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1. INTRODUCTION. The Texas Department of Insurance proposes amendments to 28 TAC §§12.1, 12.3 - 12.6, 12.101 - 12.110, 12.201 - 12.208, 12.301 - 12.303, 12.401 - 12.406, 12.501, 12.502, and new §12.111, concerning independent review organizations (IROs). The amendments and new section are necessary to implement HB 2645, 83rd Legislature, Regular Session (2013), which amends Insurance Code Chapter 4202, relating to the certification and operation of IROs in Texas. HB 2645 allows TDI to continue to regulate IROs after January 1, 2016. It also establishes an advisory group.

HB 2645

Insurance Code §4202.002, concerning 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 Insurance Code Chapter 4201, Subchapter I, and the suspension and revocation of the certification of registration issued to IROs. HB 2645 amends Insurance Code §4202.002(c), which specifies that the commissioner must adopt standards and rules that prohibit an individual who serves as an officer, director, manager, executive, or supervisor of an IRO from serving as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of another IRO. Amendments to §12.204(d) implement the prohibition of persons from serving in certain positions with other IROs mandated in Insurance Code §4202.002(c).

HB 2645 also amends Insurance Code §4202.002, in part, to require an IRO to maintain a physical address and a mailing address in this state, notify TDI of an agreement to sell the IRO or shares in the IRO, and to complete the transfer of ownership after TDI has sent written confirmation that the requirements are met. Amendments to §12.103(13) provide that an IRO must locate and maintain its primary office at a physical address in this state as noted on its application. Amendments to §12.103(13) further require as a condition of being certified to conduct business of independent review in this state, that the physical address of the IRO's primary office be maintained in this state. The amendments to §12.5 add a new paragraph (30) to define the term "physical address," and change the definition of "primary office" in redesignated paragraph (32) to clarify how an IRO may comply with the requirements in Insurance Code §4202.002(c). These amendments are necessary to implement the requirement

in Insurance Code §4202.002(c) mandating location and maintenance of the IRO's primary office at a physical address in this state. Amendments to §12.110 are necessary to ensure TDI receives notice of an agreement to sell or transfer the ownership or shares in the IRO, and require certain information be disclosed to TDI.

HB 2645 adds Insurance Code §4202.002(f), in part, to require the commissioner to adopt standards requiring that the IRO's primary office be equipped with a computer system capable of processing requests for independent review and made available to TDI on request. Additionally, in the case of an office located in a residence, the working office must be located in a room set aside for independent review business purposes and in a manner to ensure confidentiality. Amendments to §12.103 add a new subparagraph (B) to require an applicant for an initial or renewal certificate of registration in this state to submit as part of the application process evidence that the applicant's primary office is equipped with a computer system capable of certain requirements. Additionally, amendments to §12.103(13)(B) require that if the IRO's primary office is in a residence, dedicated space is set aside for business purposes. These amendments implement the requirements in Insurance Code §4202.002(f).

HB 2645 amends Insurance Code §4202.003 to require each IRO to make the IRO's determination for a life-threatening condition as defined by Insurance Code §4201.002 not later than the earlier of the third day, rather than the fifth day, after the date the IRO receives the information necessary to make the

determination. With respect to a review of a health care service provided to a person eligible for workers' compensation medical benefits, the IRO must make its determination for a life-threatening condition the eighth day after the date the IRO receives the request that the determination be made.

HB 2645 amends Insurance Code §4202.004 to require a description of any relationship the applicant or the named individual has with specified entities. HB 2645 amendments to Insurance Code §4202.004 require the IRO application form to include the procedures used by the applicant to verify physician and provider credentials, including the computer processes, electronic databases, and records, if any, used and the software used by the credentialing manager for managing the processes, databases, and records. Insurance Code §4202.004(a)(8) requires the IRO application form to require a description of the applicant's use of communications, records, and computer processes to manage the independent review process. Additionally, Insurance Code §4202.004 requires the commissioner to establish certifications for independent review of health care services provided to persons eligible for workers' compensation medical benefits and other health care services after considering accreditation, if any, by a nationally recognized accrediting organization that imposes requirements for accreditation that are the same as, substantially similar to, or more stringent than TDI's requirements for accreditation. HB 2645 amends Insurance Code §4202.004(g) to require that certification be renewed biennially.

HB 2645 amends Insurance Code §4202.005(c) to require that information regarding a material change be submitted on a form adopted by the

commissioner not later than the 30th day after the date the material change occurs. It also requires the IRO, if the material change is a relocation of the IRO, to inform TDI that the location is available for inspection by TDI before the date of the relocation, and an officer of the IRO to attend the inspection, on request of TDI. Amendments to §12.5 define the term "IRO application form" to include an IRO reporting a material change to TDI. Amendments to §12.102 provide that an IRO must report a material change to a certificate of registration by submitting the IRO application form to TDI.

In compliance with new Insurance Code §4202.011, the commissioner appointed an IRO advisory group composed of members as required by Insurance Code §4202.011(a). Agency staff met with the advisory group on September 9, 2014.

Insurance Code §4202.012 requires the commissioner by rule to require referral by random assignment of adverse determinations under Chapter 4201, Subchapter I (Independent Review of Adverse Determination), to IROs and requires the commissioner, on referral of a determination, to notify specified persons. Amendments to §12.501 and §12.502 are necessary to implement the requirement in Insurance Code §4202.012 mandating the commissioner to adopt rules requiring referral by random assignment and notification.

Additionally, the applicability date of April 1, 2015, in §12.4(b) gives IROs time to comply with HB 2645 and the adopted rules, and allows time for IROs to complete the last reviews assigned to the IROs under the current rules for those IROs that cannot or do not wish to comply with the new provisions. Section

12.103(13) requires a sworn statement from an officer of the IRO of certain requirements made on or after April 1, 2015.

In addition, TDI has determined that other amendments are necessary to effectively enforce Insurance Code Chapter 4202. Insurance Code §4202.002(a) requires the commissioner to adopt "standards and rules for…the certification, selection, and operation of independent review organizations." Under Insurance Code §4202.002(b), these standards must ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO.

TDI proposes amendments throughout the rule text to: (i) correct typographical, grammatical, and punctuation errors in the current rule text, (ii) make changes to conform rule text to current department drafting style, (iii) update statutory citations to conform with the nonsubstantive revisions to the Insurance Code, and (iv) nonsubstantively simplify and clarify provisions in Chapter 12.

TDI posted to its website an informal draft of these rules on August 5, 2014, with a comment period that ended on August 15, 2014. Based on the stakeholder comments received, TDI revised the informal draft and proposes these amendments. A thorough discussion of the proposed amendments and new section to the rules follows.

Proposed §12.1. Statutory Basis. The proposed amendment to §12.1 is necessary to change the date from September 1, 2009, to September 1, 2013,

to conform with revisions to the Insurance Code under HB 2645, 83rd Legislature, Regular Session (2013), which amends Insurance Code Chapter 4202.

Proposed §12.3. Effects of Chapter. TDI proposes nonsubstantive amendments to §12.3 to conform to current agency writing style.

Proposed §12.4. Applicability. Amendments to §12.4(a) are necessary to update the title of the reference to 28 TAC §12.6. Amendments to §12.4(b) insert language clarifying that the applicability date applies to requests for independent review and "applications for a certificate of registration as an IRO, and for renewal of a certificate of registration as an IRO."

Proposed §12.5. Definitions. New §12.5(4) adds the definition for the term "biographical affidavit." This new definition is necessary to specify that the biographical affidavit form used in IRO applications must be the National Association of Insurance Commissioners biographical affidavit form. The biographical affidavit form is necessary because, under 28 TAC §1.502(c) and (e), TDI developed guidelines relating to the matters that TDI will consider in determining whether to grant, deny, suspend, or revoke any license or authorization under its jurisdiction. These matters include criminal background checks for each director, officer, and executive of the applicant and for each owner or shareholder of the applicant, or if the applicant is publicly held, each owner or shareholder of more than 5 percent of any of the applicant's stock or options.

New §12.5(9) adds the definition of "control." This new definition is necessary to clarify how an IRO may comply with the mandate in Insurance Code §4202.008, which prohibits an IRO from being a subsidiary of, or in any way owned or controlled by, a payor or a trade or professional association of payors. The definition of the term "control" is also necessary to clarify the use of the term in the existing definition of "affiliate" in §12.5(2), for disclosure to TDI in the original application under §12.103(10), and for the commissioner to determine whether control exists under §12.203(b).

Insurance Code §4202.002(a) requires the commissioner to adopt "standards and rules for … the certification, selection, and operation of independent review organizations." The definition of "control" under new §12.5(9) will assist TDI in its goal to ensure compliance with Insurance Code Chapter 4202 and also to ensure that there are no conflicts of interest involving an IRO being controlled by a payor or professional association of payors. New §12.5(9) is also proposed under the general rulemaking authority in the Insurance Code §4202.002(a)(1).

New §12.5(22) adds the definition of "IRO application form." The definition is necessary to clarify that the form is to be used to apply for certification as an IRO in Texas, for renewal of a certification, and also to report a material change to a certification form previously submitted to TDI. Insurance Code §4202.004 requires an organization to submit an application in the form required by the commissioner. Additionally, this definition clarifies the use of the form and implements Insurance Code §4202.005(c), which provides that an IRO shall

report any material change to the information submitted on a form adopted by the commissioner not later than the 30th day after the date the material change occurs.

New §12.5(30) adds the definition of "physical address." This definition is necessary to clarify the use of the term in amended §12.103, which implements the requirement in Insurance Code §4202.002(c)(2)(A)(i) and (f), as enacted by HB 2645. Insurance Code §4202.002(c)(2)(A)(i) requires the commissioner to adopt rules that require IROs to maintain a physical address in this state. Insurance Code §4202.002(f) requires the commissioner to adopt standards requiring an officer of an organization to attest that its office is located at a physical address in its application for certification.

Amendments to the definition of "primary office" in §12.5(32) delete the phrase "based upon the totality of the business activities related to independent review performed under this chapter" and adds the phrase "maintains its physical address" to implement the requirement in Insurance Code §4202.002(c)(2)(A)(i) and (f), as enacted by HB 2645. HB 2645 amends Insurance Code §4202.002(c), which requires the commissioner to adopt standards and rules that require an IRO to maintain a physical address in this state. HB 2645 also adds Insurance Code §4202.002(f), which requires the commissioner to adopt standards requiring that, on application for certification, an officer of the IRO attest that the office is located at a physical address. Amendments to §12.5(32) also replace the term "stored" with the phrase "maintained and accessible" regarding the IRO's books and records. These amendments implement

Insurance code §4202.002(a) and are necessary for TDI staff to be able to conduct on-site examinations that include an examination of the IRO's records.

Proposed §12.6. Independent Review of Adverse Determinations of Health Care Provided Under Labor Code Title 5 or Insurance Code Chapter 1305. TDI proposes nonsubstantive amendments to §12.6 to conform to current agency writing style.

