Organizations. Section 12.204 prohibits certain activities of IROs, individuals, and entities, including provisions that (i) an IRO may not operate out of the same office or other facility as another IRO; (ii) an individual or entity may not own more than one IRO; (iii) an individual may not own stock in more than one IRO; (iv) an individual may not serve on the board of more than one IRO; and (v) an individual who has served on the board of an IRO that has had its certificate of registration

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. The prohibitions under §12.204(c) – (g) apply only to (i) an IRO that is licensed on or after December 26, 2010 or has its certificate of registration renewed in Texas on or after December 26, 2010; and (ii) an individual or entity whose activity involves an IRO that is licensed on or after December 26, 2010 or has its certificate of registration renewed in Texas on or after December 26, 2010.

§12.205. Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients. Section 12.205 governs the IRO's contact with and receipt of information from health care providers and patients. It sets forth procedures for (i) the IRO's contact with the health care provider and/or designated persons; (ii) the timely delivery of pertinent files to the IRO; (iii) health care providers' charges for providing medical information; (iv) submission of pertinent records to the IRO by a patient, representative of a patient, or a provider of record; (v) an IRO's request for additional information; and (vi) an IRO's sharing of information among its various divisions.

§12.206. Notice of Determinations Made by Independent Review Organizations. Section 12.206 contains requirements for IRO's notification of determinations, including a list of elements that such a notification must include. This section also provides a website where example templates of a notification of determination may be obtained.

§12.207. Independent Review Organization Telephone Access. Section 12.207 contains requirements for an IRO's telephone accessibility, including requirements that an IRO (i) shall have appropriate personnel reasonably available by telephone at least 40 hours per week during normal business hours in both time zones in Texas; and (ii) must have a telephone system capable of accepting or recording or providing instructions to incoming calls related to utilization review during other than normal business hours and shall respond to such calls not later than one working day from the date the call was received.

§12.208. Confidentiality. Section 12.208 sets forth confidentiality requirements for IROs, addressing the IRO's preservation of confidential, information that is provided to a provider who is under contract to perform a review, IRO's procedures addressing confidentiality, and confidentiality requirements during the suspension or surrender of an IRO's certificate of registration or upon failure to renew the certificate of registration.

§12.301. Complaints, Oversight, and Information. Section 12.301 describes how a complaint regarding an IRO may be filed with the Department, and provides that the Department may make necessary inquiries to investigate such complaints. The section also authorizes the Department to conduct compliance audits and clarifies that 28 TAC Chapter 12 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 or violations of the Labor Code Title 5 or applicable TDI-DWC rules.

§12.302. Administrative Violations. Section 12.302 sets forth regulations governing the prosecution of administrative violations. The section allows the Department or TDI-DWC to initiate proceedings under 28 TAC Chapter 12 or the Labor Code Title 5 and TDI-DWC rules. This section also sets forth the penalties that the commissioner may impose if a violation has occurred. The section also clarifies that 28 TAC Chapter 12 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 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.

§12.303. Surrender of Certificate of Registration. Section 12.303 sets forth the requirement for an IRO to surrender its certificate of registration while the IRO is under investigation or as part of an agreed order. The section defines "investigation," clarifies that a certificate of registration that is surrendered under §12.303 is temporarily suspended while the investigation is pending, and states that independent reviews shall not be assigned to an IRO during a surrender of the IRO's certificate of registration. The section also clarifies that confidentiality requirements still apply during the surrender of an IRO's certificate of registration. Finally, this section only applies to an IRO that is licensed on or after December 26, 2010 or has its certificate of registration renewed in Texas on or after December 26, 2010.

§12.402. Classification of Specialty. Section 12.402 divides specialty classifications of independent review into two tiers for purposes of setting fees.

§12.403. Fee Amounts. Section 12.403 sets forth fee amounts for the two specialty classification tiers prescribed by §12.402. Section 12.403(b) clarifies that the fees in 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 IRO's receipt of notice from the Department that the initial notification of decision is incomplete.

§12.404. Payment of Fees. Section 12.404 sets forth information regarding the payment of fees established in this subchapter.

§12.405. Failure to Pay Invoice. Section 12.405 addresses the failure of payors to pay invoices for the independent review within a certain timeframe and sets forth applicable enforcement actions and penalties.

§12.406. Certificate of Registration and Renewal Fees. Section 12.406 sets forth the fees for an application for a certificate of registration or renewal of a certificate of registration.

§12.501. Requests for Independent Review. Section 12.501 sets forth the manner in which requests for independent review are made to the Department.

§12.502. Random Assignment. Section 12.502 describes the procedure for random assignment of requests for independent review to IROs by the Department. Subsection (b) requires the Department to screen payors and URAs for potential conflicts of interest with the IRO before making an assignment to the IRO. Subsection (f) provides that independent reviews will not be assigned (i) 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 application for renewal of its certificate of registration and the application fee have been received by the Department; or (ii) during the time that an IRO has surrendered its certificate of registration pursuant to §12.303 and the Insurance Code §4202.002(c)(2)(B).

4. SUMMARY OF COMMENTS AND AGENCY RESPONSE.

General Comments.

Comment: Three commenters express their support and appreciation for the Department's rulemaking efforts. The first commenter supports the Department's efforts to amend these rules since many of the amendments are required to implement statutory amendments under HB 4519 and HB 4290.

A second commenter states that the rules as proposed adequately implement HB 4519 and HB 4290 and will strengthen the IRO statute for Health and Workers' Compensation. Revising the definition of "adverse determination" by including determinations regarding the experimental or investigational nature of a service will assist health care consumers by providing for the independent review of claims that previously were denied without such recourse. This commenter supports the adoption of the rules as proposed.

A third commenter has a keen interest in advocating for insurance reform measures directed at patient and consumer protection. The commenter strongly supports the additional patient protections provided in HB 4519 and HB 4290, which

include additional conflicts of interest provisions applicable to IROs and which extend the requirements of independent review to health care services deemed "investigational or experimental" by health insurers, as well as to retrospective determinations.

Agency Response: The Department appreciates the supportive comments.

Comment: Two commenters ask that the Department request an Attorney General Opinion regarding the constitutionality of the new regulations to ensure the Department's regulations do not violate the U.S. Constitution and/or damage the current IRO system. One commenter specifically requests that the following issues be addressed by an Attorney General Opinion: (i) the provision requiring a voluntary suspension of a license while an IRO is under investigation; (ii) the prohibition on out-of-state IROs engaging in business in Texas; (iii) the requirement that a registered agent cannot be employed to represent the IRO; and (iv) the economic impact statement and regulatory flexibility analysis conducted by the Department. Both commenters further request the Department to suspend the implementation process pending such review. The second commenter states that legal action may be taken to challenge the constitutionality of the rules once adopted.

Agency Response: The Department declines to seek an Attorney General Opinion and asserts that the rules do not violate the U.S. Constitution. The Department is implementing the requirements of HB 4519, which, et alia, requires the commissioner to adopt standards and rules that require (i) an IRO to voluntarily surrender the organization's certification while the organization is under investigation or as part of an agreed order; and (ii) an IRO to be based and certified in this state and to locate the

organization's primary offices in this state. The right to conduct independent reviews is a statutory right. A licensee does not have a vested right in the continuation of laws. The Legislature may, in the exercise of the police power, regulate by reasonable requirements the conduct of IROs and, by proper grant, delegate the exercise of police power to the Department. The exercise of the police power hinges upon the public need for safety, health, security, and protection of the general welfare of the community. When there is a public interest involved, the rights of individual licensees may yield to the overriding public interests and are regulated under the state's police power.

Regarding the issue of voluntary surrender, the Department has revised §12.303 by (i) removing the terms "voluntary" and "voluntarily"; (ii) adding subsection (c) to state, "A certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending;" and (iii) adding subsection (f) to state, "Notwithstanding §12.4(b) of this chapter (relating to Applicability), this section only applies to an independent review organization that: (1) is licensed on or after December 26, 2010; or (2) has its certificate of registration renewed in this state on or after December 26, 2010."

The Department has removed the terms "voluntary" and "voluntarily" to clarify that the surrender is required and to avoid confusion as to whether the surrender is mandatory or voluntary. Additionally, the Department has provided that a certificate of registration that is surrendered under §12.303 is temporarily suspended while the investigation is pending, clarifying that the certificate of registration is not permanently revoked without due process of law. This temporary suspension of rights may be

necessary to protect the patients whose claims are being reviewed by the IRO and to avoid harm to the patients. Finally, the addition of subsection (f) makes this provision only applicable to IROs newly licensed on or after December 26, 2010 or to existing IROs upon renewal of their certificates of registration on or after December 26, 2010. Thus, any potential applicant will be aware of the surrender process set forth in §12.303 before deciding whether to apply for licensure or renewal.

Regarding the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas, it is important for the regulation of IROs conducting independent reviews in this state that the records be available for on-site examinations. The Department could incur substantial costs in conducting on-site examinations if the necessary records were located out of state, and untimely delays in examinations could result in the destruction of records. However, to avoid an unnecessarily broad application of this provision, the Department has amended §12.5(28) to define “primary office” as “the place where, based upon the totality of the business activities related to independent review performed under this chapter, an independent review organization’s books and records pertaining to independent reviews assigned by the Department are stored.” Additionally, the Department has amended §12.103(10) to state, “(10) for an application for a certificate or renewal of registration as an independent review organization in this state made on or after December 26, 2010, evidence that the applicant’s primary office is located in this state. As a condition of being certified to conduct the business of independent review in this state, an independent review organization must locate its primary office in this state.” These revisions narrow the

definition of “primary office” and apply the requirement that the primary office be located in Texas only to applicants for a new license or renewal on or after December 26, 2010. Thus, any potential applicant will be aware of the primary office requirement set forth in §12.103(10) before deciding whether to apply for licensure or renewal. This revision to §12.103(10) also removes the requirement that Form No. LHL006 include evidence that the applicant *is based* in Texas. However, the Department asserts that removal of the “is based” language still complies with the HB 4519 requirement that the commissioner adopt standards and rules that require an IRO to be based and certified in this state and to locate the organization’s primary offices in this state. It is the Department’s position that the “is based” language does not necessarily require the IRO’s headquarters to be located in Texas, but that the IRO’s records related to independent reviews conducted in Texas be located in Texas. Since the records are already accounted for in the requirement that the primary office be located in Texas, including the “is based” language would be redundant. Further, the IRO is still required to be certified in Texas, as set forth under 28 TAC Chapter 12, Subchapter B.

The Department has considered proposed §12.204(h) further and has determined that the provision governs the practice of law by limiting the conduct of certain licensed attorneys in the state of Texas. Because the Department’s regulatory authority does not extend to the practice of law, the Department has deleted this provision. Therefore, there is no need to seek an Attorney General Opinion on this provision, as one of the commenters requests.

The Department has revised §12.204 by adding a new subsection (h), which states, *"Notwithstanding §12.4(b) of this chapter (relating to Applicability), the prohibitions in subsections (c) – (g) of this section apply only to: (1) an independent review organization that: (A) is licensed on or after December 26, 2010; or (B) has its certificate of registration renewed in this state on or after December 26, 2010; and (2) an individual or entity whose activity involves an independent review organization that: (A) is licensed on or after December 26, 2010; or (B) has its certificate of registration renewed in this state on or after December 26, 2010."* This change makes §12.204(c) – (g) applicable only to IROs whose certificate of registration is issued or renewed on or after December 26, 2010 or to individuals or entities whose activity involves an IRO whose certificate of registration is issued or renewed on or after December 26, 2010. This change was in response to the general comment that legal action may be taken to challenge the constitutionality of the rules once adopted. The Department's revision clarifies that the requirements in §12.204(c) – (g) only apply to IROs that are licensed or whose certificates of registration are renewed on or after December 26, 2010 or to individuals or entities whose activity involves an IRO that is licensed or whose certificate of registration is renewed on or after December 26, 2010. This revision avoids disruption of any expectations, rights, or privileges under or related to a current certificate of registration that has already been issued to an IRO and has not yet expired.