Proposed §12.101. Certification of Registration for Independent Review. Amendments to §12.101 change the heading of the section from "Where to File Application" to "Certification of Registration for Independent Review" to more accurately reflect the content of the section. TDI clarifies that the fees for certification of registration for independent review are not proposed for change.

Proposed §12.102. IRO Application Form. Amendments to §12.102 include changing the title of the section to "IRO Application Form," and other amendments to conform to current agency writing style. Amendments to §12.102(a) delete the adoption by reference of Form No. LHL006 (IRO Application Form). Instead of adopting the form by referencing a form number, TDI lists the elements of the application in amended §12.103. Amendments to §12.102(a) also instruct applicants to use the IRO application form in the format prescribed by TDI for reporting a material change to a certificate of registration. These amendments are necessary to implement Insurance Code §4202.005(c). HB 2645 amends Insurance Code §4202.005(c) to require that information regarding a material change be submitted on a form adopted by the

commissioner not later than the 30th day after the date the material change occurs. It also requires the IRO, if the material change is a relocation of the IRO, to inform TDI that the location is available for inspection before the date of the relocation by TDI, and an officer to attend the inspection, on request of TDI. Amendments to §12.102(c) are necessary to provide the correct Internet and mailing addresses from which an applicant can obtain a form to apply for certification as an IRO.

Proposed §12.103. Information Required in Original Application for Certificate of Registration. Amendments to §12.103 change the name of the section from “Information Required in Application and Renewal Form” to “Information Required in Original Application for Certificate of Registration” to distinguish the requirements for an original application for certificate of registration from the requirements for a renewal in §12.108 and reporting material changes to TDI under §12.111. Amendments to §12.103 also delete the reference to Form No. LHL006 to conform to proposed amendments to §12.102.

Amendments to §12.103(1)(C) delete the phrase “an authorized representative” and add the phrase “the IRO’s medical director” as the person who must sign the certification that criteria and review procedures for review determinations are established with input from appropriate health care providers and physicians under §12.201(3). The requirement that a medical director sign the certification ensures that an appropriately qualified individual approves criteria to ensure a higher quality of review. These amendments are necessary to implement Insurance Code §4202.002, which requires the commissioner to

adopt standards to ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO.

Amendments to §12.103(1)(D) update the reference from §12.105(d) and §§12.108(e) - 12.111(a) to more accurately reflect the new content of the section.

New §12.103(1)(E) requires an IRO applicant to include a summary of the description of criteria and review procedures to be used by the medical director to conduct quality assurance audits under §12.202(c)(2). These amendments are necessary to implement Insurance Code §4202.002, which requires the commissioner to adopt standards to ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO.

Amendments to §12.103(3) require an officer, director, or owner of the IRO to certify compliance with the Insurance Code Chapter 4202 and department rules, instead of only an authorized representative, as currently required. The named individuals must also certify that any party that performs an IRO function through contracts and subcontracts will comply with 28 TAC Chapter 12 and Insurance Code Chapter 4202. The certification must also state that the IRO retains the ultimate responsibility for compliance. Insurance Code §4202.002(a), in part, authorizes the commissioner to adopt standards and rules for the certification, selection, and operation of IROs to perform independent review.

New §12.103(4)(A) and (B) requires an IRO applicant to include in the application for certification a description of the credentialing and recredentialing procedures, computer processes, electronic databases, records, and software used by the applicant to verify physician and provider credentials. These amendments are necessary to implement the requirements in Insurance Code §4202.004(a)(6)(B) and (C). HB 2645 amends Insurance Code §4202.004(a) to require the IRO application form to require a description of the procedures used by the applicant to verify physician and provider credentials, including the computer processes, electronic databases, and records, if any, used and the software used by the credentialing manager for managing those processes, databases, and records.

New §12.103(6) requires the applicant to include a description of the applicant's use of communications, records, and computer processes to manage the independent review process. These amendments are necessary to implement Insurance Code §4202.004(a)(8). HB 2645 amends Insurance Code §4202.004(a) to require the IRO application to include a description of the applicant's use of communications, records, and computer processes to manage the independent review process.

New §12.103(7) requires the applicant to include a description and evidence of accreditation from a nationally recognized accrediting organization, if any, that imposes the same or stricter requirements than TDI's for certification in the IRO application form. New §12.103(7) also requires this evidence to be maintained in TDI's file for the applicant and allows the applicant to request

expedited approval of the certification based on the evidence of accreditation. These amendments are necessary to implement Insurance Code §4202.004(e) and (f). HB 2645 amends Insurance Code §4202.004(e), in part, to require that an application for certification for review of health care services require an organization that is accredited by an organization described Insurance Code §4202.004(b) to provide TDI with evidence of the accreditation. It also requires the commissioner to consider the evidence if the accrediting organization published and made available to the commissioner the IRO's requirements for and methods used in the accreditation process, and authorizes an accredited IRO to request that TDI expedite the application process. HB 2645 amends Insurance Code §4202.004(f) to authorize a certified IRO that becomes accredited by an organization described by Subsection (b) to provide evidence of that accreditation to TDI and requires that evidence be maintained in TDI's file related to the IRO's certification.

New §12.103(8)(A) requires the applicant to submit written evidence that the applicant is incorporated in this state, which may include a letter from the Texas secretary of state, indicating that the applicant has filed the appropriate information about the incorporation. These amendments are necessary to implement Insurance Code §4202.002(c)(2)(a)(i) as enacted by HB 2645, requiring an IRO to be incorporated in this state. Amendments to §12.103(8)(A) also delete language requiring the applicant to submit documents relating to its internal affairs because TDI has included updated requirements regarding the

information necessary for the commissioner to determine whether an applicant is qualified to be certified as an IRO.

Amendments to §12.103(8)(B) require applicants to submit the address and Federal Employer Identification Number (EIN) for each stockholder or owner of more than 5 percent for applicants that are publicly held. These amendments implement Insurance Code §4202.002(a), requiring the commissioner to adopt "standards and rules for … the certification, selection, and operation of independent review organizations." These amendments are necessary for TDI staff reviewing IRO applications for certification to quickly and efficiently verify the identification information submitted by the applicant in the IRO application form. Amendments to §12.103(8)(D) clarify the contents of the chart of contractual arrangements required under §12.103(8)(D) to include contracts between the IRO and any persons and all subcontracts with other persons to perform any business or daily functions of an IRO. These amendments are necessary to implement Insurance Code §4202.002(a), ensuring that the IRO is retaining the responsibility for compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12 and to ensure TDI is aware of the actual parties conducting IRO functions.

New §12.103(8)(E) requires the applicant to submit copies of the contract and subcontract the applicant has with any person who will perform functions of the IRO and new §12.103(8)(e)(i) - (iv) lists the elements those contracts must include. These amendments are necessary to implement Insurance Code §4202.002(a), ensuring that the IRO is retaining the responsibility for compliance

with Insurance Code Chapter 4202 and 28 TAC Chapter 12 and to ensure TDI is aware of the actual parties conducting IRO functions.

Amendments to redesignated §12.103(10) require the applicant to submit the address and EIN of any organization the applicant controls or is affiliated with. These amendments implement Insurance Code §4202.002(a) and are necessary for TDI staff reviewing IRO applications for certification to quickly and efficiently verify the identification information submitted by the applicant in the IRO application form.

Amendments to redesignated §12.103(11) change “Form No. FIN311 (Biographical Affidavit)” to “biographical affidavit” and “Application and Renewal of Certificate of Registration Form; How to Obtain Forms” to “IRO Application Form” to conform to new §12.5(4) and §12.5(22). New §12.103(11)(A) requires the applicant to submit fingerprints for each director, office, executive, owner, or shareholder of the applicant. These amendments are necessary to implement Insurance Code §4202.004(d). HB 2645 amends Insurance Code §4202.004(d) to require the commissioner to obtain from each officer of the applicant and each owner or shareholder of the applicant, or, if the purchaser is publicly held, each owner or shareholder described by Subsection (a)(1) a complete and legible set of fingerprints for obtaining criminal history record information from the Texas Department of Public Safety (DPS) and the FBI. It also requires TDI to conduct a criminal history check of each applicant using information provided under this section, and made available to TDI by DPS, the FBI, and any other criminal justice agency under Government Code Chapter 411 (Department of Public

Safety of the State of Texas). Additionally, 28 TAC §1.501(b)(1)(B) provides that TDI is authorized to determine a person's fitness for holding a certification or registration or a person's fitness to have the ability to control entities when that person has committed a criminal offense or has engaged in fraudulent or dishonest activity, including applicants for a certificate of registration under Insurance Code Chapter 4202. Title 28 TAC §1.503, in part, provides that the fingerprint requirement in 28 TAC §1.504 applies to applicants for certification or registration under Insurance Code Chapter 4202.

Amendments to redesignated §12.103(11)(B) delete the application of the fingerprint requirement because that requirement is found in proposed new §12.103(11)(A). Amendments to §12.103(11)(D) require the applicant to submit a list of any outstanding loans or contracts to provide service to "any other person relating to any functions performed by or on behalf of the IRO." These amendments are necessary to ensure that the IRO retains the responsibility for compliance with Insurance Code Chapter §4202 and 28 TAC Chapter 12 and implement Insurance Code §4202.002(a). New §12.103(12) requires the applicant to submit documentation from the comptroller demonstrating the applicant's good standing and the right to transact business in this state. This amendment is necessary to implement Insurance Code §4202.002(c)(2)(A)(iii). HB 2645 amends Insurance Code §4202.002 by amending subsection (c), which specifies that the commissioner must adopt standards and rules that, among other things, require the IRO to be in good standing with the comptroller.

Amendments to redesignated §12.103(13) require a sworn statement from an officer of the IRO of information required in amended §12.103(13)(A) - (D). The additional information required in the sworn statement in amendments to §12.103(13)(A) - (D) are necessary to implement Insurance Code §4202.002(f). HB 2645 amends Insurance Code §4202.002 by adding subsection (f), which requires the commissioner to adopt standards requiring that: (1) on application for certification, an officer of the IRO attest that the office is located at a physical address; (2) the office be equipped with a computer system capable of processing requests for independent review and accessing all electronic records related to the review and the independent review process; (3) all records be maintained electronically and made available to TDI on request; and (4) in the case of an office located in a residence, the working office be located in a room set aside for independent review business purposes and in a manner to ensure confidentiality.

New §12.103(13)(E) adds a requirement for the sworn statement that medical records be maintained according to §12.208 of this chapter. This amendment is necessary to implement Insurance Code §4202.002(e). HB 2645 amends Insurance Code §4202.002 by adding subsection (e), which requires that the standards to ensure the confidentiality of medical records transmitted to an IRO under subsection (b)(2) require organizations and utilization review agents to transmit and store records in compliance with the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.) and the regulations and standards adopted under that Act.