Finally, the Department has complied with the Government Code §2006.002, which requires the Department to reduce the adverse economic effects on small or

micro businesses if doing so is legal and feasible considering the purpose of the statute under which the rule is to be adopted. The Department prepared an economic impact statement estimating the number of small and micro businesses subject to the proposed rule, projecting the economic impact of the rule on these entities and describing the alternative methods of achieving the purpose of the proposed rule. The Department also prepared a regulatory flexibility analysis that included the Department's consideration of alternative methods of achieving the purpose of the proposed rule. The Department estimated in the proposal that approximately 35 IROs of the 43 IROs that are currently certified are small or micro business IROs. Making the rules inapplicable to such a large number of IROs would effectively negate the provisions, and in most cases the rule would not serve its intended purposes. Requiring such a small number of IROs to comply with the rules would result in an unfair competitive market and unfair loss of income for a few IROs. Therefore, the Department declines to seek an Attorney General Opinion on the economic impact statement or regulatory flexibility analysis, which already meet the requirements of the Government Code §2006.002.

Comment: Three commenters request that the implementation of the rules be delayed for reasons other than to await an Attorney General's Opinion. Two commenters assert that the newly passed federal healthcare legislation will almost certainly require the Texas Legislature to address many of the issues raised by these rules in the upcoming legislative session. These commenters strongly believe implementation of these proposed rules should be delayed pending further legislative action. One of these two commenters further states that the current system is working

very well. The commenter's IRO has a good record of compliance. Although the commenter acknowledges that the rules are proposed pursuant to the statutes, the commenter asserts that these rules are designed to reduce competition. The second commenter states that the purpose of the law was to prevent people from gaming the system. This commenter does not fault the Department for drafting the rules because they are consistent with the statutes. However, none of the 18 IROs that are members of AAIRO were aware of the legislation when it was passed. There was not enough stakeholder input. As a result, the Department has instructions from the Legislature to do things that are problematic. The law says that the Department shall make rules to make the conduct illegal. The Legislature instructed the Department to make rules as opposed to simply stating the prohibitions in the law, and with that responsibility the Department should ensure that the rules do not have unfair impact on people currently operating in the state who have such a good track record with the Department and have contributed to a system that is doing very well.

A third commenter believes that IROs are here in Texas to address situations when doctors are abusing the system by giving care that is not needed or when a patient needs care. The commenter further asserts that this law was passed by one or two IROs for personal gain to decrease competition. Texas should be the gold standard in the country for IROs. According to the commenter, adopting these rules will not accomplish that objective.

Agency Response: The Department declines to delay the implementation of the proposed rules. The Department acknowledges that federal legislation under the

Patient Protection and Affordable Care Act requires a group health plan and a health insurance issuer offering group or individual health insurance coverage to comply with the applicable State external review process for such plans and issuers that, at a minimum, include the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners. The federal Department of Health and Human Services (HHS) has issued "Technical Guidance For Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review For Health Insurance Issuers in the Group and Individual Markets under the Patient Protection and Affordable Care Act" that deems Texas' external review process compliant with federal law and regulations regarding external review processes until July 1, 2011. HHS has indicated that additional regulations to accompany this statutory provision will be promulgated. This federal legislation, along with the anticipated regulations, may require further Texas statutory amendments. Therefore, the Department awaits additional guidance and authorization from the Texas Legislature to implement changes related to the federal legislation.

Additionally, as two of the commenters note, the rules are consistent with the statutory language in HB 4519. As additional legislation is passed relating to IROs, the Department will continue to implement such legislation as authorized.

§12.5. Definitions.

Comment: Two commenters recommend revising the definition of "adverse determination." The first commenter recommends revising the definition to track the definition in Texas Insurance Code §4201.002(1) which reads: "Adverse determination" means 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."

The second commenter recommends that §12.5(1) be revised to the following: "Adverse determination – a determination *by an insurance carrier or* by a utilization review agent made on behalf of any payor that health care services provided or proposed to be provided to a patient are not medically necessary or appropriate, or are experimental or investigational." This commenter cites the following reasons for the suggested change: (i) this revision recognizes that an adverse determination may be made by a workers' compensation insurance carrier in addition to a URA; and (ii) Title 28 TAC §133.308(i) addresses timeliness of a request for an IRO in a workers' compensation claim and it provides in relevant part: "A requestor shall file a request for independent review *with the insurance carrier (carrier) that actually issued the adverse determination* or the carrier's utilization review agent (URA) that actually issued the adverse determination no later than the 45th calendar day after receipt of the denial of reconsideration" (emphasis added); although it appears that a URA generally makes the adverse determination, even in workers' compensation cases, the plain language of §133.308(i) demonstrates that the insurance carrier may also issue the adverse determination.

Agency Response: The Department declines to revise the definition of "adverse determination." The definition's inclusion of the phrase "made on behalf of any payor" clarifies that the definition includes those payors who conduct utilization review in-house. The Department asserts that adverse determinations should include determinations made on behalf of all payors, and the first commenter's suggested language would remove this clarifying language. The Department agrees with the second commenter that an adverse determination may be made by a workers' compensation insurance carrier but asserts that insurance carriers are already accounted for in the phrase "made on behalf of any payor." If the text included "by an insurance carrier or," it would also have to include other entities that could perform utilization review, such as third party administrators. To avoid having to produce an exhaustive list of entities, the language "made on behalf of any payor" encompasses all entities that can perform utilization review.

Comment: A commenter recommends that the Department delete the definition of "evidence-based medicine" in proposed §12.5(10) and its later use in the definition of "evidence-based standards" in proposed §12.5(11). In the alternative, the commenter strongly recommends that the Department modify the language to ensure that it is focused on medical and clinically-oriented research as follows: "Evidence-based medicine--The use of current best quality *clinically-based* scientific and medical evidence formulated from credible *medical and* scientific studies, including *studies published in* peer-reviewed medical literature and other current *clinically-oriented* scientifically based texts, and treatment and practice guidelines in making decisions

about the care of individual patients." The commenter cites the following reasons for the suggested deletion or alternative text: (i) there is no current consensus as to a definition for "evidence-based medicine"; (ii) although many of the definitions added by the Department in the proposed rules were modeled after the National Association of Insurance Commissioners (NAIC) Uniform Health Carrier External Review Model Act ("Model Act"), it is important to note that the NAIC itself does not include a definition of "evidence-based medicine" in its Act; rather, it only includes a definition of "evidence-based standard," which is also proposed by the Department in §12.5(11); and (iii) it is important to note that the NAIC's definition of "evidence-based standard" (unlike the Department's definition) does not include a reference to "evidence-based medicine."

Agency Response: The Department declines to make the requested deletions or the suggested changes. Although the Model Act does not include a definition of "evidence-based medicine," the Department's definition of "evidence-based medicine" does not conflict with the Model Act. The Labor Code §401.011(18-a) 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." The Department's inclusion of a definition for "evidence-based medicine" in the adopted rules harmonizes the text with the existing Labor Code provision.

Comment: A commenter recommends that proposed §12.5(21) be amended to clarify that an independent review of an adverse determination of health care provided

through a workers' compensation health care network must be consistent with the network's treatment guidelines.

Agency Response: The Department declines to make the suggested change. An IRO is free to adopt any evidence-based review criteria it chooses for its independent review plan and only has to consider the treatment guidelines, treatment protocols, and pharmacy closed formulary adopted by TDI-DWC when deciding on what review criteria to adopt as part of its independent review. Under 28 TAC §133.308, if the IRO's decision is contrary to (i) the policies or guidelines adopted under the Labor Code §413.011, the IRO must indicate in the decision the specific basis for its divergence in the review of medical necessity of non-network health care; or (ii) the network's treatment guidelines, the IRO must indicate in the decision the specific basis for its divergence in the review of medical necessity of network health care.

Comment: A commenter strongly recommends that the reference to "peer-reviewed abstracts accepted for presentation at major medical association meetings" in proposed §12.5(21)(F) be retained in the definition of "Medical and scientific evidence." The commenter notes that although the Department's proposed definition of "medical and scientific evidence" in proposed §12.5(21) of the rules largely tracks the language of the NAIC's Model Act, it is unclear why the Department proposes the deletion. The commenter cites the following reasons for retaining this language: (i) the NAIC's failure to include peer-reviewed abstracts does not, per se, make the abstracts invalid as a source of medical and scientific evidence reviewable by IROs in the state of Texas; (ii) the Department previously considered the abstracts to be a valid source of medical and

scientific evidence and, absent a compelling reason, should continue to do so; (iii) the fact that the abstracts are (a) peer reviewed, and (b) accepted for presentation at a major medical association meeting is sufficient indicia of reliability and acceptance in the medical community to warrant their consideration and use by IROs in their decision-making process; and (iv) to narrow the universe of acceptable material on which the aforementioned decisions are based may have the unintended result of unjustifiably restricting the consumer/patient's access to payment for health care services for which he or she contractually bargained and that he or she is, therefore, legally entitled to receive. The commenter cautions the Department not to unnecessarily restrict the universe of materials that may properly be considered as medical and scientific clinical evidence used by IROs in evaluating the medical necessity and appropriateness or the investigational/experimental nature of a health care service.

Agency Response: The Department agrees to retain "peer-reviewed abstracts accepted for presentation at major medical association meetings" in proposed §12.5(21)(F) (currently redesignated §12.5(22)(F)) in the definition of "Medical and scientific evidence" and has made the suggested change.

Comment: A commenter recommends that the Department modify proposed 12.5(21)(G) as follows: “(G) any other medical or scientific *clinical* evidence that is comparable to the sources listed in subparagraphs (A) – (E) [~~(F)~~] of this paragraph.” The commenter suggests two modifications to subparagraph (G). First, the commenter recommends modifying subparagraph (G) to reference other medical or scientific clinical evidence that is comparable to the sources listed in subparagraphs (A) - (E), rather than

(A) - (F). The commenter opines that subparagraph (F) is limited to and specifically tailored to independent review of adverse determinations of health care provided pursuant to Labor Code Title 5 (e.g., workers' compensation decisions). Thus, it would not make sense to consider "comparable" evidence to workers' compensation treatment guidelines, treatment protocols, etc. in the context of decisions falling outside of Labor Code Title 5.

The second modification limits the "comparable" scientific evidence considered to scientific evidence that is of a *clinical* nature. The commenter cites the following reasons for the suggested change: (i) the basic definition of scientific evidence contained earlier within the same section of the rule in subparagraph (A) refers to scientific evidence contained in medical journals, which necessarily implies a limitation to scientific evidence of a clinical nature; the addition of "clinical" to subparagraph (G) would make this limitation explicit as applied to "comparable" scientific evidence and would ensure that subparagraph (G) is interpreted consistently with subparagraph (A); and (ii) without limiting the scientific evidence to clinical information, insurers may improperly argue that scientific evidence that is of a purely cost/efficiency nature or of an actuarial nature should be considered in the IRO process; consideration of cost/efficiency evidence would be contrary to the clinically-oriented decision-making process that must be undertaken when assessing medical necessity and/or whether a particular treatment is investigational or experimental.

Agency Response: The Department agrees in part and disagrees in part. The Department agrees that because proposed subparagraph (F) was limited to workers'

compensation decisions, proposed subparagraph (G) should not have referenced proposed subparagraph (F). However, because the language under the previously adopted subparagraph (F) was reinstated as a result of a separate comment, proposed subparagraphs “(F)” and “(G)” were redesignated “(G)” and “(H),” respectively. Thus, the practical effect of leaving the reference to subparagraphs “(A) – (F)” within the text in newly redesignated subparagraph (H) is to exclude the reference to proposed subparagraph (F) (since it is now “(G)”) as the commenter requested, without the need for an actual text change.

However, the Department declines to make the commenter’s second suggested change to limit the "comparable" scientific evidence considered to scientific evidence that is of a *clinical* nature. Although the Department agrees that the scientific evidence is limited to that of a clinical nature, the inclusion of the word “clinical” is unnecessarily redundant.

Comment: A commenter recommends that the Department adopt the following definition of "medical necessity": “Medical necessity--All health care reasonable and necessary for the diagnosis or treatment of a mental or physical illness, disease or disorder or a physical deformity or injury.” The commenter cites the following reasons for the suggested definition: (i) a definition of the term "medical necessity” is conspicuously absent from the definitions contained within §12.5; (ii) given the fact that rendering a final and binding decision based upon the "medical necessity" of health care services is a key function of an IRO, defining the term "medical necessity" in the regulations would provide needed guidance to IROs in fulfilling their statutorily-

mandated charge; (iii) the definition of "medical necessity" should be specific enough to provide direction to IROs, while flexible enough to encompass the goal of the legislation regarding IROs, which is to provide broad oversight and fairness in rendering ultimate decisions regarding medical necessity; (iv) in constructing a definition of medical necessity, the Department should acknowledge and stay true to the clear distinction between medical necessity and coverage decisions; and (v) the definition would ensure that those health care services that are denied by insurers on "medical necessity" grounds are properly encompassed within the definition of "adverse determinations" that must be reviewed by independent review panels (if properly requested) and that a single standard of "medical necessity" is adhered to by IROs.

Agency Response: The Department declines to define “medical necessity.” What constitutes “medical necessity” should be determined by a clinician on a case-by-case basis considering all of the relevant patient’s medical records and medical evidence, not by the Department. The NAIC also declined to define “medical necessity” in the Model Act.

Comment: Two commenters request that §12.5(23) be revised as follows: “Patient--The enrollee or an eligible dependent of the enrollee under a health benefit plan or health insurance policy, or *an injured employee* [~~a person~~] entitled to receive workers’ compensation benefits pursuant to the Labor Code Title 5.” The commenters cite the following reasons for the suggested change: (i) health care providers are persons who receive the payment portion of the workers’ compensation medical benefit, and injured employees are persons who received the health care service portion of the

workers' compensation medical benefit; (ii) the use of the term "patient" for workers' compensation claims could lead to some confusion with the use of the term "person" in the definition of "patient" since "person" is defined in definition §12.5(25) to include corporations, associations, and similar business entities; (iii) the use of the term "injured employee" instead of "person" would avoid any confusion as to whether or not the term includes persons who receive payments for workers' compensation medical benefits; and (iv) the use of the term "injured employee" would be consistent with draft Department rules regarding URAs currently under consideration.

Agency Response: The Department agrees and has made the suggested change.

§12.103. Information Required in Application and Renewal Form.

Comment: Three commenters state that the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas is in violation of the Commerce Clause of the U.S. Constitution as discussed in *Lewis v. BT Inv. Managers,* 447 U.S. 27 (U.S. 1980). In that case, at issue was a regulation that bank holding companies domiciled outside of Florida could not purchase banks in Florida. The U.S. Supreme Court found this prohibition "directly burdens interstate commerce in a manner that contravenes the Commerce Clause's implicit limitation on state power." *Id.* at 44. Three other commenters oppose the provision as unnecessary.

One commenter requests that the constitutionality of this provision be addressed by an Attorney General Opinion and further elaborates that although a State's power to regulate the business of insurance is broadened by the McCarran-Ferguson Act, this

extended power does not grant the Department the power to restrict all out-of-state IROs from engaging in business in Texas. The McCarran Ferguson Act was adopted by Congress to allow the states to regulate and tax the business of insurance. There are three criteria relevant in determining whether a particular practice is part of "business of insurance" exempted from antitrust laws by section of McCarran-Ferguson Act which are (1) whether practice has effect of transferring or spreading a policyholder's risk, (2) whether practice is integral part of policy relationship between insurer and insured, and (3) whether practice is limited to entities within the insurance industry. McCarran-Ferguson Act §2(b), 15 U.S.C.A. §1012(b) (1945). According to the commenter, based on these criteria an IRO is not an insurance entity in the "business of insurance," and therefore is not exempted from federal regulation under the McCarran-Ferguson Act. Furthermore, the 5th Circuit has held that the IRO provisions reflect Texas' effort to mandate and regulate the quality of medical care for a covered condition and are not a system for implementing a mandated term of insurance regulating a minimal standard of care. *Corporate Health Ins., Inc.* v. *Texas Dept. of Ins.,* 220 F.3d 641, 644 (5th Cir. 2000).

Determining that the McCarran-Ferguson Act does not protect an IRO or regulation of an IRO, §12.103 of the proposed rule imposes a substantial burden on interstate commerce and is therefore unconstitutional. The commenter has not seen any evidence that out-of-state IROs pose any problems within the regulatory confines of this state. Department staff has not offered any testimony or indications that out-of-state IROs have been a problem.

Absent a determination that §12.103 is unconstitutional, the commenter recommends removing "is based" in §12.103(10) and amending §12.103 to read as follows: “(10) Evidence the Independent Review Organization has a primary office physically located in this State, and that this is reported and declared as the Business Office of the IRO in the IRO's Application for Certification, and in annual renewal statements, and that at any time that this address is changed, that TDI be notified 10 days prior to the change of such Business Address. The primary office of an IRO shall be the physical Business Address of the IRO that is declared in the Application for Certification as an IRO, must be where the management of the processes of independent review occur, and the location where corporate records case files, and files containing information on the Medical and Reviewers of the IRO are maintained. With regard to credentialing and case files, IROs must maintain at the primary office documents that demonstrate that all Reviewers on the IRO's medical review panel are licensed to practice in the State of Texas, and that, on a case by case basis, the IRO has assigned fully credentialed Reviewers to each case, and that reviewer has signed no conflict of interest statements.” Further, the commenter suggests that entities that were certified prior to the new Code shall have a grace period of 120 days to comply with the new law. During this grace period, an IRO will have the option of opening a primary office for independent review in Texas, or of selling the IRO to an owner in Texas who agrees to open a primary office, as defined above. During this grace period, which would begin on the date of the adoption of the new rules, the IRO would continue to be required to follow rules currently in effect, not the new proposed rules.

The commenter cites the following reasons for the suggested change: (i) unless this matter is deemed unconstitutional, the commenter understands that IROs will be required to comply with the Insurance Code §4202.002(c)(2)(A) provision mandating that an IRO's primary office be located in the State; however, the commenter believes that proposed language offered for implementing this Insurance Code provision does not provide sufficient guidance to operating IROs; (ii) the current language suggests that the actual medical reviews take place at the primary office which is a practical impossibility; and (iii) it should be clarified that IROs may maintain a separate mailing address in order to avoid inappropriate visits from an interested patient, which could jeopardize the independence of the process.

The second commenter states that if we eliminate the out-of-state IROs, we are going to lose their knowledge. These IROs were involved in drafting federal legislation. The small out-of-state IROs cannot afford to move to Texas. The large IROs are not going to move either, because the IRO business in Texas is not lucrative enough. This portion of the law is unnecessary. The first two levels of review are by URAs, who are located all over the country. The federal legislation is going to change the game completely. The out-of-state IROs were not involved in the stakeholder meetings. Some IROs did not know that the law had been passed.

The third commenter states the following reasons that the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas should be deleted: (i) the commenter's out-of-state IRO consistently receives 100% on its report card issued by the Department; (ii) the commenter's IRO has done nothing

unscrupulous and can be trusted; (iii) the IRO has learned and abided by all of the rules and regulations of the Department that govern the IRO business and, to the commenter's knowledge, has never had a complaint filed against it; (iv) the commenter sees no public purpose for this new law; (v) the law was written by another IRO owner who was trying to increase his own business by putting out-of-state IROs out of business; and (vi) this regulation does nothing to help the patients of Texas get fairness in the health care process, which is what we should be spending time and energy discussing.

The fourth commenter states that if the number of IRO cases is going to increase, now is not a good time to eliminate IROs. Some of the out-of-state IROs are big IROs that conduct business nationally, and the commenter asserts that they are good companies. The commenter further states that there is no indication that out-of-state IROs posed a problem.

The fifth commenter states the following reasons for deleting the requirement that the IRO be based in Texas: (i) the commenter's IRO received a 100% score in Department rankings; (ii) the IRO has never had a complaint filed against it by a patient, provider, insurance company, or URA; (iii) working with the Department is a pleasure under current rules; (iv) URAs that are similarly regulated by the Department are located all over the country; (v) one IRO owner is trying to manipulate the system for his own personal gain; (vi) there are numerous other out-of-state IROs that will be forced to relocate under this provision in order to keep their IRO business in Texas; (vii) for the commenter's family to relocate, it would cost tens of thousands of dollars and the

commenter's wife would not be able to keep her job; therefore, the commenter would be forced to sell his IRO; and (viii) the effect of this regulation would be to eliminate 20% of the IROs certified in Texas, bringing less competition and less independence to the system; with the new federal legislation, Texas will need more IROs, not less, to deal with the expanding system.

A sixth commenter cited the following reasons for deleting this requirement: (i) forcing a company to move its office to Texas puts an unnecessary financial strain on the company; (ii) people working for these companies will undoubtedly lose their jobs as a result of this provision, further worsening the economy; and (iii) many of the top rated IROs will no longer find it financially feasible to do Texas independent reviews and the Department will lose these quality reviewers.

Agency Response: The Department agrees in part and disagrees in part. The Department disagrees that the case law on which the commenter relies supports the proposition that an IRO's activity is not considered the "business of insurance" or that the requirement in §12.103 that an IRO must be based in Texas and have its primary office in Texas violates the Commerce Clause of the U.S. Constitution. The right to conduct independent reviews is a statutory right. A licensee does not have a vested right in the continuation of laws. The Legislature, in HB 4519, required the commissioner to adopt standards and rules that require an IRO to be based and certified in this state and to locate the organization's primary offices in this state. The Legislature may, in the exercise of the police power, regulate by reasonable requirements the conduct of IROs and, by proper grant, delegate the exercise of police

power to the Department. The exercise of the police power hinges upon the public need for safety, health, security, and protection of the general welfare of the community. When there is a public interest involved, the rights of individual licensees may yield to the overriding public interests and are regulated under the state's police power. It is important for the regulation of IROs conducting independent reviews in this state that the records be available for on-site audits. The Department would incur substantial costs in conducting on-site audits if the necessary records were located out of state, and untimely delays in audits could result in the destruction of records.

However, as previously discussed in response to the requests that the Department seek an Attorney General Opinion, to avoid an unnecessarily broad application of this provision, the Department has amended §12.5(28) to define "primary office" as "the place where, based upon the totality of the business activities related to independent review performed under this chapter, an independent review organization's books and records pertaining to independent reviews assigned by the Department are stored." Additionally, the Department has amended §12.103(10) to state, "(10) for an application for a certificate or renewal of registration as an independent review organization in this state made on or after December 26, 2010, evidence that the applicant's primary office is located in this state. As a condition of being certified to conduct the business of independent review in this state, an independent review organization must locate its primary office in this state." These revisions narrow the definition of "primary office" and apply the requirement that the primary office be located in Texas only to applicants for a new license or renewal on or after December 26, 2010.

This revision to §12.103(10) also removes the requirement that Form No. LHL006 include evidence that the applicant *is based* in Texas, as the first commenter requests.

Additionally, the revision imposes the requirement that the primary office be located in Texas only on applicants for a new license or renewal on or after December 26, 2010. Thus, any potential applicant will be aware of the primary office requirement set forth in §12.103(10) before deciding whether to apply for licensure or renewal. Although in some instances this applicability date may result in a shorter time period than the 120 day grace period the commenter suggests, in other cases it may create a longer time period with which to comply.

The Department's revision to the definition of "primary office" addresses the first commenter's request that books and records should be maintained at the primary office. This revision should also alleviate the commenter's concern that the rule requires actual medical reviews take place at the primary office, which was not the Department's intent.

Finally, the Department agrees that IROs may maintain a separate mailing address to avoid unexpected visits from patients, but asserts that a revision to the text is unnecessary. Regardless of whether a separate mailing address is maintained for patients, the IRO should provide the Department with the correct physical address for regulatory purposes.

Comment: A commenter suggests adding the following subparagraph to §12.103: "(11) information related to out-of-state licensure of legal process. All applicants must furnish a copy of the Certificate of Registration or other licensing document from the domiciled state's licensing authority. As a condition of being certified

to conduct the business of independent reviews in this State, an Independent Review Organization must locate its primary office in this State."

Agency Response: While the Department declines to use the commenter's language, the Department has revised §12.103(10) in a way that is consistent with some of the commenter's suggested language. As previously discussed, the Department has amended §12.103(10) to state, "(10) for an application for a certificate or renewal of registration as an independent review organization in this state made on or after December 26, 2010, evidence that the applicant's primary office is located in this state. As a condition of being certified to conduct the business of independent review in this state, an independent review organization must locate its primary office in this state." However, the Department does not intend on accepting a copy of a foreign Certificate of Registration as the only other required criterion for an IRO to conduct business in Texas.

§12.106. Qualifying Examinations.