Proposed §12.104. Review of Original Application. The title of the section is changed from “Review of Application” to “Review of Original Application” to distinguish the review of an original application from §12.105 and §12.108. Amendments to §12.104(a) and new §12.104(b)(1) - (3) delete the process for TDI’s review of an original application and replace it with a new process that mirrors TDI’s review of certification or registration of Utilization Review Agents in 28 TAC §19.1704(e) and (f). These amendments are necessary to maintain consistency across TDI’s processes. TDI has determined that the process for reviewing original applications for certification as IROs should be consistent with the process for review of applications for certification or registration of URAs. This streamlines these processes and enables TDI to process both types of applications efficiently for the benefit of regulated entities. TDI recognizes that uniform standards offer a more consistent process for ease of stakeholder interpretation and compliance.

New §12.104(1) provides that TDI will grant or deny an original certification within 60 days of receipt of a complete original application.

New §12.104(2)(A) provides that TDI will send the applicant written notice of any omissions or deficiencies in the original application. An applicant has 15 days from the date of TDI’s latest notice of omissions or deficiencies to correct any omissions or deficiencies in the application. New §12.104(2)(B) changes the requirement in existing §12.104(2) by lessening the number of days that an applicant has to correct any omissions or deficiencies in the application from 30 days to 15 days from the date of TDI’s latest notice of the omissions or

deficiencies. This reduction in applicant response time is necessary to streamline the application process, providing TDI with information more quickly. Section §12.104(2)(B) also provides that the applicant may request in writing additional time to correct the omissions or deficiencies in the application. TDI clarifies that the request for additional time must be approved by TDI in writing for the requested extension to be effective.

New §12.104(2)(C) provides that an applicant's failure to correct omissions or deficiencies will result in the application being closed as incomplete and provides that the application fee is not refundable. These amendments are proposed under the commissioner's authority in Insurance Code §4202.004(a) to prescribe the application form and its authority to adopt standards and rules for the certification, selection, and operation of IROs to perform independent review.

Proposed §12.105. Revisions During Review Process. Amendments to §12.105(a) clarify that revisions made by the applicant must be submitted electronically in the manner specified by TDI in correspondence with the applicant or sent by mail. Amendments to §12.105(a) also correct the mailing address where applicants send revisions to TDI. Amendments to §12.105(b) delete the requirement that revisions to bylaws submitted with revisions be accompanied by a notarized certification because the requirement to submit bylaws in existing §12.103 is also proposed for deletion. Amendments to §12.105(d) - (f) also delete the requirements for an applicant to report material changes to the application because that information is in proposed amendments to §12.111.

Proposed §12.106. Examinations. TDI is proposing to amend this section's title from "Qualifying" to "Examinations" to reflect that this section applies to all examinations. Amendments to §12.106(a) change "may" to "will" and remove "qualifying" to clarify that TDI will conduct an examination as a requirement of certification of an IRO. Amendments to §12.106(a) also clarify that the examination will be at the applicant's primary office and are necessary to implement Insurance Code §4202.013, which requires an IRO to maintain its primary office in this state.

New §12.106(b) clarifies that TDI may conduct examinations as often as the commissioner deems necessary to determine compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

New §12.106(c) includes a list of documents that an IRO must make available for review during the examinations. These amendments implement Insurance Code §4202.002(a) and are necessary for TDI staff conducting on-site examinations to quickly and efficiently verify the IRO is in compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

New §12.106(d) requires the IRO's owner and staff to be available at the IRO's primary office during the on-site examination. These amendments implement Insurance Code §4202.002(a) and are necessary for TDI staff conducting on-site examinations to quickly and efficiently verify the IRO is in compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

Proposed §12.107. Withdrawal of an Original Application Prior to Certification and Subsequent Renewal Applications. Amendments to

§12.107 revise the section title to more accurately reflect the content of the section.

Proposed §12.108. Renewal of Certificate of Registration. Amendments to §12.108(a) and (b) change the requirement that an IRO must apply for renewal of its certification of registration from every year to requiring renewal every two years to implement Insurance Code §4202.004(g), as amended by HB 2645. Amendments to §12.108(b) replace references to "Form No. LHL006" and "renewal form" with "IRO application form" to conform the new reference to language in the proposed amended §12.102 and §12.101. TDI proposes to amend §12.108(b) and delete sections (e) - (g) to remove language about reporting material changes because those requirements are proposed in new §12.111. Amendments to §12.108(b) and (d) delete the requirement that an IRO submit a summary of their current review criteria with the completed IRO application form. This summary submission would be unnecessary because TDI would already have this information from either the original application for certification or the IRO reporting it as a material change required under new §12.111.

Proposed §12.109. Appeal of Denial of Application or Renewal. TDI proposes nonsubstantive amendments to §12.109 to conform to current agency writing style.

Proposed §12.110. Effect of Sale or Transfer of Ownership of an Independent Review Organization. Amendments to §12.110 update the requirements in existing §12.110 to implement the requirements in Insurance

Code §4202.002 as amended by HB 2645. Amendments to §12.110(a) require the IRO to notify TDI of the agreement to sell or transfer the ownership of the IRO no later than 60 days before the date of the sale or transfer of ownership, and provides the TDI address where the owner must send the notification. Amendments to §12.110 (a)(1) require the IRO to submit the name of the purchaser and a complete set of fingerprints for each officer, owner, and shareholder of the purchaser. Amendments to §12.110 (b) require the IRO to send TDI written confirmation that the requirements under Insurance Code §4202 and this chapter have been satisfied before completing the sale. These sections are necessary to implement Insurance Code §4202.002(c)(2)(C). HB 2645 amends Insurance Code §4202.002(c)(2)(C) to require an IRO to: (i) notify TDI of an agreement to sell the IRO or shares in the IRO; (ii) not later than the 60th day before the date of the sale, submit the name of the purchaser and a complete and legible set of fingerprints for each officer of the purchaser and for each owner or shareholder of the purchaser or, if the purchaser is publicly held, each owner or shareholder described by Insurance Code §4202.004(a)(1), and any additional information necessary to comply with Insurance Code §4202.004(d); and (iii) complete the transfer of ownership after TDI has sent written confirmation that the requirements of this chapter have been satisfied.

Amendments to §12.110 (a)(1)(B) require an IRO to notify TDI of any material changes in their notice of intent to sell or transfer ownership. Insurance Code §4202.005(c) requires the IRO to submit information regarding a material change to TDI not later than the 30th day after the date the material change

occurs; however, in the case of a sale or transfer of ownership of an IRO, TDI has determined that this rule is necessary under TDI's general rulemaking authority in Insurance Code §4202.002(a) for department staff to review all changes regarding an IRO sale or transfer of ownership at the same time for the sake of efficiency. The amendments to §12.110 (c) change "the sale" to "the sale or transfer of ownership" for consistency throughout §12.110.

Proposed §12.111. Regulatory Requirements Subsequent to Certification. New §12.111(a) adds the requirement that an IRO must report to TDI a material change in the information required in the IRO application form no later than the 30th day after the date the change takes effect. New §12.111(b) contains the requirements for reporting a material change if the material change is a relocation of the IRO's primary office. These sections are necessary to implement Insurance Code §4202.005(c). HB 2645 amends Insurance Code §4202.005(c) to require that information regarding a material change be submitted on a form adopted by the commissioner not later than the 30th day after the date the material change occurs. It also requires the IRO, if the material change is a relocation of the IRO, to inform TDI that the location is available for inspection by TDI before the date of the IRO's relocation, and that an officer of the IRO attend the inspection, on request of TDI.

New §12.111(c) exempts IROs from compliance with §12.111(a) in the event a contracted specialist IRO reviewer is unavailable and immediate contracting with a new specialist is necessary to complete an independent review. New §12.111(d) requires the IRO to notify TDI within 10 days after it

enters into any new contracts under subsection (c), and that the notification must include a complete explanation of the circumstances. These amendments implement Insurance Code §4202.002(a) and are necessary for the IRO to be able to comply with both this section and other time frames set out in this chapter.

Proposed §12.201. Independent Review Plan. Amendments to §12.201 change “a physician” to “the IRO’s medical director” as the person who must review and approve the IRO’s independent review plan. These amendments are necessary to implement Insurance Code §4202.002, which requires the commissioner to adopt standards that must ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO. The medical director is best qualified to ensure these requirements.

Proposed §12.202. Personnel and Credentialing. New §12.202(a)(1) requires personnel conducting independent reviews for health services to hold an unrestricted license, an administrative license, or otherwise be authorized to provide the same or similar specialty health services by a licensing agency in the United States. New §12.202(a)(2) requires personnel conducting independent reviews for health services to hold an unrestricted license, an administrative license, or otherwise be authorized to provide the same or similar specialty health services by a licensing agency in this state. Amendments to §12.202(b)(1) require the IRO to send, in addition to the preexisting

requirements, the name, license number, state of licensure, and date of contract of personnel employed or under contract to perform independent reviews. Amendments to §12.202(b)(2) delete language regarding the IRO's maintenance of reviewer qualification records and profiles of reviewers. These requirements are now in §12.202(d). Amendments to §12.202(c)(1) - (3) describe the functions of the IRO medical director. These functions include, but are not limited to, the annual review and approval of screening criteria, annual quality assurance audits of at least 25 percent of all decisions, and annual quality assurance audits of at least 25 percent of all assignments. New §12.202(d) requires the IRO to maintain credentialing and recredentialing files of personnel employed or under contract to perform independent reviews. New §12.202(d)(1) - (4) lists the minimum types of credentialing and recredentialing information that the IRO must maintain current and available for review by TDI. Amendments to §12.202(d) also delete language regarding the IRO's credentialing requirements because they are redundant in light of the more detailed credentialing requirements in amended §12.202. New §12.202(g) requires the providers conducting independent review to sign and date the certification of independence and qualifications of the reviewer in the format prescribed by TDI. New §12.202(g)(i) - (viii) list the required elements of the certification of independence and qualifications of the reviewer. New §12.202(g) requires the IRO to make the information required in §12.202 available to TDI on request. New §12.202(i) requires providers conducting independent reviews to notify the IRO of any changes in the information in §12.202(d). These amendments to §12.202

implement Insurance Code §4202.002(b) and are necessary to ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO.

Proposed §12.203. Conflicts of Interest Prohibited. Amendments to §12.203 revise existing language in the section for clarity, replacing “is a subsidiary of, or in any way owned or controlled by” with “has any ownership interest in or control over the person, or if the person has any ownership interest in or control over a payor.”

Proposed §12.204. Prohibitions of Certain Activities of Independent Review Organizations and Individuals or Entities Associated with Independent Review Organizations. New §12.204(d) prohibits an officer, director, manager, executive, or supervisor of an IRO from serving as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of another IRO. This amendment is necessary to implement Insurance Code §4202.002(c)(1)(E). HB 2645 amends Insurance Code §4202.002(c) to require the commissioner to adopt standards and rules that prohibit an individual who serves as an officer, director, manager, executive, or supervisor of an IRO from serving as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of another IRO. Amendments to §12.204 also delete §12.204(h) as its applicability dates are no longer relevant.