Comment: Two commenters request that §12.106 be amended to require the Department to provide fair and timely notice of an impending audit by the Department staff. The first commenter requests that the following text be added to §12.106: "The department shall notify an IRO of a pending routine audit no later than 60 days before the audit is performed. The department shall specify which patient and/or doctor files it wants to audit, in writing, by certified letter and/or facsimile. The department shall notify an IRO of a targeted audit no later than 30 days before the audit is to be performed.

The department shall specify which patient and/or doctor files it wants to audit, in writing, by certified letter and/or facsimile. In the case of imminent danger to the public, including but not limited to, patient confidentiality breaches, late findings on life threatening issues and other issues that are deemed to be an emergency, the department may perform an on-site audit with 2 working days notice. In such a case, the department shall specify the issue(s) to the IRO and why such issues are a danger to the public. The IRO must be notified by facsimile, email and/or certified letter of the pending audit. The department shall specify which patient and/or doctor files it wants to audit in the notification to the IRO. All notifications given by the department for on-site audits shall be calculated in calendar days. All deadlines for submission for both the IRO and the department are measured in calendar days. The department shall respond to the audit and all of its components within 10 days of the audit. Should the department be unable to do that, the department shall notify the IRO of the expected date of completion.**"**

The second commenter recommends that the following language be added to the rule: "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. *The commissioner or the commissioner's designee shall provide adequate notice of the*

intent to conduct an on-site qualifying examination of an applicant for certification or renewal of certification that is not less than 30 days notice."

The first commenter cites the following reasons for the suggested change: (i) the suggested language informs the IRO of what to expect; (ii) in the past, the rule has only pertained to new licensees and now the department is including those IROs who apply for renewal; the suggested language offers a clarification in absence of published "Principles and Policies" regarding on-site audits; (iii) these audits are stressful, consume enormous amounts of time for the IROs to comply with the requested audit deadlines and the audits are arbitrary in how they are performed at this time; (iv) some IROs have been given as little as 24 hour notice and lacked life-threatening issues, while others have been given 2 months to prepare for the audit; (v) the "gotcha" aspects of the targeted audits are disturbing and interfere with the ability of the IRO to perform its normal duties while trying to find archived information, as requested by the Department, with the audits being performed by Department staff; (vi) there has been no imminent danger to the public which the department has identified in recent audits; and (vii) the suggested addition will create standards for such audits.

The first commenter further states that the intent is not to stop audits, and that the audits are a good thing that make the IROs more accountable and prevent them from being or becoming a danger to the public. The commenter further argues that the department has clear authority to make the suggested change without legislative intervention.

The second commenter cites the following reasons for the suggested change: (i) the proposed rule does not include any provision that requires Department staff to give fair and timely notice of the intention of the Department to audit an IRO who is seeking to renew their certificate as an IRO; (ii) the failure to give adequate notice to an entity regulated by the Department of an on-site audit may result in a waste of valuable resources and time of both the audited entity and the Department staff; and (iii) it is not fair nor is it prudent use of state resources to not give a regulated entity fair and timely notice of an audit whether that audit is a desk audit or on-site audit.

Agency Response: The Department declines to make the suggested change. The Department needs to maintain flexibility in its ability to monitor regulated entities, such as IROs, for compliance with statutory and regulatory requirements imposed on those entities for the protection of the patient. If a certain amount of advance notice would allow for an IRO to destroy records or otherwise alter evidence, the examination may not serve the intended purpose under certain circumstances. The Department recognizes the need for flexibility to work with the IRO on the starting date of the examination, as the circumstances allow. Additionally, there is no specific statutory requirement for advance notice.

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

Comment: A commenter requests that §12.110 be deleted. Two commenters, including the one requesting deletion of this section, state that the certificate is integral to the value of the IRO business. One of the key incentives for an IRO to provide

exceptional service to the citizens of Texas is the potential to build the value of the business. The result of this provision is to virtually confiscate the value of the business, since the new owner would have to reapply for certification, rather than purchasing a fully functioning business entity with an established and efficient way of conducting business. This provision is not necessary to control the quality of IROs because the Department is informed when an IRO is sold or transferred and obtains information on the new owners. If an IRO was transferred to a person or entity to which the Department objects, it would be able to take appropriate action

One of these commenters further argues that this provision confiscates the value built up by IRO owners and amounts to a taking of their equity in a business. The proposed amendment to §12.110 is particularly troubling because it appears to prevent IRO owners from increasing the value of their businesses or selling them for a profit.

Agency Response: The Department declines to delete §12.110. This section 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. Additionally, the Department needs to ensure that the new owner is not a payor and to obtain fingerprint information on the new directors and officers before they engage in the business of independent review. While this information would be available to the Department after the IRO is sold, advance approval reduces the likelihood of consumer harm because of individuals to whom the Department would ultimately object.

§12.201. Independent Review Plan.

Comment: A commenter recommends that proposed §12.201(3)(A) be modified to read as follows: “(3) required use of written medically acceptable review criteria that are: (A) established with consideration, as appropriate, given to [~~based on~~] medical and scientific evidence and [~~utilize~~] evidence-based standards;. . . .” The commenter cites the following reasons for the suggested change: (i) this language will ensure that the purpose of the HB 4290 is fulfilled; (ii) proposed §12.201(3)(A) will be consistent with 12.201(3)(B), which requires the review criteria to 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;" (iii) under current §12.201, the components of the independent review plan are somewhat broadly-defined (presumably in order to provide flexibility in their application); (iv) under the current regulations, the independent review plan must be developed with input from appropriate health care providers and reviewed and approved by physician, which is similar to the statutory requirement for utilization review plans under Texas Insurance Code §4201.151; (v) the Department's proposed modifications to §12.201 provide an extra layer of detail and, unfortunately, inflexibility to the independent review plan by requiring that the plan use written medically acceptable review criteria that are "based on medical and scientific evidence and utilize evidence-based standards;" (vi) as proposed, the standards established by 12.201(3)(A) may be too rigid to account for varying circumstances and emerging science in the practice of medicine; (vii) although the commenter supports the consideration and use of appropriately tested and peer-

reviewed evidence in making independent review determinations, given that the practice of medicine is an art as well as a science, it is critical that the proposed rules not be overly prescriptive in the use of so called "best evidence" to the detriment of payment for the provision of sound patient care; (viii) to require a strict adherence to the evidence-based standards would sacrifice legitimate determinations concerning medical necessity and the investigational/experimental nature of a particular treatment or drug in favor of uniform (if, sometimes, inaccurate) decisions using so-called "evidence based standards;" (ix) the Department must be mindful that what is the "best evidence" today may be outdated tomorrow and that which is the cutting edge today may be the state of the art and then the standard practice tomorrow; (x) the rules must be flexible enough to acknowledge a wide array of treatments and services that have been proven to be beneficial to patients; (xi) without providing for adequate flexibility in the rule, the review criteria required under the rule may be so stringent that many appropriate and beneficial health care services will be inaccurately classified as investigational or experimental, while HB 4290 was designed to ensure that those health care services that insurers deemed "investigational" or "experimental" were properly reviewed by an IRO; (xii) this modification would be consistent with the NAIC Model Act's focus on reviewing guidelines, as appropriate, when making the independent review determination; and (xiii) modification would be consistent with subparagraph (E) which requires the review criteria to be used only as a tool in the review process (and not determinative of the ultimate decision).

Agency Response: The Department agrees with the commenter that proposed §12.201(3)(A) was too rigid, as evidence-based medicine may not be available in every situation and thus cannot always be relied upon. The Department also clarifies that nothing in these proposed rules prohibits injured employees from obtaining reasonable and necessary investigational or experimental medical treatments or services when appropriate under Labor Code, Title 5. However, the Department asserts that evidence-based standards should be used when available. The Department has revised §12.201(3)(A) to state, "(A) based on medical and scientific evidence and utilize evidence-based standards, or if evidence is not available, generally accepted standards of medical practice recognized in the medical community."

Comment: Two commenters recommend that §12.201(3)(D) be amended to read as follows: "(D) [~~developed based on consideration of~~] including 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 review of workers' compensation non-network health care provided pursuant to the Labor Code Title 5; and including the treatment guidelines, treatment protocols, and return-to-work guidelines adopted by certified workers' compensation health care networks for review of workers' compensation network health care."

A third commenter recommends that: (i) the amended rules are consistent with the requirements set out in §413.011 of the Labor Code and 28 TAC §137.100; (ii) the

inclusion of language in the proposed rules that allows other "written medically acceptable review criteria" to be considered by the IRO doctor undermines the required use of the adopted treatment guidelines; this language should be deleted; and (iii) the amended rules should also require IRO doctors to consider and apply the DWC's closed drug formulary rules once the rules are adopted and the adopted treatment guidelines when reviewing medical necessity issues associated with the prescribing and use of prescription drugs.

The first two commenters disagree with §12.201 as written. These commenters assert that the proposed rule amendment suggests that the IRO is free to adopt any evidence-based review criteria it chooses for its independent review plan and only has to consider the treatment guidelines, treatment protocols, and pharmacy closed formulary adopted by TDI-DWC when deciding on what review criteria to adopt as part of its Independent Review Plan. This conflicts with the statutory standards for review of workers' compensation medical care as found in the Texas Labor Code and the Texas Insurance Code in the following respects: (i) Review of WC Non-network Health Care. The proposed rule does not require the IRO to include TDI-DWC adopted treatment guidelines, treatment protocols, and pharmacy closed formulary as part of the review criteria in its independent review plan. Consequently, the IRO may review workers' compensation non-network health care without considering the TDI-DWC adopted guidelines if it chose not to include those guidelines in the review criteria specified in its Independent Review Plan. This conflicts with the legislatively mandated review of workers' compensation non-network medical claims found in Labor Code §413.011 and

conflicts with DWC Rule 137.100 which requires health care providers to provide medical care in accordance with the DWC adopted treatment guidelines. Consequently, the rule should direct the IRO to include the TDI-DWC adopted treatment guidelines, treatment protocols and pharmacy closed formulary in its review criteria and to utilize that review criteria for its review of non-network workers' compensation health care; (ii) Review of WC Network Health Care. Similarly, the proposed rule conflicts with Texas Insurance Code §1305.351 and 28 TAC §10.101(a) which requires that the review criteria used for workers' compensation network health care be consistent with the network's treatment guidelines, return-to-work guidelines and individual treatment protocols. Consequently, the rule should require the IRO to include the workers' compensation health care network adopted medical treatment guideline, return-to-work guideline, and individual treatment protocols as part of its review criteria and to utilize that criteria for its review of network workers' compensation health care. Pursuant to §1305.351 (a), "In the event of a conflict between Chapter 4201 and this chapter, this chapter controls." One commenter further notes that the rule should not allow an IRO to use other treatment guidelines or other "written medically acceptable review criteria."

The third commenter cites the following reasons for the suggested changes: (i) §413.011 of the Labor Code provides, in part, that the commissioner of workers' compensation by rule shall adopt treatment guidelines and return-to-work guidelines and may adopt individual treatment protocols; treatment guidelines and protocols must be evidence-based, scientifically valid, and outcome-focused and designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care; (ii)

Title 28 TAC §137.100 requires health care providers to provide medical care in accordance with the DWC adopted treatment guidelines; (iii) with the provisions of the Labor Code §413.011 and 28 TAC §137.100 in mind, it is only appropriate that the IRO rule amendments require the use of the adopted treatment guidelines and not expand the scope of the IRO doctor's review beyond what the adopted treatment guidelines provide for; and (iv) use of other "written medically acceptable review criteria" would allow the IRO doctor to inappropriately ignore and unlawfully override the closed drug formulary rules and adopted treatment guidelines.

Agency Response: The Department declines to make the suggested changes. Section 12.201(3) requires the IRO to consider the treatment guidelines, treatment protocols, and pharmacy closed formulary as provided in orders issued or rules adopted by TDI-DWC. The IRO can consider other medically acceptable review criteria. The IRO is free to adopt any evidence-based review criteria it chooses for its independent review plan and only has to consider the treatment guidelines, treatment protocols, and pharmacy closed formulary adopted by TDI-DWC when deciding on what review criteria to adopt as part of its independent review plan. Under 28 TAC §133.308, if the IRO's decision is contrary to (i) the policies or guidelines adopted under the Labor Code §413.011, the IRO must indicate in the decision the specific basis for its divergence in the review of medical necessity of non-network health care; or (ii) the network's treatment guidelines, the IRO must indicate in the decision the specific basis for its divergence in the review of medical necessity of network health care.

Comment: A commenter recommends that the Department add to proposed §12.201(4) language establishing the standard for determinations that health care services are "investigational or experimental." Specifically, the commenter recommends the following language for inclusion in the IRO's independent review plan: §12.201(4) “independent review determinations that: . . . (E) a health care service or treatment is investigational or experimental may only be made if the procedure, course of treatment or health care service lacks sufficient medical or scientific evidence of benefit for a particular condition. A procedure, course of treatment, or health care service is not "investigational or experimental" if it: (i) is generally accepted by the provider of record as effective and appropriate for the condition in question; or (ii) is supported by an overall balance of objective medical and scientific evidence, in which the potential risks and potential benefits are examined.” The commenter asserts the following reasons for the suggested change: (i) adding such a definition would ensure that there is transparency and uniformity in the decision making process among IROs with regard to decisions concerning the investigational or experimental nature of a treatment; and (ii) this definition would be consistent with the goals of HB 4290 in requiring a meaningful review of treatments that insurers have denied based upon their findings that such treatments are investigational or experimental.

Agency Response: The Department agrees to include a definition of “experimental or investigational” but declines to use the commenter’s suggested language. Instead of revising §12.201(4), the Department has defined “experimental or investigational” in §12.5(12) as “A service or device for which there is early, developing

scientific or clinical evidence demonstrating the potential efficacy of the treatment, service, or device but that is not yet broadly accepted as the prevailing standard of care." The Department asserts that this definition is consistent with the commenter's suggested definition. This change also resulted in redesignating proposed §12.5(12) – (33) to §12.5(13) – (34), respectively.

Comment: A commenter recommends amending §12.201 by adding new subsection (5) as follows: "(5) a policy indicating that a treatment or service that has been approved by the U.S. Food and Drug Administration and commercially available for not less than two years shall not be considered experimental or investigational." The commenter cites the following reasons for the suggested change: (i) the proposed rule allows for denials based on a treatment being considered experimental or investigational to be appealed to an IRO; (ii) one of the stated goals of the legislation as cited in the rule preamble is "to ensure that carriers have consistent standards for what is considered experimental and investigational;" (iii) there is little consistency or rationality in how the insurance industry defines "experimental and investigational;" and (iv) while this addition would not directly change the policy of the health insurer or workers' compensation carrier directly, it should help forward the stated legislative goal of developing consistent standards since over time carriers and insurers may modify their policies to match this standard based on decisions that are rendered by IROs.

Agency Response: The Department disagrees with the suggested change. A treatment or service that has been approved by the U.S. Food and Drug Administration and has been available for a set time period could still be considered experimental or

investigational. For example, a treatment or service could be approved because it does no harm to a patient, but it may not yet have been proven to cure a specific condition. Additionally, in response to a separate comment, the Department has defined "experimental or investigational" as "A service or device for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, service, or device but that is not yet broadly accepted as the prevailing standard of care." The commenter's suggested change would be inconsistent with this definition.

Comment: A commenter suggests requiring and enforcing insurance carriers to forward all documents attached to the required LHL009 form, not simply those that the insurance carrier or URA feel is relevant, which are likely to be different than the documents that an injured employee believes are relevant. The commenter cites the following reasons for the suggested change: (i) IROs may be receiving information from insurance carriers that support only their position rather than all of the relevant information that the IRO needs to make an informed decision on the medical necessity issue under review; and (ii) while the IRO has the ability to request additional information, it appears such requests are not occurring.

Agency Response: The Department disagrees with the requested change. Such a requirement could be very onerous and result in the production of documents that are not relevant to anyone. The carrier or its URA is required to forward all documents relied upon in making the adverse determination. Any party can forward documents that are relevant to the adverse determination to the IRO for consideration.

Comment: A commenter recommends that the Department add to proposed §12.201(4) a requirement that independent review determinations be based upon consideration of relevant supporting documentation, including the patient's medical records, the recommendation of the provider of record and consulting reports. Specifically, the commenter recommends the following language: "§12.201(4): independent review determinations that: (D) are made taking into consideration, as appropriate and as available: (i) the patient's medical records; (ii) the recommendation of the provider of record; (iii) consulting reports from appropriate health care providers; and (iv) other documents submitted by the patient, the patient's authorized representative, or the patient's provider of record." This language is based upon consideration of documentation that must be reviewed by the independent review panel in the NAIC Model Act. This requirement provides additional guidance to independent review panels without being overly prescriptive in terms of the information that must be considered.

Agency Response: The Department declines to make the suggested change. The documentation that was reviewed and where the support comes from is already required.

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

Comment: Three commenters request clarification of the prohibition against the use of shared staff. The first commenter objects to this prohibition for the following reasons: (i) the use of shared clerical staff, a bookkeeper and tax accountant became necessary in order to control costs and remain in business; (ii) the nature of processing quality reviews requires the skills and professionalism of an intelligent and responsible person; (iii) the small quantity of reviews currently assigned does not financially allow for full-time employment of such an individual even though the new rules require that such a person be made available to answer to all parties involved; (iv) by eliminating a clerical worker's right to work for more than one IRO, the rule is interfering with the worker's right to gainful employment; (v) the original law and the "Author's/Sponsor's Statement of Intent" makes no mention of shared clerical staff or prohibiting employment of staff by more than one IRO; HB 4519 is aimed at business owners and not staff workers; and (vi) sharing clerical staff has made it feasible for the commenter to maintain the best standards in qualify as the number one IRO in Texas, while also remaining in business.

The second commenter objects to the requirement that IROs not share clerical staff for the following reasons: (i) as the rule is written, an individual cannot use bookkeepers, accountants, transcriptionists, or contract labor if they are used by another IRO; (ii) an IRO could unwittingly violate this amendment; (iii) it is the right of every American to seek life, liberty and the pursuit of happiness; seeking to exclude a person from earning money in a paying job is an affront to the American way of life; this rule seeks to nullify this basic principle of the Declaration of Independence; (iv) an

individual should not have his or her ability to work restricted without cause; (v) the prohibition is not found in the HB 4519 bill analysis and seems to be adding to the language of the statute; and (vi) it violates the Government Code §2006.002(c-1).

The third commenter requests that the Department clarify and define the terms "clerical staff," "office," "other facility," and "subcontractor services or personnel . . . to perform independent review." The commenter questions whether the term "subcontractor services or personnel . . . to perform independent review" means only the physician reviewer or whether it also encompasses transcription services and sort and summary services. The commenter asks whether a transcriptionist is a subcontractor utilized to perform independent review. The commenter further questions whether the prohibition of shared staff extends to independent contractors such as bookkeepers, accountants and transcriptionists. The commenter asserts that when considering the anticipated income of $1,931, it is economically feasible to share a part-time experienced independent contractor such as a bookkeeper or transcriptionist but would not be economically feasible to hire independent staff to mandate that the independent contractor cannot work for any other IRO performing similar duties. If the income is $1,931 and the cost of an office clerk averages $1,755, there are essentially no funds for additional staff members.

Agency Response: The Department declines to make any additional clarifications in §12.204 on the prohibition against shared staff. The Department disagrees that the rule prohibits the shared use of independent contractors. Section 12.204(c)(2) specifically states, "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."

Comment: A commenter recommends that to the extent that this rule will be in place as required by the statute, the term "facility" should be defined as "a space which has a separate entrance and is separated from another facility or another office completely by four walls, but not necessarily in a different building." The commenter asserts that prohibition of an IRO from operating in the same facility with another IRO or from sharing resources and personnel that comprise an office, while is required by statute, is likely unenforceable. The commenter is unable to ascertain a rational basis for this new provision. The commenter asserts that a failure to define "facility" will create numerous problems and ambiguity. For example, the commenter opines that it is obviously not the intent of the rule that IROs be prohibited from having an office in the same multi-office building, but under the current language, such an arrangement is unclear.

Agency Response: The Department declines to make the suggested change. The sharing of an office by more than one IRO could potentially erode the independence of the review process and/or compromise patient confidentiality. However, it is not the intent of §12.204 to prohibit the use of offices in the same multi-office building.

Comment: Two commenters argue that Section 12.204(h) appears to be in violation of the U.S. Constitution. Both commenters note that it is clearly unconstitutional unless the State can articulate a *compelling* reason for denying IROs

the right to choose its own counsel. *Texas Catastrophe Property Ins. Ass'n* v. *Morales,* 975 F.2d 1178, 1181 (5th Cir. Tex. 1992) ("If the state can show 'compelling reasons,' then a party's right to choose its own (civil) counsel may be overridden."). See also *Gates* v. *Cook,* 234 F.3d 221, 227 (5th Cir. Miss. 2000) and *Rehabilitation Facility* v. *Cooper,* 962 S.W.2d 151, 156 (Tex. App.Austin 1998, no pet.). Since there does not seem to be a valid reason for §12.204(h), the first commenter, who has acted as a registered agent for two IROs, asserts that it is possible that §12.204(h) was specifically included in the bill to harm him personally because of past dealings with an individual who was involved in drafting the legislation. This provision, when enacted, will require the commenter to end representation of current IRO clients and to deny his clients the right to choose him as their attorney. There does not seem to be a logical reason or any public policy justification for §12.204(h). A registered agent simply accepts service for his or her client. Registered agents include attorneys, entity officers, professional services and others. There is a trust that has been built up and will be lost. It is also a long tradition that an individual should be able to select his own lawyer.

The second commenter recommends that the Department request an Attorney General Opinion on the constitutionality of this provision. Both commenters also note that there is no reference to what this regulation is intended to remedy.

Agency Response: As previously discussed in response to the requests that the Department seek an Attorney General Opinion, the Department has considered §12.204(h) further and has determined that the provision governs the practice of law by limiting the conduct of certain licensed attorneys in the state of Texas. Because the

Department's regulatory authority does not extend to the practice of law, the Department has deleted this provision.

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

Comment: Two commenters disagree with proposed §12.205(d) and request that it be deleted. The commenters cite the following reasons for the suggested deletion: (i) the proposed rule amendment implies that there is a requirement that the URA, carrier, or other payor must get pertinent medical information to the IRO within three working days of receipt of the IRO assignment; there is no such requirement in Chapter 4202 of the Texas Insurance Code; (ii) there does not appear to be any purpose for imposing that reporting requirement on the IRO or imposing that implied filing requirement on URAs, carriers, or other payors; and (iii) the commenters can recognize a potential public policy reason to impose such a requirement for life-threatening conditions, but this subsection does not limit its application to life-threatening conditions and is not even necessary for life-threatening conditions in light of the IRO requirements found in §12.205(c).

Agency Response: The Department declines to delete §12.205(d). This revision was made to harmonize the rule with §133.308(l), which requires the carrier or the carrier's URA to submit specific documentation to an IRO not later than the third working day after the date the carrier receives the notice of IRO assignment.

Comment: A commenter requests that §12.205(f) be modified to clarify that an Office of Injured Employee Counsel (OIEC) Ombudsman assisting an injured employee is also permitted to send pertinent records to the IRO conducting the independent review. An OIEC Ombudsman provides assistance to an injured employee and is statutorily prohibited from providing representation. Since there is no provision for payment of attorney's fees in medical dispute resolution cases in workers' compensation, OIEC Ombudsmen provide assistance in the vast majority of those cases. A significant part of providing effective assistance to the injured employee is helping to ensure that the IRO receives pertinent records and modifying the rule language to permit the Ombudsman to send those records would further that objective.

Agency Response: The Department disagrees with the suggested change. Section 12.205(f) does not prohibit the OIEC Ombudsman from assisting the injured employee in sending the pertinent records. However, expanding the role of the OIEC is beyond the Department's authority.

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

Comment: Two commenters recommend that §12.206(d)(18) be expanded to include an explanation of how the review criteria were utilized to make the determination. One commenter recommends the following specific language: "(18) a description of the source of the review criteria that were utilized to make the determination *including an analyses of how the reviewed treatment is within the scope and extent of medical treatment recommended by the review criteria or how the clinical*

evidence justifies a deviation from the review criteria; . . . ." Both commenters assert that the Department and the Division of Workers' Compensation cannot effectively review whether or not IROs are complying with the Texas Insurance Code and Texas Labor Code unless the IRO decision explains how the reviewed treatment is within the scope and extent of medical treatment recommended by the review criteria or how the clinical evidence justifies a deviation from the review criteria.

Agency Response: The Department declines to make the suggested change. The IRO is already required to explain its decision, so the commenter's suggested language will not provide any additional information.