Proposed §12.205. Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients. Amendments to §12.205(e) made for clarity include deleting “such expense shall be reimbursed by the,” adding “The,” and adding “must pay these unreimbursed costs to the health care provider.”

Proposed §12.206 Notice of Determinations Made by Independent Review Organizations. An amendment to §12.206(c)(1) changes “5th” day to “third” day. New §12.206(c)(2) adds language regarding a review of a health care service provided to a person eligible for workers’ compensation medical benefits” and “that the determination be made; or.” New §12.206(c)(3) adds language regarding the review of a health care service other than a service described in §12.206(c)(2). These amendments are necessary to implement Insurance Code §4202.003(1). HB 2645 amends Insurance Code §4202.003 to require that the standards adopted under §4202.002 require each IRO to make the IRO’s determination for a life-threatening condition as defined by §4201.002, not later than the earlier of the third day, rather than the fifth day, after the date the IRO receives the information necessary to make the determination. With respect to a review of a health care service provided to a person eligible for workers’ compensation medical benefits, the IRO must make its determination for a life-threatening condition the eighth day after the date the IRO receives the request that the determination be made. With respect to a review of a health care service other than services provided to a person eligible for workers’

compensation medical benefits, the IRO must make its determination the third day after the date the IRO receives the request that a determination be made.

An amendment to §12.206(e) updates the web address for TDI's forms.

Proposed §12.207. Independent Review Organization Telephone Access. Amendments to §12.207(a) change "both time zones in Texas" to "both Central and Mountain time zones" for clarity. Amendments to §12.207(b) require an IRO's phone system to be "dedicated." TDI clarifies that a dedicated telephone system is a phone system intended primarily for use in the IRO business. These amendments implement Insurance Code §4202.002(a) and (b) and are necessary for TDI staff to be able to contact the IRO and for the IRO to maintain patient information confidentiality.

Proposed §12.208. Confidentiality. Amendments to §12.208(a) include changing "shall include, at a minimum" to "includes" to conform to current agency writing style. New §12.208(b) adds language regarding the public disclosure of patient information necessary to implement Insurance Code §4202.002(c)(1)(F). New §12.208(c) adds a reference to the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.) to implement Insurance Code §4202.002(c)(1)(F). Amendments to §12.208(h) add a sentence requiring IROs to transmit and store records in compliance with the Act of 1996 to implement Insurance Code §4202.002(c)(1)(F). HB 2645 amends Insurance Code §4202.002(c) by requiring the commissioner to adopt standards and rules that, among other things, prohibit publicly disclosing patient information protected by the Act of 1996, or transmitting the information to a subcontractor involved in

the independent review process that has not signed an agreement similar to the business associate agreement required by regulations adopted under the Act of 1996.

Proposed §12.301. Complaints, Oversight, and Information. Amendments to §12.301 are proposed to conform to current agency writing style.

Proposed §12.302. Administrative Violations. Amendments to §12.302 are proposed to conform to current agency writing style.

Proposed §12.303. Surrender of Certificate of Registration. Amendments to §12.303(a) clarify when an IRO must surrender its certificate of registration and delete “while the organization is under investigation or as part of an agreed order.” Amendments to §12.303(b) delete the definition of “investigation” and “a certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending.” These amendments are necessary to implement Insurance Code §4202.002(c)(2)(B). HB 2645 amends Insurance Code §4202.002(c)(2)(B) to require the commissioner to adopt standards and rules that require an IRO to surrender its certification as part of an agreed order. Amendments to §12.303 delete current §12.303(f), which states that this section only applies to IROs licensed after or that have certificates of registration renewed in this state after December 26, 2010, as this section is no longer relevant.

Proposed §12.401. Fees. TDI proposes non-substantive amendments to §12.401 to conform to agency style.

Proposed §12.402. Classification of Specialty. TDI proposes non-substantive amendments to §12.402 to conform to agency style.

Proposed §12.403 Fee Amounts. TDI proposes non-substantive amendments to §12.403 to conform to agency style.

Proposed §12.404. Payment of Fees. Amendments to §12.404(c) change the number of days in which the utilization review agents or payors must pay IROs from “30” to “15.” These amendments implement Insurance Code §4202.002(a) and are necessary because TDI has determined 15 days is a sufficient amount of time for utilization review agents or payors to pay IROs.

Proposed §12.405. Failure To Pay Invoice. TDI proposes non-substantive amendments to §12.405 to conform to agency style.

Proposed §12.406. Certification and Renewal Fees. Amendments to §12.406 change the fee for an original certificate of registration as an IRO from “$800” to “$1000” and the fee for renewal of a certificate of registration from “$200” to “$400.” The increase in the fee for original certificate of registrations is necessary because the new fee better reflects the cost to TDI of regulating IROs. The increase in the fee for the renewal of a certificate of registration is necessary because the renewal is now every two years instead of every year. The net cost of renewal for an IRO will remain the same. New language clarifies that there is no fee for reporting a material change to a certification as an IRO. These amendments are proposed under the general rulemaking authority in Insurance Code §4202.002(a)(1).

Proposed §12.501. Requests for Independent Review. Amendments to §12.501 include inserting "Chapter 4201," a reference to Subchapter U, and a reference to "Chapter 134 of this title." These amendments are necessary under Insurance Code §4202.002(a) to properly cite the sections of the Insurance Code pertaining to utilization review.

Proposed §12.502. Random Assignment. TDI proposes non-substantive amendments to §12.502(b) to conform to agency style.

2. FISCAL NOTE. Debra Diaz-Lara, director, Managed Care Quality Assurance Office, has determined that for each year of the first five years the proposed amendments and new sections will be in effect, there will be no fiscal impact to state and local governments as a result of the enforcement or administration of the proposal. There will be no measurable effect on local employment or the local economy as a result of the proposal.

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

ANTICIPATED PUBLIC BENEFITS

The anticipated public benefits in general are the updating of existing rules regulating IROs to comply with legislation enacted by the 83rd Legislature; clarification of existing rules to facilitate compliance, implementation, and enforcement of these rules; and an improved regulatory framework for the assignment of independent reviews. Specifically, the anticipated public benefits of the proposed rules and amendments related to compliance with legislation include: (i) the establishment of a regulatory framework that supports the operation of an IRO in compliance with the prohibitions and requirements mandated under HB 2645 and (ii) a regulatory framework that will provide a more diverse pool of IROs that are based in Texas and that are available to accept assignment of requests for independent review.

Additionally, the anticipated public benefits of the proposed rules and amendments related to clarification of existing rules are: (i) clarification concerning the transfer of rights and responsibilities of persons with respect to an IRO that is sold or anticipated to be sold; (ii) improved telephone access to IROs that will provide consumers with easier and more efficient access to IROs; (iii) increased clarity in existing rules to assist persons applying for or renewing a certificate of registration; (iv) increased clarity concerning confidentiality requirements to better protect enrollee heath care information; (v) enhanced oversight of IROs that will result in better compliance with requirements; and (vi) better preservation of patients' rights to independent review of adverse determinations.

ANTICIPATED COSTS

Ms. Diaz-Lara anticipates that there will be probable costs to persons required to comply with several of the proposed amendments and new sections during each year of the first five years that the rule will be in effect. These proposed amendments and new sections are necessary to implement HB 2645 and to promulgate standards and rules, under the commissioner's rulemaking authority in Insurance Code §4202.002(a)(1), for the certification, selection, and operation of IROs to perform independent review.

Anticipated Costs for Compliance with Proposed Amendments and New Sections that Implement HB 2645. The following proposed amendments and new sections are necessary to implement HB 2645: (i) proposed new §12.204(d), prohibits an individual who serves as an officer, director, manager, executive, or supervisor of an IRO from serving as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of another IRO; (ii) amendments to §12.110 relating to requirements concerning the sale of an IRO; (iii) proposed new §12.103(13)(B)-(D) relating to requirements concerning an IRO's computer system, electronic records, and location of the working office if inside a residence; (iv) proposed new §12.206(c) reduces the time frame for response to IRO request in a life-threatening case from five days to three days; (v) proposed new §12.103(4)(A) and (B), relating to credentialing policies and procedures; (vi) proposed new §12.103(6), relating to the required description of

the applicant's use of communications, records, and computer processes to manage the IRO process; (vii) proposed new §12.103(11)(a), relating to fingerprinting requirements for each officer, owner, or shareholder of the applicant; and (viii) proposed new §12.103(7), relating to evidence of accreditation. TDI anticipates that there will be costs for IROs to comply with these requirements but these costs are a direct result of the new requirements in HB 2645, not the rules implementing these requirements.

Anticipated Costs for Compliance with Other Proposed Amendments. Several other proposed amendments are not necessary to implement HB 2645 but are necessary to promulgate standards and rules for the certification, selection, and operation of IROs to perform independent review under the commissioner's rulemaking authority in Insurance Code §4202.002(a)(1). These amendments: (i) address medical director functions; (ii) require IROs to send the address and EIN for each stockholder or owner of more than 5 percent for applicants that are publicly held; (iii) require IROs to send copies of contracts and subcontracts with any person who will perform IRO functions on behalf of the IRO; (iv) require the owner and IRO staff, including the CEO, medical director, and operations staff, to be available at the IRO's primary office during on-site examinations; and (v) require IROs to have a dedicated phone line.

Proposed amended §12.202(c): medical director functions. Amendments to §12.202(c) describe functions of the IRO medical director. These functions

include, but are not limited to, the annual review and approval of screening criteria, annual quality assurance audits of at least 25 percent of all decisions, and annual quality assurance audits of at least 25 percent of all assignments. The cost to the IROs for these functions is difficult to calculate as TDI does not know exactly how long the functions will take to complete. TDI estimates the annual quality assurance audits will take a medical director approximately 80 hours per year to complete. Therefore, the estimated cost of compliance for an IRO per year is $6926.40 (80 hours multiplied by a median hourly rate of $86.58). The median hourly rate for a medical director was taken from the Texas Workforce Commission website. The medical director must be a physician currently licensed and in good standing to practice medicine by a state licensing agency in the United States under amended §12.202(c).

Proposed amended §12.103(8)(B) and (10): require IROs to send the address and EIN for each stockholder or owner of more than 5 percent for applicants that are publicly held in an application for certification and of any organization the applicant controls or is affiliated. TDI estimates it would take clerical staff up to four hours to compile the information. The estimated cost of compliance for an IRO application is $63.40 (4 hours multiplied by a median hourly rate of $15.85). The median hourly salary for a clerical worker was taken from the Texas Workforce Commission website. The IRO would send the information with the other required elements of the IRO application form so there would be no or only a negligible increase in mailing costs.

Proposed new §12.103(8)(E): requires IROs to send copies of contracts and subcontracts with any person who will perform IRO functions on behalf of the IRO. This cost is also difficult to calculate as it will depend on how individual IROs delegate these responsibilities. TDI estimates the cost of having a clerical staff for creating and mailing each contract at $63.40 (4 hours multiplied by a median hourly rate$15.85). The median hourly salary for a clerical worker was taken from the Texas Workforce Commission website. TDI estimates the legal fees for a lawyer to create each contract at $500 (2 hours of work multiplied by a median hourly rate of $250). The median hourly rate was taken from the Texas Workforce Commission website. The cost to mail each contract to TDI is $0.50 per contract.