Comment: A commenter recommends amending proposed §12.206(d)(18) as follows: "(18) a description and the source of the review criteria, *including a copy or excerpt of the specific provision of the review criteria*, that were utilized to make the determination; . . . ." While the information in the proposed rule is helpful, the commenter recommends that the IRO be required to provide the specific citation and language from their screening criteria that was used to make the determination so that the appealing parties have a full understanding of the rationale for the determination. This information may assist the parties in their decision to further appeal the determination and thereby limit appeals to those with appropriate merit.

Agency Response: The Department declines to make the suggested change. Such a requirement may require the copying and production of information in violation of copyright law.

§12.207. Independent Review Organization Telephone Access.

Comment: A commenter opposes the amendments to §12.207 for the following reasons: (i) the new rule requires that IROs should be "generally (sic) available by telephone" to parties other than URAs; while this appears to make no substantive change to broaden the telephone availability requirements for IROs, in effect it would require IROs to communicate with anyone and everyone; (ii) under amended §12.207, an IRO would be compelled to discuss details of individual cases with persons other than URAs, which hinders both the patient privacy and the independence of the process; (iii) this open access creates an economic burden on IROs, which was not present in prior rules; (iv) previously, the IRO had to return calls "to URAs" in 2 working days, which allowed plenty of time to address any issue during the 20-day review process; (v) amended §12.207 significantly increases costs to the IROs, by encouraging patients to directly contact them; (vi) the proposed rule change jeopardizes the independent status of the IROs; and (vii) any change that increases the workload of the IROs should also have a corresponding fee increase.

Agency Response: The Department agrees that proposed §12.207 was unintentionally broad and has revised §12.207(b) to state, “An independent review organization must have a telephone system capable of accepting or recording or providing instructions to incoming calls *related to utilization review* during other than normal business hours and shall respond to such calls not later than one working day from the date the call was received.” The Department’s revision narrows the scope of §12.207(b) to calls related to utilization review.

Comment: A commenter fully supports the change in proposed §12.207(b) that reduces the time to return a telephone call made outside of business hours to one working day from the date the call was received rather than two working days. Timely receipt of medical care is critical to an injured employee's physical recovery and ability to return to work. Any provision that hastens an IRO determination is beneficial.

Agency Response: The Department appreciates the supportive comment.

§12.208. Confidentiality.

Comment: A commenter fully supports the provisions of §12.208 that serve to protect patient confidentiality. There appears to be universal agreement that maintaining the confidentiality of medical information is paramount. Accordingly, the commenter agrees that a strong confidentiality provision, such as one in §12.208, is imperative.

Agency Response: The Department appreciates the supportive comment.

Comment: A commenter suggests that the Department clarify that the rule does not prohibit the provision of confidential information to a third party for legitimate IRO purposes when there is a HIPAA-compliant confidentiality agreement with a third party in place. As written, the proposed rule seems to exclude the possibility of providing confidential information to a third party such as a transcriber or recordkeeping service, even when there is a HIPAA-compliant confidentiality agreement in place. Removing the ability for IROs to contract with third parties to provide routine services would

jeopardize the ability of IRO to continue to function in an economical manner and continue to provide new services to the State of Texas.

Agency Response: The intent of the rule is not to prohibit the provision of confidential information to a third party when a HIPAA compliant confidentiality agreement with a third party is in place. However, the Department declines to expand the scope of §12.208 to include HIPAA privacy law. Section 12.208(b) states that an IRO 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 by law*. This reference to other law includes relevant state and federal privacy laws.

§12.303. Surrender of Certificate of Registration.

Comment: A commenter applauds §12.303, stating that this provision gives greater emphasis to the protection of the patient than to the interests of a suspect IRO. It is expected that the Department would have a solid basis for pursuing an investigation of an IRO and, as a result, it is appropriate that the Department would also have the discretion to limit the IRO's authority to operate during that period.

Agency Response: The Department appreciates the supportive comment.

Comment: Two commenters assert that §12.303 contains no due process of law. One commenter recommends that the Department request an Attorney General Opinion on the constitutionality of this requirement. The commenter further recommends removing the reference to a voluntary surrender of certificate and

suggests referencing a surrender of certificate only after an IRO has been provided due process on the issue. This commenter further states that the provision requiring a "voluntary suspension of a license" is neither voluntary nor legally permissible as it eliminates a vested right to continue to operate without any due process. According to the commenter, when the state vests a right to do business to a company, certain due process standards must be afforded prior to suspension of their ability to continue to do business. *See, Guerrero-Ramirez* v. *Texas State Rd. of Medical Examiners,* 867 S.W.2d 911 (Tex.App.-Austin 1993); *Texas Dept. of Health* v. *Gulf Nuclear,* Inc., 664 S.W.2d 847,850 (Tex. App.-Austin 1984)(stating an agency is required by law to give notice and provide an opportunity for a hearing prior to suspension of a license). The proposed rules afford no due process protection to the companies affected and require a "voluntary suspension" without any proceeding to determine whether wrongdoing in fact occurred.

The commenter further asserts that the Department is subject to Chapters 2001 and 2002 of the Texas Government Code. *See* Tex. Ins. Code Ann. §31.101 (Vernon 1999). These chapters have been deemed by Texas courts to require agencies to assure fairness to affected persons and to assure that the public and affected persons are heard on matters that involve their interests and affairs. *Amarillo Indep. Sell. Dist.* v. *Meno,* 854 S.W.2d 950 (Tex.App.-Austin 1993). A *mandatory voluntary* surrender of the certificate runs afoul with the rules that govern Texas agencies because it hinders an IRO's ability to be heard and provided due process before the certificate is required to be surrendered.

Agency Response: As previously discussed in response to the requests that the Department seek an Attorney General Opinion, the Department has revised §12.303 by (i) removing the terms “voluntary” and “voluntarily”; (ii) adding subsection (c) to state, “A certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending;” and (iii) adding subsection (f) to state, “Notwithstanding §12.4(b) of this chapter (relating to Applicability), this section only applies to an independent review organization that: (1) is licensed on or after December 26, 2010; or (2) has its certificate of registration renewed in this state on or after December 26, 2010.”

The Department has removed the terms “voluntary” and “voluntarily” to clarify that the surrender is required and to avoid confusion as to whether the surrender is mandatory or voluntary. Additionally, the Department has provided that a certificate of registration that is surrendered under §12.303 is temporarily suspended while the investigation is pending, clarifying that the certificate of registration is not permanently revoked without due process of law. This temporary suspension of rights may be necessary to protect the patients whose claims are being reviewed by the IRO and to avoid harm to the patients. Finally, the addition of subsection (f) makes this provision only applicable to IROs newly licensed on or after December 26, 2010 or to existing IROs upon renewal of their certificates of registration on or after December 26, 2010. Thus, any potential applicant will be aware of the surrender process set forth in §12.303 before deciding whether to apply for licensure or renewal.

The right to conduct independent reviews is a statutory right. A licensee does not have a vested right in the continuation of laws. The Legislature, in HB 4519, required the commissioner to adopt standards and rules that require an IRO to voluntarily surrender its certification while the IRO is under investigation or as part of an agreed order. The Legislature may, in the exercise of the police power, regulate by reasonable requirements the conduct of IROs and, by proper grant, delegate the exercise of police power to the Department. The exercise of the police power hinges upon the public need for safety, health, security, and protection of the general welfare of the community. When there is a public interest involved, the rights of individual licensees may yield to the overriding public interests and are regulated under the state's police power.

§12.402. Classification of Specialty.

Comment: A commenter strongly recommends that the Department replace the reference to "medical or surgical care" with "health care services" in §12.402(2) as reflected in the following: "(2) Tier two fees will be for the independent review <u>of health care services</u> [~~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." The commenter cites the following reasons for the suggested change: (i) the commenter strongly objects to the Department's proposed reference to

"medical or surgical care" rendered by the specialties listed in proposed §12.402(2); the specialties listed in proposed §12.402(2) are not M.D.s or D.O.s and, therefore, are not statutorily authorized to practice medicine or to provide general medical or surgical care; rather, they are authorized only to provide the limited health care services consistent with and within the scope of their respective enabling statutes; (ii) it is important to note that current §12.402(1) references tier one fees provided for "medical or surgical care" rendered by a doctor of medicine or doctor of osteopathy; this reference is accurate, because M.D.s and D.Os are statutorily authorized to provide medical and surgical care by the Texas Medical Practice Act; (iii) the suggested revision makes the proposed language of §12.402(2) consistent with Texas law.

Agency Response: The Department agrees and has made the suggested change.

§12.403. Fee Amounts.

Comment: Two commenters recommend that the fee amounts be revised. The first commenter recommends that the two-tier system should be abolished and the current Tier 1 and Tier 2 fees should be increased to a single fee of $950, with all tiers having the same billing procedure with the current 15 day rule that is in effect for Tier 1 cases. In addition, there needs to be a provision to increase the fee on a schedule into the future to avoid having to amend the law continuously to meet this anticipated change.

As previously explained to Department staff during informal stakeholder meetings, the costs of operating an IRO have increased dramatically while the fees have stayed the same. In 1998 when the IRO law was enacted there was no provision for the rising cost of doing business, and fees were set when there was only one kind of IRO review, for HC cases. The rationale for those fees was based on HC, not WC or WCN cases. With the merger of the Texas Workers' Compensation Commission into the Department, and the creation of the new network organizations, IROs now have to keep in place and maintain three separate sets of procedures for managing three different kinds of reviews, which is a heavy administrative and regulatory burden. Indeed, the regulatory burden alone suggests that the prudent IRO should set up a reserve for Regulatory Compliance on their balance sheets.

The two-tier system now in place allows payors in certain cases 30 days to pay IROs, and the 30 days begins after the case is complete. These cases are often far more complex to administer, are paid in arrears after the IRO has incurred substantial costs-and yet they pay only $460, rather than the current standard for Tier 1 of $650.

The second commenter states that every fee has increased in the past 12 years. There is a possibility that there may be more IRO cases, but the commenter has been in the business for five years and there has not been an increase in IRO cases. The commenter once received a case that had 684 items in dispute. The fee in that case clearly would not exceed the disputed amounts.

Agency Response: The Department declines to increase the fees at this time. However, future implementation of federal healthcare reform may cause the Department to revisit the fee structure.

Comment: A commenter recommends that a fee of $1500 should be established for life threatening cases. The commenter cites the following reasons for the suggested fee increase: (i) life threatening cases require IROs to have a fourth set of procedures in place, which must be completed in 8 days, rather than the longer periods allowed for other cases; (ii) these cases are extremely labor intensive and require the IRO to pay larger fee to reviewers, medical professionals who must in certain cases do their work on weekends, to meet the 8 day deadline; and (iii) the patient or worker who requested these reviews are in a special status and the IRO should be funded appropriately to meet the short deadline.

Agency Response: The Department declines to make the suggested change. There is no statutory requirement that a separate fee be established for life-threatening cases.

Comment: A commenter recommends that §12.404 regarding payment of fees be amended to address the following concerns: (i) IROs should not be allowed to submit an invoice to a URA or payor until their services have been rendered; in workers' compensation many deadlines for payment of a bill are based on receipt of the invoice, and requests for a review may be withdrawn prior to the review being performed; (ii) an administrative process, with appropriate penalties, should be created to allow URAs or payors to recover overpayments to IROs; and (iii) the rule should be clarified to

reference the Division of Workers' Compensation rules, which have different payment timelines for workers' compensation URAs.

Agency Response: The Department agrees in part and disagrees in part. The Department has revised §12.404(c) by adding the following second sentence: "For workers' compensation network and non-network disputes, the independent review organization fees shall be paid in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations)." However, the Department is unaware of a problem with overpayments that would require a specific rule. Further, the Department is able to assess administrative penalties and does not need a specific penalty for recovery of overpayments.

Economic Impact Statement/Regulatory Flexibility Analysis

Comment: Four commenters assert that the figures used to calculate the economic impact of this rule were incorrect. The report states that "Based on Department records, an IRO receives an average of 10 independent review assignments per month." Three commenters assert that IROs actually receive an average of seven independent review assignments per month as per 2010 figures. Based on seven assignments, two commenters calculate a gross income of $4,170 per month, while the third commenter calculates a gross income of $4131 per month.