Proposed new §12.106(d): requires the owner and IRO staff, including the CEO, medical director, and operations staff, to be available at the IRO's primary office during the on-site examination. TDI estimates no additional cost for the operations staff to be present because they would otherwise be working at the primary office. However, a medical director may not be located at the primary office. TDI estimates the cost of the medical director being present at the primary office for an on-site examination to be $275 per examination, which is the average, lowest-cost airfare within Texas with 2 weeks' notice. Department examiners provide 3 months' notice prior to an examination unless it is a targeted exam.

Proposed amended §12.207(b): requires a dedicated IRO telephone line. Costs vary depending on phone carriers, the type of service, and whether it is a cellular or landline. TDI estimates $100 per month for a business landline.

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

In accord with the Government Code §2006.002(c), TDI has determined that there are several proposed amendments and new sections that may have an

adverse economic impact on all of the approximately 41 IROs currently licensed in Texas. They all qualify as small or micro businesses under the Government Code §2006.001(1) and (2) and are all required to comply with the proposed rules. This estimate is based on TDI's review of information relating to the amount of gross receipts for the 41 IROs currently licensed in Texas. The cost of compliance with the proposal will not vary between large businesses and small or micro-businesses, as all 41 IROs, and TDI's cost analysis and resulting estimated costs in the Public Benefit/Cost Note portion of this proposal are equally applicable to small or micro-businesses.

Regulatory Flexibility Analysis

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

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

As previously stated, eight of the proposed amendments and new sections necessary to implement HB 2645, which may have an adverse economic impact on small or micro business IROs, reflect the mandated standards and rules of a legislative mandate, i.e., the Insurance Code §4202.002(c). As a result, in accord with the Guidelines, "the mandated language may be considered per se consistent with the health, safety, or environmental and economic welfare of the state and the agency need not consider other regulatory methods." These eight proposed amendments and new sections are: (i) proposed §12.204(d), which prohibits an individual who serves as an officer, director, manager, executive, or supervisor of an IRO from serving as an officer, director, manager, executive, supervisor, employee, agent, or independent contractor of another IRO; (ii) amendments to §12.110 relating to requirements concerning the sale of an IRO; (iii) proposed new §12.103(13)(B)-(D) relating to requirements concerning an

IROs computer system, electronic records, and location of the working office if inside a residence; (iv) proposed new §12.206(c), which reduces the time frame for response to IRO request in a life-threatening case from five days to three days; (v) proposed new §12.103(4)(A) and (B), relating to credentialing policies and procedures; (vi) proposed new §12.103(6), relating to the required description of the applicant's use of communications, records, and computer processes to manage the IRO process; (vii) proposed new §12.103(11)(a), relating to fingerprinting requirements for each officer, owner, or shareholder of the applicant; and (viii) proposed new §12.103(7), relating to evidence of accreditation.

Because these proposed amendments and new sections would constitute rules that adopt specific standards under the legislative mandate in HB 2645, they may be considered per se consistent with the health, safety, and environmental and economic welfare of the state, and TDI is not required to consider other regulatory methods. Therefore, under Government Code §2006.002(c-1) a regulatory flexibility analysis is not required for these proposed amendments and new sections that implement HB 2645.

For the amendments proposed under the general rulemaking authority in Insurance Code §4202.002(a)(1), the other regulatory methods considered by TDI to accomplish the objectives of the statute and the proposal and to minimize any adverse impact on IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2) include: (i) not adopting the proposed regulations; and (ii) not requiring compliance with the proposed regulations for

the 41 IROs that qualify as small or micro businesses under the Government Code §2006.001(1) and (2). The effect of not requiring compliance with the proposed regulations for the 41 IROs that qualify as small or micro businesses would be effectively the same as not adopting the amendments to 28 TAC Chapter 12 as all 41 IROs licensed in Texas are small or micro businesses.

Proposed amended §12.202(c): medical director functions. Amendments to §12.202(c) describe functions of the IRO medical director. These functions include but are not limited to the annual review and approval of screening criteria, annual quality assurance audits of at least 25 percent of all decisions, and annual quality assurance audits of at least 25 percent of all assignments. Not adopting proposed amended §12.202(c). The effect of not adopting amendments to §12.202(c) would be that IROs would otherwise have to incur costs to pay a physician medical director to carry out these functions. However, TDI has determined that requiring all IROs to follow this review criteria is important and necessary to ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO.

Proposed amended §12.103(8)(B) and (10): require IROs to send the address and EIN for each stockholder or owner of more than 5 percent for applicants that are publicly held in an application for certification and of any organization the applicant controls or is affiliated with. Not adopting proposed amended

§12.108(8)(B). The effect of not adopting amendments to §12.108(8)(B) would be that IROs would otherwise have to incur the costs of paying clerical staff to compile the information. TDI has determined that requiring IROs to submit the address and EIN for each stockholder or owner of more than 5 percent for applicants that are publicly held is necessary for TDI staff reviewing IRO applications for certification to quickly and efficiently verify the identification information submitted by the applicant in the IRO application form.

Proposed new §12.103(8)(E): requires IROs to send copies of contracts and subcontracts with any person who will perform IRO functions on behalf of the IRO. Not adopting proposed amended §12.103(8)(E). The effect of not adopting amendments to §12.103(8)(E) would be that IROs would not otherwise have to incur costs of paying clerical staff or attorneys to complete and send to TDI each contract or subcontract with any person who will perform IRO functions on behalf of the IRO. However, TDI has determined that requiring all IROs to send copies of these contracts is important and necessary to ensure that the IRO is retaining the responsibility for compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12 and to ensure TDI is aware of the actual parties conducting IRO functions.

Proposed new §12.106(d): requires the owner and IRO staff, including the CEO, medical director, and operations staff, must be available at the IRO's primary office during the on-site examination. Not adopting proposed amended

§12.106(d). The effect of not adopting amendments to §12.106(d) would be that IROs would not otherwise have to incur the travel costs for a medical director to be present for an on-site examination that may not be located at the primary office. However, TDI has determined that requiring the owner and IRO staff, including the CEO, medical director, and operations staff to be present for on-site examinations is necessary for TDI staff conducting on-site examinations to quickly and efficiently verify the IRO's compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

Proposed amended §12.207(b): requires dedicated IRO telephone line. Not adopting proposed amended §12.207(b). The effect of not adopting amendments to §12.207(b) would be that IROs would not otherwise have to incur costs of maintaining a dedicated telephone line. However, TDI has determined that requiring a dedicated telephone line is necessary for TDI staff to be able to contact the IRO and to maintain patient information confidentiality.

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

6. REQUEST FOR PUBLIC COMMENT. To be considered, written comments on the proposal must be submitted no later than 5:00 p.m. on December 29, 2014 to Office of the Chief Clerk, Texas Department of Insurance, Mail Code 113-2A, P.O. Box 149104, Austin, Texas 78714-9104 or by email to chiefclerk@tdi.texas.gov. An additional copy of the comment must be simultaneously submitted to Debra Diaz-Lara, Director, Managed Care Quality Assurance Office, Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104, or by email to Debra.Diaz-Lara@tdi.texas.gov.

The commissioner will consider the adoption of the proposed amendments and new sections in a public hearing under Docket No. 2776 scheduled for December 15, 2014 at 9:00 a.m. in Room 100 of the William P. Hobby, Jr. State Office Building, 333 Guadalupe Street, Austin, Texas. Written and oral comments presented at the hearing will be considered.

7. STATUTORY AUTHORITY. The amendments/new sections are proposed under Insurance Code §§4202.002, 4202.003, 4202.004, 4202.005, and §36.001. 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. Insurance Code §4202.002(b) provides that the standards must ensure the qualifications and independence of each reviewer, the fairness of the procedures used by an IRO in making review determinations, and the confidentiality of medical records transmitted to an IRO.

Insurance Code §4202.003 provides that the standards adopted under Insurance Code §4202.002 must require each IRO to make the IRO's determination with respect to life-threatening conditions and nonlife-threatening within the time limits in Insurance Code §4202.003.

Insurance Code §4202.004 requires an organization to submit an application in the form required by the commissioner. Insurance Code §4202.004(a) requires the IRO application form to require a description of the procedures used by the applicant to verify physician and provider credentials, including the computer processes, electronic databases, and records, if any, used and the software used by the credentialing manager for managing those processes, databases, and records. Insurance Code §4202.004(d) requires the commissioner to require each officer of the applicant and each owner or shareholder of the applicant or, if the purchaser is publicly held, each owner or shareholder described by Subsection (a)(1) to submit a complete and legible set of fingerprints to TDI for the purpose of obtaining criminal history record information from DPS and the FBI. It also requires TDI to conduct a criminal history check of each applicant using information provided under this section, and made available to TDI by DPS, the FBI, and any other criminal justice agency under Chapter 411, Government Code. Insurance Code §4202.004(e), in part, requires that an application for certification for review of health care services require an organization that is accredited by an organization described Insurance Code §4202.004(b) to provide TDI with evidence of the accreditation. It also requires the commissioner to consider the evidence if the accrediting

organization published and made available to the commissioner the IRO's requirements for and methods used in the accreditation process and authorizes an IRO that is accredited by an organization to request that TDI expedite the application process. Insurance Code §4202.004(f) authorizes a certified IRO that becomes accredited by an organization described by Subsection (b) to provide evidence of that accreditation to TDI and requires that evidence be maintained in TDI's file related to the IRO's certification. Insurance Code §4202.004(g) requires an IRO to apply for renewal of its certification of registration every two years.

Insurance Code §4202.005(c) requires IROs to submit information regarding a material change on a form adopted by the commissioner not later than the 30th day after the date the material change occurs. It also requires the IRO, if the material change is a relocation of the IRO, to inform TDI that the location is available for inspection before the date of the relocation by TDI, and an officer to attend the inspection, on request of the department. Insurance Code §4202.008 prohibits an IRO from being a subsidiary of, or in any way owned or controlled by, a payor or a trade or professional association of payors. Insurance Code §4202.013 requires an IRO to maintain its primary office in this state. Section 36.001 provides that the commissioner of insurance may adopt any rules necessary and appropriate to implement the powers and duties of the Texas Department of Insurance under the Insurance Code and other laws of this state.

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

The amendments to Chapter 12, Subchapter A, affect Insurance Code Chapter 4202, including §§4202.001 - 4202.014. The amendments to Chapter 12, Subchapter B, affect Insurance Code Chapter 4202, including §§4202.002, 4202.004, 4202.005, and 4202.013. The amendments to Chapter 12, Subchapter C, affect Insurance Code Chapter 4202, including §§4202.002 and 4202.003. The amendments to Chapter 12, Subchapter D, affect Insurance Code §4202.002. The amendments to Chapter 12, Subchapter E, affect Insurance Code §4202.002. The amendments to Chapter 12, Subchapter F, affect Insurance Code §4202.002.