Three commenters also state that they pay more to their reviewers than the figure provided by "one" IRO used for the example. The first commenter further asserts that this increased pay for the reviewer actually leaves $2,370 available to the

commenter for *all expenses* after the reviewers are paid. This amount must then be divided to cover clerical staff, a bookkeeper, rent, utilities, copier maintenance, office supplies (paper, toner, folders, pens, labels, staples), postage fees, internet fees, telephone lines, bank service charges, storage fees and annual expenses to include tax return preparation, 1099s, W2s, and annual State License renewal. According to the Department's calculated employee costs of $1,334 to $2,176, the commenter argues that the actual figure of $2,370 does not appropriately cover the cost of this employee as well as the operating expenses actually incurred by an IRO.

The second commenter asserts that the actual pay to a reviewer is approximately $1,800 per month. This commenter agrees that the cost of an employee or employees is approximately correct, and further estimates that rent, utilities, phone, fax, internet, taxes, and other such costs are approximately $950 per month. Thus, calculating the gross income of $4,170 per month, less (i) $1,800 for reviewers; (ii) $1,334 for employees; and (iii) $950 for other office costs, this commenter projects a profit margin of $86.

The third commenter states that the compensation for reviewers is based on information from one IRO that pays $250 for Tier 1 reviews and $150 for Tier 2 reviews, but that these figures are not reflective of all IROs and a greater cross-section of payments to reviewers should be acquired prior to making a financial analysis. The commenter asserts that if in actuality an IRO pays $350 for a Tier 1 review and $200 for a Tier 2 review, and the gross income is based on 7 assignments instead of 10, the

actual anticipated income would be $4,131 less $2,150 for an anticipated net income of $1,931 (sic).

The fourth commenter states that HB 4519 does nothing to improve the independent review process but puts unfair restrictions on small business. These restrictions are so unfair that they will likely cause many businesses to fail. The economic impact numbers are ridiculous. Specifically, the commenter notes that there is no place in this country that a company can move an office for $3,000 within that state, let alone a cross country move. The commenter asserts that the anticipated one-time cost of establishing a new physical location of $2,500 - $3,000 is very unrealistic.

Agency Response: The estimated average of 10 assignments per month to an IRO was based on the Department's records. At the time of the proposal, the number of IRO assignments divided by the number of IROs in Texas was 10. The Department relied on that information in estimating the average number of assignments. The Department acknowledges that the cost for a reviewer was based on information from *one* IRO and specifically stated in the proposal that "the overhead costs will vary for each IRO based on the IRO's business model and expenses." As previously discussed, the Department's revisions to the definition of "primary office" and §12.103(10) requires out-of-state IROs to provide evidence that its primary office is located in Texas. "Primary office" is defined as "The place where, based upon the totality of the business activities related to independent review performed under this chapter, an independent review organization's books and records pertaining to independent reviews assigned by

the Department are stored." Therefore, this narrower requirement should limit the cost of compliance.

Comment: Two commenters request that the Department reconsider the economic impact of the prohibition on sharing staff. The first commenter states that the rule's prohibition on the use of shared staff places an undue financial burden on the commenter's company, which is a micro-business. The Government Code §2006.002(c) requires that if a proposed rule has an adverse economic impact on a small business, alternative methods of achieving the proposed rule must be presented. If this portion of the rule is to remain in place, the commenter requests that the Department provide an alternative method to pay operating costs and clerical staff while still maintain a profitable company.

The second commenter states that the economic impact and regulatory flexibility should be further considered in regards to part-time staff and independent contractors such as bookkeepers, accountants, and transcriptionists, for small and micro businesses. Given the fact that the actual anticipated income is $1931 per month, it is unrealistic and a financial burden to require multiple full-time staff members to carry out the duties of the IRO. Utilizing part-time experienced independent contractors to perform essential duties of the IRO is a necessary and economically viable choice for operating an IRO. Utilizing part-time experienced independent contractors is not inconsistent with the health, safety, or environmental and economic welfare of the state as referenced in the Government Code 2006.002(c-l). There will be a substantial

adverse effect on the micro-businesses to comply with the prohibition of shared staff and regulatory flexibility should be considered.

Agency Response: The Department declines to make the suggested change. Utilizing part-time independent contractors is not prohibited by the rule. Section 12.204(c)(2) specifically states, “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.”

Comment: A commenter requests that the Department revisit the idea of not applying the new rules to micro entities. These rules will put many small IROs out of business even though they have fulfilled their responsibilities and have contributed enormously to a healthy, well functioning IRO system. In these hard economic times, a more thorough study of the impact on these small businesses is vital. The commenter states that the Department, in its published proposal on the new rules, has conducted and published an initial economic impact analysis required by law on costs of regulations for micro entities, and this analysis demonstrates that the costs are substantial to small IROs. The commenter further notes that almost all IROs in Texas are micro entities, very small business organizations with fewer than 5 staff members and only some $50,000 in annual revenues. At one point in the Department’s analysis, the Department states that it considered not applying the new regulations to any micro entities that were IROs, but then the idea was discarded and not mentioned again.

If the Department rejects this request, the commenter asks that the Department conduct a thorough financial study of all the costs to a single micro entity, which

includes the loss of shareholder value for the IRO that will almost certainly result from the many restrictions in the new regulations on the transfer of ownership at the time of a sale of an IRO.

The commenter opines that even if the Department simply added up all the costs specified in the Department's current economic impact analysis, and placed that in the context of how marginal the profits are for these micros entities financially, the Department would conclude that an unintended consequence of the new regulations would be that large numbers of small IROs (perhaps over 70%) would be put out of existence by the financial costs of the new regulations. Moreover, the commenter points out that the five large, financially robust, IROs that are departments of large multimillion dollar entities, would also be put out of existence by the provision that the primary office be based in Texas, since most of these companies are out of state.

Perhaps as few as 10 of the current IROs would be left standing, which may have actually been the objective of the 2 IROs out of 43 that spoke in favor of the new regulations in the Legislature. Financially, if this occurred, the remaining 10 IROs would immediately expand from $50,000 a year in sales to approximately $220, 000 a year in sales.

Agency Response: The Department appreciates the commenter's concerns and considered the impact when preparing the economic impact statement and regulatory flexibility analysis. The Department has complied with the Government Code §2006.002, which requires the Department to reduce the adverse economic effects on small or micro businesses if doing so is legal and feasible considering the purpose of

the statute under which the rule is to be adopted. The Department prepared an economic impact statement estimating the number of small and micro businesses subject to the proposed rule, projecting the economic impact of the rule on these entities, and describing the alternative methods of achieving the purpose of the proposed rule. The Department also prepared a regulatory flexibility analysis that included the Department's consideration of alternative methods of achieving the purpose of the proposed rule.

Therefore, the Department declines to reconsider exempting micro entities from the requirements of the rules. The Department estimated in the proposal that approximately 35 IROs of the 43 IROs that are currently certified are small or micro business IROs. Making the rules inapplicable to such a large number of IROs would effectively negate the provisions, and in most cases the rule would not serve its intended purposes. Requiring such a small number of IROs to comply with the rules would result in an unfair competitive market and unfair loss of income for a few IROs.

Additionally, revisions to the definition of "primary office" and to §12.103(10), as previously discussed, may alleviate the commenter's concern that the large out-of-state IROs will no longer conduct business in Texas.

5. NAMES OF THOSE COMMENTING FOR AND AGAINST THE PROPOSAL.

For: Office of Public Insurance Counsel.

For, with recommended changes: Insurance Council of Texas.

Neither for nor against, with recommended changes: Aurora; Med Health Review, Inc.; Medtronic; Office of Injured Employee Counsel; Property Casualty Insurers Association of America; Specialty IRO, Inc.; Texas Medical Association; Texas Mutual Insurance Company; ZRC Medical Resolutions, Inc.

Against: Advanced Reviews; American Association of Independent Review Organizations; Clear Resolutions, Inc.; I-Decisions, Inc.; Medical Review Institute of America; P&S Network, Inc.; four individuals.

6. STATUTORY AUTHORITY. The amendments and new sections are adopted 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; and (v) 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.

7. TEXT.

SUBCHAPTER A. GENERAL PROVISIONS

§12.1. Statutory Basis. This chapter implements the Insurance Code Chapter 4202 as of September 1, 2009.

§12.2. Severability Clause. If a court of competent jurisdiction holds that any provision of this chapter or its application to any person or circumstance is invalid for any reason, the invalidity does not affect other provisions or applications of this chapter that can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

§12.4. Applicability.

(a) All independent review organizations performing independent reviews of adverse determinations made by utilization review agents, health insurance carriers, health maintenance organizations, and managed care entities, 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) Except as otherwise provided, this chapter is applicable to all requests for independent review filed with the department on or after December 26, 2010. All

independent reviews filed with the department prior to December 26, 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) Adverse determination--A determination by a utilization review agent made on behalf of any payor that the health care services provided or proposed to be provided to a patient are not medically necessary or appropriate, or are experimental or investigational.

(2) 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) Commissioner--The Commissioner of Insurance.

(8) Department--Texas Department of Insurance.

(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.

(12) Experimental or investigational--A service or device for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of

the treatment, service, or device but that is not yet broadly accepted as the prevailing standard of care.

(13) 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.

(14) 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.

(15) Health care provider or provider--A person, corporation, facility, or institution that is:

(A) licensed by a state to provide or otherwise lawfully providing health care services; and

(B) eligible for independent reimbursement for those services.

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

(17) 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.

(18) 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. 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 (relating to Classification of Specialty).

(19) Independent review plan--The review criteria and review procedures of an independent review organization.

(20) 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.

(21) 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.

(22) Medical and scientific evidence--Evidence found in the following sources:

(A) 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 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);

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

(D) 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;

(iii) the American Dental Association Accepted Dental Therapeutics; and

(iv) the United States Pharmacopoeia--Drug Information;

(E) 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;

(ii) the National Institutes of Health;

(iii) the National Cancer Institute;

(iv) the National Academy of Sciences;

(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) peer-reviewed abstracts accepted for presentation at major medical association meetings;

(G) 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

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

(23) Nurse--A registered or professional nurse, a licensed vocational nurse, or a licensed practical nurse.

(24) Patient--The enrollee or an eligible dependent of the enrollee under a health benefit plan or health insurance policy, or an injured employee entitled to receive workers' compensation benefits pursuant to the Labor Code Title 5.

(25) Payor--

(A) an insurer that writes health insurance policies;

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

(C) any other person or entity that 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 policy, plan, or contract.

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

(27) Physician--A licensed doctor of medicine or a doctor of osteopathy.

(28) Primary office--The place where, based upon the totality of the business activities related to independent review performed under this chapter, an independent review organization's books and records pertaining to independent reviews assigned by the Department are stored.

(29) 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 services to the patient. This definition includes any health care facility where treatment is rendered on an inpatient or outpatient basis.

(30) 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.

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

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

(33) Utilization review agent--A person holding a certificate under the Insurance Code Chapter 4201.

(34) Working day--A weekday that is not a legal holiday.

§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. CERTIFICATE OF REGISTRATION FOR 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 an independent review organization and application for a certificate of registration or renewal fee 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.

§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 forms may also be obtained from the Texas Department of Insurance, Mail Code 103-6A, 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:

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

(A) a summary description of review criteria and review procedures to be used to determine medical necessity or 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) a certification signed by an authorized representative that such review 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; and

(D) procedures ensuring that the information regarding the reviewing physicians and providers is updated in accordance with §12.105(d) of this subchapter (relating to Revisions During Review Process) and §12.108(e) of this subchapter (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 (relating to Confidentiality);

(3) a certification signed by an authorized representative that the independent review organization will comply with the Insurance Code Chapter 4202.

(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 (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 (relating to Independent Review Organization Telephone Access);

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

(A) the bylaws, rules and regulations, or any similar document regulating the conduct of the internal affairs of the applicant with a notarized certification bearing the original signature of an officer or authorized representative of the applicant that they are true, accurate, and complete copies of the originals;

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

(C) a chart showing the internal organizational structure of the applicant's management and administrative staff; and

(D) a chart showing contractual arrangements of the applicant.