9. TEXT.

SUBCHAPTER A. GENERAL PROVISIONS

§12.1. Statutory Basis. This chapter implements [~~the~~] Insurance Code Chapter 4202 as of September 1, 2013 [~~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.

§12.3. Effect of Chapter. This[~~The sections in this~~] chapter governs[~~are prescribed to govern~~] the performance of appropriate statutory and regulatory functions and is[~~are~~] not to be construed as limiting[~~limitations upon~~] the exercise of statutory authority by the commissioner[~~Commissioner~~] of insurance[~~Insurance~~].

§12.4. Applicability.

(a) All independent review organizations (IROs) 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. IROs[~~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) Unless[~~Except as~~] otherwise provided, this chapter applies[~~is applicable~~] to all requests for independent review, applications for a certificate of registration as an IRO, and for renewal of a certificate of registration as an IRO filed with the department on or after April 1, 2015[~~December 26, 2010~~]. All independent reviews filed with the department prior to April 1, 2015,

will[~~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, will[~~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) Biographical affidavit--National Association of Insurance Commissioners biographical affidavit to be used as an attachment to the IRO application form.

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

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

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

(8)[~~(7)~~] Commissioner--The commissioner [~~Commissioner~~] of insurance [~~Insurance~~] or designee.

(9) Control--The power to direct, or cause the direction of, the management and policies of a person, other than power that results from an official position with or corporate office held by the person. The power may be possessed directly or indirectly by any means, including through the ownership of voting securities or by contract, other than a commercial contract for goods or nonmanagement services. A person controls another if the person possesses the power described above with regard to the other person. The commissioner presumes control to exist if any person, directly or indirectly, or with members of the person's immediate family, owns, controls, or holds the power to vote, or if any person other than a corporate officer or director of a person holds proxies representing 10 percent or more of the voting securities or authority of any other

person. A person may rebut the presumption by showing that control does not exist in fact.

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

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

(12)[~~(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.

(13)[~~(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.

(14)[~~(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.

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

(16)[~~(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.

(17)[~~(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.

(18)[~~(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.

(19)[~~(17)~~] Independent review--A system for final administrative review by a designated IRO[~~independent review organization~~] of an adverse determination regarding the medical necessity and appropriateness or the experimental or investigational nature of health care services.

(20)[~~(18)~~] Independent review organization or IRO--An entity that is certified by the commissioner to conduct independent reviews[~~review~~] under the authority of[~~ the~~] Insurance Code Chapter 4202. An IRO [~~Such entity~~] must have the capacity for independent review of all specialty classifications and subspecialties [~~thereof~~]contained in the two-tiered[~~two tiered~~] structure of

specialty classifications set out[~~forth~~] in §12.402 of this chapter[~~ (relating to Classification of Specialty)~~].

(21)[~~(19)~~] Independent review plan--The review criteria and review procedures of an IRO[~~independent review organization~~] .

(22) IRO application form--A form for an original application for, renewal of, or reporting a material change to a certification as an IRO in this state.

(23)[~~(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~~].

(24)[~~(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.

(25)[~~(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, under[~~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 under[~~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 under[~~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.

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

(27)[~~(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 under[~~pursuant to the~~] Labor Code Title 5.

(28)[~~(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.

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

(30) Physical address--Location where the activities and computer systems described in Insurance Code §4202.002(f) are maintained, performed, and located and where personnel are reasonably available by telephone at least 40 hours per week during normal business hours in both Central and Mountain time zones, to discuss or respond to requests for independent review.

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

(32)[~~(28)~~] Primary office--The place where[~~, based upon the totality of the business activities related to independent review performed under this chapter,~~] an IRO maintains its physical address, and where its[~~independent review organization's~~] books and records pertaining to independent reviews assigned by the department[~~Department~~] are maintained and accessible[~~stored~~].

(33)[~~(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.

(34)[~~(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.

(35)[~~(31)~~] Review criteria--The written policies, medical protocols, previous decisions and[~~/or~~] guidelines used by the IRO[~~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.

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

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

(38)[~~(34)~~] Working day--A weekday that is not a legal holiday.

§12.6. Independent Review of Adverse Determinations of Health Care Provided Under[~~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 must[~~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 under[~~pursuant to the~~] Labor Code Title 5 or [~~the~~] Insurance Code Chapter 1305:

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

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

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

SUBCHAPTER B. CERTIFICATION OF REGISTRATION FOR INDEPENDENT REVIEW

§12.101. Certification of Registration for Independent Review[~~Where to File Application~~]. An application for a certificate of registration and for renewal of a certificate of registration as an IRO[~~independent review organization~~] and associated fees[~~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. IRO Application Form[~~Application and Renewal of Certificate of Registration Form; How to Obtain Forms~~].

(a) Applicants must submit the IRO application form[~~The commissioner adopts by reference Form No. LHL006 (IRO Application Form) to be used~~] for an original application for, [~~for a certificate of registration and for~~] renewal of, and reporting a material change to a certificate of registration as an IRO[~~independent review organization~~] in this state in the format prescribed by the department.

(b) The commissioner adopts the biographical affidavit by reference[~~Form No. FIN311 (Biographical Affidavit)~~] to be used as an attachment to the IRO application form[~~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 www.tdi.texas.gov/forms[~~http://www.tdi.state.tx.us/forms~~]. Applicants may also obtain the 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 Original Application for Certificate of Registration[~~and Renewal Form~~]. The IRO application form[~~Form No. LHL006~~] requires information that is necessary for the commissioner to[~~properly~~] determine whether an applicant is qualified to be certified as an IRO under [~~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)~~], which[~~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 the IRO's medical director[~~an authorized representative~~] that the[~~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 under[~~in accordance with~~] §12.201(3) of this chapter;[~~ and~~]

(D) procedures ensuring that the information regarding the reviewing physicians and providers is updated under[~~in accordance with~~] §12.111(a)[~~§12.105(d)~~] of this title[~~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; and[~~.~~]

(E) a summary description of criteria and review procedures to be used by the medical director to conduct quality assurance audits under §12.202(c)(2) of this subchapter.

(2) copies of policies and procedures that[~~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 officer, director, or owner of the IRO,[~~authorized representative~~] that the IRO[~~independent review organization~~] and any party that performs an IRO function through contracts and subcontracts will comply with[~~ the~~] Insurance Code Chapter 4202 and this chapter. The certification must include a statement that the IRO is responsible for ensuring that all contracted and subcontracted functions are performed according to

Insurance Code Chapter 4202 and this chapter, subject to the IRO's oversight and monitoring, and that the IRO retains ultimate responsibility for compliance;[~~.~~]

(4) a description of personnel and their credentials[~~credentialing~~], and a completed profile for each physician and provider, both as described in §12.202 of this chapter that must include:[~~ (relating to Personnel and Credentialing)~~]

(A) the credentialing and recredentialing procedures used by the IRO applicant to verify physician and provider credentials, and the computer processes, electronic databases, and records used to make the verification; and

(B) the credentialing software used by the applicant for managing the processes, databases, and records described above;

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

(6) a description of the applicant's use of communications, records, and computer processes to manage the independent review process;

(7) a description and evidence of accreditation from a nationally recognized accrediting organization, if any, that imposes requirements for accreditation that are the same as, substantially similar to, or more stringent than the department's requirements for certification. Evidence of accreditation will be maintained in the department's file for the IRO applicant, and the applicant may

request expedited approval of the certification with evidence of accreditation from a nationally recognized accrediting organization.

(8)[~~(6)~~] the organizational information, documents, and all amendments that must include[~~, including~~]:

(A) written evidence that the applicant is incorporated in this state, which may include a letter from the Texas Secretary of State, indicating that the applicant has filed the appropriate information about the incorporation [~~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, address, and Federal Employer Identification Number (EIN) of each stockholder or owner of more than 5[~~five~~] percent of any stock or options, for an applicant that is publicly held;

(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, including all contracts between the IRO and any person and all subcontracts with other persons to perform any business or daily functions of an IRO; and[~~.~~]

(E) copies of the contract and subcontract with any person who will perform IRO functions on behalf of the IRO. All contracts and subcontracts must include at a minimum:

(i) a provision that the contracted or subcontracted party will comply with §12.208 of this chapter.

(ii) a provision that the IRO is responsible for ensuring that all contracted and subcontracted functions are performed under Insurance Code Chapter 4202 and this chapter, subject to the IRO's oversight and monitoring,

(iii) a provision that the IRO retains ultimate responsibility for compliance, and

(iv) a provision that, on request, the contracted party will provide the IRO with data necessary for the IRO to comply with department requests for information about IRO functions.

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

(10)[~~(8)~~] the name, address, EIN, 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;

(11)[~~(9)~~] biographical information about officers, directors, and executives, including information requested in the biographical affidavit[~~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 a complete set of fingerprints for each director, officer, and executive of the applicant and for each owner or shareholder of the applicant, or if the applicant is publicly held, each owner or shareholder of more than 5 percent of any of the applicant's stock or options as described by Insurance Code §4202.004(a)(1), in compliance with §1.503 and §1.504 of this title.

(B)[~~(A)~~] the applicant must submit the name and[~~,~~] biographical information[~~, and, in compliance with §1.503 and §1.504 of this title (relating to Application of Fingerprint Requirement and Fingerprint Requirement), a complete set of fingerprints~~] for each director, officer, and executive of the applicant and of[~~,~~] any entity listed under paragraph (10)[~~(8)~~] of this section[~~,~~] and a description of any relationship the named individual has that[~~which~~] represents revenue equal to or greater than 5[~~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 IRO[~~independent review organization~~];

or

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

(C)[~~(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 5[~~five~~] percent or more interest;

(D)[~~(C)~~] the applicant must submit a list of any currently outstanding loans or contracts to provide services between the applicant,[~~and any~~] affiliates, or any other person relating to any functions performed by or on behalf of the IRO;

(12) documentation from the comptroller demonstrating the applicant's good standing and right to transact business in this state;

(13)[~~(10)~~] for an application for a certificate or renewal of registration as an IRO[~~independent review organization~~] in this state made on or after April 1, 2015[~~December 26, 2010~~], a sworn statement from an officer of the organization that:

(A)[~~evidence that~~] the applicant's primary office noted on the application is located and maintained at a physical address in this state. As a condition of being certified to conduct the business of independent review in this state, an IRO[~~independent review organization~~] must locate and maintain its primary office at a physical address in this state;

(B) the primary office is equipped with a computer system capable of:

(i) processing requests for independent review; and

(ii) accessing all electronic records related to the review and the independent review process;

(C) all records are maintained electronically and will be made available to the department on request;

(D) in the case of an office located in a residence, the working office must be located in a room set aside for independent review business purposes and in a manner to ensure confidentiality; and

(E) medical records are maintained according to §12.208 of this chapter.

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

(15)[~~(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 Original Application. The original application process is as follows:

(1) Original application process. Within 60 days after receipt of a complete original application, the department will process the application and

grant or deny an original certification. The department will send a certificate to an entity that is granted certification. The applicant may waive the time limit described in this subsection.