(7) the name of any holder of bonds or notes of the applicant that exceed $100,000;

(8) the name and type of business of each corporation or other organization that the applicant controls or is affiliated with and the nature and extent of the affiliation or control and a chart or list clearly identifying the relationships between the applicant and any affiliates;

(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 must submit the name, 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 of that individual's total annual revenue or which represents a holding or investment worth $100,000 or more in any of the following entities:

(i) a health benefit plan;

(ii) a health maintenance organization;

(iii) an insurer;

(iv) a utilization review agent;

(v) a nonprofit health corporation;

(vi) a payor;

(vii) a health care provider;

(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 and any affiliate or other organization in which an officer, director, or employee of the applicant holds a five percent 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 affiliates;

(10) for an application for a certificate or renewal of registration as an independent review organization in this state made on or after December 26, 2010, evidence that the applicant's primary office is located in this state. As a condition of being certified to conduct the business of independent review in this state, an independent review organization must locate its primary office in this state;

(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 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.

(2) The applicant must correct the omissions or deficiencies in the application within 30 days of the date of the department's notice of such omissions or deficiencies.

(3) The applicant may waive any of the time limits specified in this section, except as set forth in paragraph (2) of this section. The applicant may waive the time limit in paragraph (2) of this section 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 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 applicant must specifically set out the length of time requested, not to exceed 90 days, and must include sufficient detail for the commissioner or the commissioner's designee to determine whether good cause for such extension exists. The commissioner or the commissioner's designee may grant or deny any request for an extension of time at the 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) The department shall maintain a charter file which shall contain the application, notices of omissions or deficiencies, responses, and any written materials generated by any person that were considered by the department in evaluating the application.

§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, 333 Guadalupe, P.O. Box 149104, Austin, Texas 78714-9104.

(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 contain the changed item or information "red-lined" or otherwise clearly designated. The original revised page required to be submitted under subsection (b) of this section 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) not later than the 30th day before the date on which the change takes effect.

(e) Compliance with subsection (d) of this section is exempted in the event that a contracted specialist is unavailable for review, and subsequent immediate contracting

with a new specialist is necessary to complete independent review within the timeframes set forth in this chapter.

(f) The independent review organization shall notify the department within 10 days of any contracts entered into pursuant to subsection (e) of this section, and shall include in such notification a complete explanation of the circumstances necessitating such contracts.

§12.106. Qualifying Examinations. The commissioner or the commissioner's designee may conduct an on-site qualifying examination of an applicant as a requirement of applying for a certificate of registration or renewing a certificate of registration 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 of the independent review organization.

§12.108. Renewal of Certificate of Registration.

(a) The commissioner shall designate annually each organization that meets the standards as an independent review organization.

(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 Form), adopted by reference in §12.102 of this subchapter (relating to Application and Renewal of Certificate of

Registration Form; How To Obtain Forms), must be used for this purpose. Form No. LHL006 can be obtained from the website and from the address listed in §12.102 of this subchapter. The completed renewal form, a summary of the current review 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 (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 criteria have been 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 criteria are 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, 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) Compliance with subsection (e) of this section is exempted in the event that a contracted specialist is unavailable for review, and subsequent immediate contracting with a new specialist is necessary to complete independent review within the timeframes set forth in this chapter.

(g) The independent review organization shall notify the department within 10 days of any contracts entered into pursuant to subsection (f) of this section, and shall include in the notification a complete explanation of the circumstances necessitating such contracts.

(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 issuance of the certificate of registration to 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 independent review plan that is consistent 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) A description of the elements of review which the independent review organization provides;

(2) written procedures for:

(A) notification of the independent review organization's determinations provided to the patient or a representative of the patient, the patient's provider of record, and the utilization review agent, in accordance with §12.206 of this

subchapter (relating to Notice of Determinations Made by Independent Review Organizations);

(B) review, including:

(i) any form used during the review process;

(ii) timeframes that shall be met during the review;

(C) accessing appropriate specialty review;

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

(3) required use of written medically acceptable review criteria that are:

(A) based on medical and scientific evidence and utilize evidence-based standards, or if evidence is not available, generally accepted standards of medical practice recognized in the medical community;

(B) established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers;

(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) used only as a tool in the review process; and

(F) available for review, inspection, and copying as necessary by the commissioner or the commissioner's designated representative in order for the commissioner to carry out the commissioner's lawful duties under the Insurance Code;

(4) independent review determinations that:

(A) utilize review procedures that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers;

(B) are made in accordance with medically accepted review criteria, taking into account the special circumstances of each case that may require a deviation from the norm; and

(C) are made by physicians, dentists, or other health care providers, as appropriate.

§12.202. Personnel and Credentialing.

(a) Personnel employed by or under contract with the independent review organization to perform independent review shall be appropriately trained and qualified and, if applicable, currently licensed, registered, or certified. Such personnel shall be

currently involved in an active practice. An exception to the active practice requirement shall be the medical director of the independent review organization. Personnel who obtain information directly from a physician, dentist, or other health care provider, either orally or in writing, and who are not physicians or dentists, shall be nurses, physician assistants, or health care providers qualified to provide the service requested by the provider. This provision shall not be interpreted to require such qualifications for personnel who perform clerical or administrative tasks.

(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 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 maintain records on such. In addition, the independent review organization is required to maintain complete profiles of anyone conducting independent review. Such profiles are required to include all information required by the department in its application form and to be kept current and made available for review by the department and TDI-DWC upon request.

(c) An independent review organization shall be under the direction of a physician currently licensed and in good standing to practice medicine by a state licensing agency in the United States.

(d) The independent review organization is required to provide to the department a copy of the applicant's credentialing policies and procedures, including:

(1) a description of the categories and qualifications of persons employed or under contract to perform independent review as described in this section;

(2) copies of policies and procedures for orientation and training of persons who perform independent review, and evidence that the applicant meets any applicable provisions of this chapter relating to the qualifications of independent review organizations or the performance of independent review.

(e) Notwithstanding subsections (c) and (d) of this section, a physician, 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 set forth in this chapter or Texas law.

(b) An independent review organization may not permit or provide compensation or anything of value to its physicians or providers that would directly or indirectly affect an independent review decision.

(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 certificate of registration 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) Notwithstanding §12.4(b) of this chapter (relating to Applicability), the prohibitions in subsections (c) – (g) of this section apply only to:

(1) an independent review organization that:

(A) is licensed on or after December 26, 2010; or

(B) has its certificate of registration renewed in this state on or after December 26, 2010; and

(2) an individual or entity whose activity involves an independent review organization that:

(A) is licensed on or after December 26, 2010; or

(B) has its certificate of registration renewed in this state on or after December 26, 2010.

§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 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) An independent review organization may not engage in unnecessary or unreasonably repetitive contacts with the health care provider or patient and shall base the frequency of contacts or reviews on the severity or complexity of the patient's condition or on necessary treatment and discharge planning activity.

(c) In addition to pertinent files containing medical and personal information, the utilization review agent or the health insurance carrier, health maintenance organization, 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). However, in instances of life-threatening condition, the independent review organization shall contact the patient or representative of the patient, and provider directly.

(d) An independent review organization shall notify the department if, within three working days of receipt of the independent review assignment, the independent review organization has not received the 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.

(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 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) 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, 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) When conducting independent review, the independent review organization shall request and maintain any information necessary to review the adverse determination not already provided by the utilization review agent, health insurance carrier, health maintenance organization, managed care entity, or other payor. This information may include identifying information about the patient, the benefit plan, the treating health care provider, 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 the treatment plan prescribed by the treating health care provider along with the provider's justification for the treatment plan.

(h) The independent review organization is required to 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) An independent review organization shall notify the patient or a representative of the patient, the patient’s provider of record, the utilization review agent, the payor, and the department of a determination made in an independent review.

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

(1) The 15th day after the date the independent review organization receives the information necessary to make a determination; or

(2) the 20th day after the date the independent review organization receives the request for the independent review.

(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) the 5th day after the date the independent review organization receives the information necessary to make a determination; or

(2) the 8th day after the date the independent review organization receives the request for independent review.

(d) Notification of determination by the independent review organization is required to 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 utilization review, or retrospective utilization review of health care services;

(7) the name and certificate 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 professional 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 provider requesting independent review;

(C) the provider 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's 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;

(18) a description and the source of the review 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.

(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 Telephone Access.

(a) An independent review organization shall have appropriate personnel reasonably available by telephone at least 40 hours per week during normal business hours in both time zones in Texas.

(b) An independent review organization must have a telephone system capable of accepting or recording or providing instructions to incoming calls related to utilization review during other than normal business hours and shall respond to such calls not later than one working day from the date the call was received.

§12.208. Confidentiality.

(a) An independent review organization shall preserve the confidentiality of individual medical records, personal information, and any proprietary information

provided by payors. Personal information shall include, at a minimum, name, address, telephone number, social security number and financial information.

(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 by law. An independent review organization may provide confidential information to a provider who is under contract 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 shall remain confidential.

(c) The independent review organization may not publish data which identify a particular payor, physician or provider, including any quality review studies or performance tracking data, without prior written consent of the involved payor, physician or provider. This prohibition does not apply to internal systems or reports used by the independent review organization.

(d) All payor, patient, physician, and provider data shall be maintained by the independent review organization in a confidential manner which prevents unauthorized disclosure to third parties. Nothing in this chapter shall be construed to allow an independent review organization to take actions that violate a state or federal statute or regulation concerning confidentiality of patient records.

(e) To assure confidentiality, an independent review organization must, when contacting a utilization review agent, a physician's or provider's office, or hospital,

provide its certificate number and the caller's name and professional qualifications to the provider or the provider's named independent review representative.

(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. 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 does not provide sufficient information to allow identification of individual patients, providers, payors or utilization review agents need not be considered confidential.

(g) Medical records and patient-specific information shall be maintained by the independent review organization in a secure area with access limited to essential personnel only.

(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.

(i) Destruction of documents in the custody of the independent review organization that contain confidential patient information or payor, physician or provider

financial data shall be by a method which ensures complete destruction of the information, when the organization determines that the information is no longer needed.

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.

(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) The department may use the authority of the Insurance Code §38.001 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 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) Proceedings under this chapter are a contested case for the purpose of the Government Code, Chapter 2001.

(d) 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 Insurance Code Chapter 4202 or this chapter, the commissioner or the commissioner's designee may:

(1) impose sanctions under the Insurance Code Chapter 82;

(2) issue a cease and desist order under the Insurance Code Chapter 83; and/or

(3) assess administrative penalties under the Insurance Code Chapter 84.

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

(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.

(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 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) A certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending.

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

(e) 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 surrender of the certificate of registration.

(f) Notwithstanding §12.4(b) of this chapter (relating to Applicability), this section only applies to an independent review organization that:

(1) is licensed on or after December 26, 2010; or

(2) has its certificate of registration renewed in this state on or after December 26, 2010.

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) Tier one fees will be for independent review of medical or surgical care rendered by a doctor of medicine or doctor of osteopathy.

(2) Tier two fees will be for the independent review of health care services 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) Independent review organizations shall bill utilization review agents or payors, as appropriate, directly for fees for independent review.

(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 (relating to Independent Review Organization Contact with and Receipt of Information from Heath Care Providers and Patients).

(c) Utilization review agents or payors, as appropriate, shall pay independent review organizations directly within 30 days of receipt of invoice. For workers' compensation network and non-network disputes, the independent review organization fees shall be paid in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).

(d) 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 §12.302 of this chapter (relating to Administrative Violations).

§12.406. Certificate of Registration and Renewal Fees. Fees to be paid to the department for the original application for a certificate of registration as an independent review organization is $800. The fee for renewal of a certificate of registration 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 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, managed care entity, or other payor requesting the independent review, the independent review organization,

the patient or a representative of the patient, and the provider of record of such assignment.

(b) The department shall screen payors and utilization review agents 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) Independent review organizations shall be added to the list from which random assignments for independent review are made in order of the date of issuance of the certificate of registration by the department.

(d) Random assignment shall be made chronologically from the list of independent review organizations with ultimate assignment to the first in line with no apparent conflicts of interest.

(e) Assignment of an independent review to an independent review organization 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 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) 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.

CERTIFICATION. This agency hereby certifies that the adopted sections have been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on December 3, 2010.

Gene C. Jarmon
General Counsel and Chief Clerk
Texas Department of Insurance

IT IS THEREFORE THE ORDER of the Commissioner of Insurance that 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 specified herein, concerning independent review organizations, are adopted.

AND IT IS SO ORDERED.

MIKE GEESLIN
COMMISSIONER OF INSURANCE

ATTEST:

Gene C. Jarmon
General Counsel and Chief Clerk

COMMISSIONER'S ORDER NO. 10-1041
DEC 06 2010