(2) Omissions or deficiencies.

(A) The department will send the applicant written notice of any omissions or deficiencies in the original application.

(B) The applicant must correct the omissions or deficiencies in the application within 15 days of the date of the department's latest notice of omissions or deficiencies. The applicant may request additional time, not to exceed 30 days, in writing to correct the omissions or deficiencies. In the request, the applicant must include sufficient detail for the commissioner to determine whether there is good cause to grant additional time for the applicant to correct the omissions or deficiencies. The decision to grant or deny a request for additional time is at the discretion of the commissioner.

(C) If the applicant fails to correct the omissions or deficiencies within 15 days, or 45 days if the applicant requested and was granted the maximum amount of additional time, the department will close the application as incomplete. The application fee is not refundable.

[~~(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.~~]

(4)[~~(5)~~] The department will[~~shall~~] maintain a charter file that will[~~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 made by the applicant during the review of the application must either be submitted electronically in the manner specified by the department in correspondence with the applicant or sent by mail[~~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.

(a) The commissioner or the commissioner's designee will[~~may~~] conduct an on-site[~~-qualifying~~] examination at the applicant's primary office[~~of an applicant~~] as a requirement of applying for a certificate of registration[~~-or renewing a certificate of registration as an independent review organization~~].

(b) The commissioner may conduct examinations of an IRO as often as the commissioner deems necessary to determine compliance with Insurance Code Chapter 4202 and this chapter, including on renewal of the certificate of registration.

(c) The following documents[~~Documents that support the application for the certificate of registration or renewal of the certificate of registration~~] must be available for review during an[~~inspection at the time of such qualifying~~]

examination at the primary office of the IRO[~~independent review organization~~] located within this state:

(1) the information required in §12.103 of this chapter;

(2) credentialing files;

(3) case decisions files;

(4) a list of personnel who are available at the IRO's primary office 40 hours a week during normal business hours in both Central and Mountain time zones;

(5) a list of directors, officers, and executives and owners or shareholders, or if the IRO is publicly held, owners or shareholders of more than 5 percent of any of the IRO's stock or options as described by Insurance Code §4202.004(a)(1);

(6) a chart showing the internal organizational structure of the IRO management and administrative staff;

(7) a chart showing the contractual relationships and arrangements of the IRO, as described in §12.103 of this chapter; and

(8) any other documents related to the operation of the IRO.

(d) The owner and IRO staff, including the CEO, medical director, and operations staff, must be available at the IRO's primary office during the on-site examination to answer all questions regarding the IRO's operations, produce documents, and demonstrate to the examiner the operations of the IRO.

§12.107. Withdrawal of an Original Application Prior to Certification and Subsequent Renewal Applications.

(a) On[~~Upon~~] written notice to the department, an applicant may request withdrawal of an application from consideration by the department.

(b) On[~~Upon~~] the department's receipt of a request to withdraw an application under[~~pursuant to~~] this section, the application will[~~shall~~] be withdrawn from consideration. Subsequent applications by the same applicant must be new submissions in their entirety.

§12.108. Renewal of Certificate of Registration.

(a) The commissioner will recertify every two years[~~shall designate annually~~] each organization that meets the standards as an IRO[~~independent review organization~~].

(b) An IRO[~~independent review organization~~] must apply for renewal of its certificate of registration every two years[~~every year~~], not later than the anniversary date of the issuance of the registration. The IRO application form [~~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. The IRO application form may[~~Form No. LHL006 can~~] be obtained from the department's website and from the address listed in §12.102(c) of this chapter[~~subchapter~~]. The completed IRO application [~~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 chapter[~~subchapter (relating to Where To File Application). Material changes shall include changes relating to physicians or providers performing independent review~~].

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

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

(1) continue to perform its duties in compliance with[~~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 under[~~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 under[~~pursuant to~~] §133.308 of this title[~~(relating to MDR by Independent Review Organizations)~~].

§12.109. Appeal of Denial of Application or Renewal. If an original or renewal application[~~or renewal~~] is[~~initially~~] denied under this chapter[~~subchapter~~],

the applicant or registrant may appeal the[~~such~~] denial under[~~pursuant to~~] the provisions of Chapter 1, Subchapter A of this title [~~(relating to Rules of Practice and Procedure)~~]and [~~the~~]Government Code, Chapter 2001.

§12.110. Effect of Sale or Transfer of Ownership of an Independent Review Organization.

(a) An IRO must notify the department of an agreement to sell or transfer the ownership of the IRO, or shares in the IRO, not later than 60 days before the date of the sale or transfer of ownership. The IRO may use the IRO application form. The IRO must file the notification with the department at the following address: Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104. The IRO must submit the following information with the notification:

(1) name of the purchaser and, in compliance with §1.503 and §1.504 of this title, a complete and legible set of fingerprints for each officer of the purchaser and for each owner or shareholder of the purchaser, or if the purchaser is publicly held, each owner or shareholder of more than 5 percent of any of the applicant's stock or options as described by Insurance Code §4202.004(a)(1), and any additional information necessary to comply with Insurance Code §4202.004(d); and

(2) any material changes including, but not limited to, policies and procedures, physical addresses, personnel, or operating locations with the notice of intent to sell or transfer ownership.

(b) The IRO may complete the sale or transfer of ownership only after the department has sent written confirmation that the requirements under Insurance Code Chapter 4202 and this chapter have been satisfied.

[~~(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.~~]

(c)[~~(d)~~] [~~Obligation to Continue Performing Duties Prior to Sale.~~] An IRO [~~independent review organization~~] must continue to perform all duties prior to the date [~~that~~] the sale or transfer of ownership of the IRO [~~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 IRO [~~independent review organization~~] does not negate the IRO's [~~independent review organization's~~] obligation to continue to perform its duties in compliance with [~~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.]~~

§12.111. Regulatory Requirements Subsequent to Certification.

(a) The IRO must report any material changes to the information required in the IRO application form required by §12.102 and §12.108 of this chapter, including changes relating to physicians and providers performing independent review, not later than the 30th day after the date on which the change takes effect.

(b) If the material change is a relocation of the primary office:

(1) the organization must inform the department that the location is available for inspection by the department at least 30 days before the date of the relocation;

(2) on request of the department, an officer must attend the inspection; and

(3) if the inspection is a result of a sale under §12.110 of this chapter, the inspection may include verification that the IRO complies with the requirements in §12.103(11) of this chapter.

(c) The IRO is exempt from compliance with subsection (a) of this section in the event that a contracted specialist IRO reviewer is unavailable for review on a specific case, and subsequent immediate contracting with a new specialist IRO reviewer is necessary to complete independent review on a specific case within the time frames set out in this chapter.

(d) The IRO must notify the department within 10 days of any contracts entered into under subsection (c) of this section, and must include in the notification a complete explanation of the circumstances necessitating the new contracts.

SUBCHAPTER C. GENERAL STANDARDS OF INDEPENDENT REVIEW

§12.201. Independent Review Plan. Independent review must[~~shall~~] be conducted under [~~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 the IRO's medical director[~~a physician~~]. The independent review plan must[~~shall~~] include the following components:

(1) A description of the elements of review that[~~which~~] the IRO[~~independent review organization~~] provides;

(2) written procedures for:

(A) notification of the IRO's[~~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, under[~~in accordance with~~]§12.206 of this chapter[~~subchapter (relating to Notice of Determinations Made by Independent Review Organizations)~~];

(B) review, including:

(i) any form used during the review process;

(ii) time frames that must[~~shall~~] be met during the review;

(C) accessing appropriate specialty review;

(D) contacting and receiving information from health care providers under [~~in accordance with~~]§12.205 of this chapter[~~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 for deviations from the norms when justified on a case-by-case basis;

(D) developed based on consideration of the treatment guidelines, treatment protocols, and the 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 under[~~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 so[~~in order for~~] the commissioner can[~~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 IRO[~~independent review organization~~] to perform independent reviews must[~~review shall~~] be appropriately trained,[~~and~~] qualified and, if applicable, currently licensed, registered, or certified. These[~~Such~~] personnel must[~~shall~~] be currently involved in an active practice. An exception to the active practice requirement is[~~shall be~~] the medical director of the IRO[~~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, must[~~shall~~] be nurses, physician assistants, or health care providers qualified to provide the service requested by the provider. This provision must[~~shall~~]not be interpreted to require such qualifications for personnel who perform clerical or administrative tasks.

(1) Personnel conducting independent reviews for health services must hold an unrestricted license, an administrative license, or otherwise be authorized to provide the same or similar specialty health services by a licensing agency in the United States.

(2) Personnel conducting independent reviews for workers' compensation health care services must hold an unrestricted license, an administrative license, or otherwise be authorized to provide the same or similar specialty workers' compensation health care services by a licensing agency in this state.

(b) The IRO[~~independent review organization~~] is required to provide to the commissioner:

(1) the name[~~number~~], type, license number, state of licensure, date of contract, and minimum qualifications of the personnel either employed or under contract to perform the independent review; and[~~.~~]

(2) [~~Independent review organizations are required to adopt~~] written procedures used to determine whether physicians or other health care providers used[~~utilized~~] by the IRO[~~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 IRO must[~~independent review organization shall~~]be under the direction of a medical director who is a physician currently licensed and in good standing to practice medicine by a state licensing agency in the United States. The medical director functions must include, but are not limited to, conducting:

(1) annual review and approval of screening criteria;

(2) annual quality assurance audits of at least 25 percent of all decisions to ensure appropriate reviews are conducted, and to provide quality assurance reports to the department when requested; and

(3) annual quality assurance audits of at least 25 percent of all assignments to ensure appropriate reviewers are assigned to cases, and to provide quality assurance reports to the department when requested.

(d) The IRO must maintain credentialing and recredentialing files of the personnel either employed by or under contract to perform independent reviews. At a minimum, the IRO must keep the following credentialing and recredentialing information current and available for review by the department and TDI-DWC on request:

(1) licensure, certification or registration, as applicable. Verification will be the state licensing board, and the license, certification, or registration must be in effect at the time of the credentialing decision;

(2) active practice in effect at the time of the credentialing decision;

(3) board certification, if applicable. The IRO may obtain verification from the American Board of Medical Specialties Compendium, the American Osteopathic Association, the American Medical Association MasterFile, or an applicable specialty board. The certification must be in effect at the time of the credentialing decision; and

(4) any sanctions or revocations by any state licensing agencies in the United States or the U.S. Department of Health and Human Services (HHS) in effect at the time of the credentialing decision. The IRO must verify sanctions or revocations with state licensing agencies, TDI-DWC, and the HHS Office of Inspector General.

[~~(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 IRO[~~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 must[~~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)~~].

(g) The IRO must require physicians and other providers who conduct independent reviews to sign and date the certification of independence and qualifications of the reviewer in the format prescribed by the department. The certification of independence and qualifications of the reviewer includes certification that the physician or other provider who conducts the independent review:

(1) holds an unrestricted license, certification, or registration and lists the relevant states, license numbers, and expiration dates;

(2) has no sanctions or revocations of the reviewer's license, certification, or registration by any state licensing agency in the United States or HHS;

(3) currently practices and lists the states;

(4) has no previous knowledge of or participation in the case prior to it being assigned to the reviewer;

(5) has no disqualifying associations, including business or personal relationships, with any involved parties in the case;

(6) does not have admitting privileges or ownership interest in, and is not a member of the board of directors, advisor to the board of directors, or officer of the health care facilities where care was provided or is recommended to be provided;

(7) does not have a contract with or an ownership interest in the utilization review agent, insurer, health maintenance organization, other managed care entity, payor, or any other party to the case and is not a member

of the board or advisor to the board of directors or an officer for any of the above referenced entities; and

(8) performed the review without bias for or against the utilization review agent, the insurer, health maintenance organization, other managed care entity, payor, or any other party to this case.

(h) The information required in this section must be available for examination and review by the department and TDI-DWC personnel on request.

(i) The IRO must require those physicians and other providers who conduct independent reviews to notify the IRO of any changes in the information in subsection (d) of this section.

§12.203. Conflicts of Interest Prohibited.

(a) A person is not eligible for certification under this chapter if any payor, or trade or professional association of payors has any ownership interest in or control over the person or if the person has any ownership interest in or control over a payor.[~~A person that is a subsidiary of, or in any way owned or controlled by, a payor or trade or professional association of payors is not eligible for certification under this chapter.~~] The department will[~~shall~~] have the discretion to determine whether any other conflicts exist.

(b) The commissioner may determine that control exists in fact, despite the absence of a presumption to that effect, where a person exercises, either alone or pursuant to an agreement with one or more persons, such a controlling influence over the management or policies of an IRO as to make it necessary or appropriate in the public interest that the person be deemed to control the IRO.

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

(a) An IRO[~~independent review organization~~] must[~~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 out[~~forth~~] in this chapter or Texas law.

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

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

(1) This prohibition extends to the shared use by IROs[~~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 IRO[~~independent review organization~~] to perform independent review.

(d) An individual who serves as an officer, director, manager, executive, or supervisor of an IRO may not serve as an officer, director, manager,

executive, supervisor, employee, agent, or independent contractor of another IRO.

(e)[~~(d)~~] An individual or [~~an~~] entity may not own more than one IRO [~~independent review organization~~].

(f)[~~(e)~~] An individual may not own stock in more than one IRO [~~independent review organization~~].

(g)[~~(f)~~] An individual may not serve on the board of more than one IRO [~~independent review organization~~].

(h)[~~(g)~~] An individual who has served on the board of an IRO [~~independent review organization~~] that has had its certificate of registration revoked for cause may not serve on the board of another IRO [~~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 IROs[~~independent review organizations~~] seeking routine information or data. In no event will[~~shall~~] the designation of [~~such~~]an individual or individuals as the initial contact prevent[~~preclude~~]an IRO[~~independent review organization~~] or medical director from also 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 IRO[~~independent review organization~~].

(b) An IRO[~~independent review organization~~] may not engage in unnecessary or unreasonably repetitive contacts with the health care provider or patient and must[~~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 is[~~shall be~~] responsible for timely delivering to and ensuring

receipt by the IRO[~~independent review organization~~] of any written narrative supplied by the patient in compliance with[~~pursuant to the~~] Insurance Code Chapter 4201 and Chapters 19 and 133 of this title[~~ (relating to Agents' Licensing and General Medical Provisions)~~]. ~~H~~However, in instances of a life-threatening condition, the IRO must[~~independent review organization shall~~] contact the patient or patient's representative[~~of the patient~~], and provider directly.

(d) An IRO must[~~independent review organization shall~~] notify the department if, within three working days of receipt of the independent review assignment, the IRO[~~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 IRO must[~~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 IRO[~~independent review organization~~]. A health care provider's charge for providing medical information to an IRO must[~~independent review organization shall~~] not exceed the cost of copying set by [~~rules of~~]TDI-DWC rules 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. The[~~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 must pay these unreimbursed costs to the health care provider[~~as an expense of independent review~~].

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

(g) When conducting independent review, the IRO must[~~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 IRO[~~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 IRO must[~~independent review organization shall~~] notify the patient or patient's representative [~~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 IRO[~~independent review organization~~] receives the information necessary to make a determination; or

(2) the 20th day after the date the IRO[~~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, and [~~to be~~] followed by facsimile, email[~~electronic mail~~], or other method of transmission not later than the earlier of:

(1) the third[~~5th~~] day after the date the IRO[~~independent review organization~~] receives the information necessary to make a determination; or with respect to:

(2) a review of a health care service provided to a person eligible for workers' compensation medical benefits,

[~~(2)~~] the eighth [~~8th~~]day after the date the IRO[~~independent review organization~~] receives the request that the determination be made; or

(3) a review of health care service other than a service described by subparagraph (A) of this paragraph, the third day after the date the IRO receives the request that the determination be made[~~for independent review~~].

(d) Notification of determination by the IRO[~~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) email[~~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 about[~~of~~]whether the type of coverage is health insurance, workers' compensation, or workers' compensation health care network;

(6) a statement about [~~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 IRO[~~independent review organization~~];

(8) a description of the services in dispute;

(9) a complete list of the information provided to the IRO[~~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 IRO[~~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 used [~~that were utilized~~]to make the determination;

(19) a certification by the IRO[~~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 by[~~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 are[~~may be found~~] on the department's website at http://tdi.texas.gov/forms[~~http://www.tdi.state.tx.us/forms~~].

§12.207. Independent Review Organization Telephone Access.

(a) An IRO must[~~independent review organization shall~~] have appropriate personnel reasonably available by telephone at least 40 hours per week during normal business hours in both Central and Mountain time zones[~~in Texas~~].

(b) An IRO[~~independent review organization~~] must have a dedicated telephone system capable of accepting or recording or providing instructions to incoming callers[~~calls~~] related to independent[~~utilization~~] review during other-than-normal[~~other than normal~~] business hours, and must[~~shall~~] respond to[~~such~~]calls no[~~not~~] later than one working day from the date the call was received.

§12.208. Confidentiality.

(a) An IRO must[~~independent review organization shall~~] preserve the confidentiality of individual medical records, personal information, and any proprietary information provided by payors. Personal information includes[~~shall~~

~~include, at a minimum,~~] name, address, telephone number, social security number, and financial information.

(b) An IRO is prohibited from publicly disclosing patient information protected by the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. Section 1320d et seq.), or transmitting the information to a subcontractor involved in the independent review process that has not signed an agreement similar to the business associate agreement required by regulations adopted under the Health Insurance Portability and Accountability Act of 1996.

(c)[~~(b)~~] An IRO[~~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, including the Health Insurance Portability and Accountability Act of 1996, if applicable. An IRO[~~independent review organization~~] may provide confidential information to a provider who is under contract with the IRO[~~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 must[~~shall~~] remain confidential.

(d)[~~(c)~~] The IRO[~~independent review organization~~] may not publish data identifying[~~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 IRO[~~independent review organization~~].

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

(f)[~~(e)~~] To ensure[~~assure~~]confidentiality, an IRO[~~independent review organization~~] must, when contacting a utilization review agent, a physician's or provider's office, or a hospital, provide its certificate number and the caller's name and professional qualifications to the provider or the provider's named independent review representative.

(g)[~~(f)~~] The IRO's[~~independent review organization's~~] procedures must[~~shall~~] specify that specific information exchanged for the purpose of conducting a review will be considered confidential, be used by the IRO[~~independent review organization~~] solely for the purposes of independent review, and may be shared by the IRO only[~~independent review organization~~] with[~~only~~] a provider who is under contract with the IRO[~~independent review organization~~] to perform an independent review. The IRO's[~~independent review organization's~~] plan must[~~shall~~] specify the procedures [~~that are~~] in place to ensure [~~assure~~]confidentiality and must[~~shall~~] acknowledge that the IRO[~~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 is not[need not be considered]confidential.

(h)[(g)] Medical records and patient-specific information must[shall] be maintained by the IRO[independent review organization] in a secure area with access limited to essential personnel only. IROs must transmit and store records in compliance with the Health Insurance Portability and Accountability Act of 1996.

(i)[(h)] Information generated and obtained by the IRO[independent review organization] in the course of the review must[shall] be retained for at least four years. This requirement is not negated by the suspension or surrender of the IRO's[independent review organization's] certificate of registration or the failure to renew the certificate of registration.

(j)[(i)] Destruction of documents in the custody of the IRO[independent review organization] that contain confidential patient information or payor, physician, or provider financial data must[shall] be by a method that[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 IRO must[~~independent review organization shall~~] be processed under[~~in accordance with~~] the department's established procedures for investigation and resolution of complaints.

(b) As part of its oversight of IROs[~~independent review organizations~~], the department will conduct compliance audits to ensure that IROs[~~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 IRO[~~independent review organization~~].

(d) This chapter does not limit the ability of the commissioner[~~Commissioner~~] of workers' compensation[~~Workers' Compensation~~] or TDI-DWC to make inquiries, conduct audits, or receive and investigate complaints against IROs[~~independent review organizations~~] or personnel employed by or under contract with IROs[~~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 this chapter 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 will[~~shall~~] notify the IRO[~~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 a[~~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 IRO[~~independent review organization~~] or a person conducting independent reviews[~~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 IRO[~~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 using[~~use of~~] certification or designation as an IRO is[~~independent organization shall be~~] a violation of [~~the~~]Insurance Code Chapter 4202.

(g) If the commissioner or the commissioner's designee determines that an IRO[~~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 under[~~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[~~Commissioner~~] of workers' compensation[~~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 IRO[~~independent review organization~~] or personnel employed by or under contract with an IRO[~~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) Under[~~Pursuant to the~~] Insurance Code §4202.002(c)(2)(B),[~~upon the request of the department,~~] an IRO that enters into an agreed order with the department that includes surrendering its certificate of registration[~~independent~~

~~review organization~~], must surrender the organization's certificate of registration immediately on the request of the department [~~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 will[~~shall~~] not be assigned to an IRO[~~independent review organization~~] during a surrender of the IRO's[~~independent review organization's~~] certificate of registration.

(c) [~~(e)~~] Surrender of an IRO's[~~independent review organization's~~] certificate of registration does not negate the requirement in §12.208(i) [~~(h)~~] of this subchapter[~~chapter (relating to Confidentiality)~~] that an IRO must[~~independent review organization~~] retain information generated and obtained by the IRO[~~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 IRO[~~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

§12.401. Fees.

(a) The commissioner will[~~shall~~] establish, administer, and enforce the certification and renewal fees under this section in amounts not greater than necessary to cover the cost of administration of this chapter.

(b) Fees for independent review will[~~shall~~] be determined by the commissioner[~~department~~], and will[~~shall~~] reflect in general the market value of services rendered.

§12.402. Classification of Specialty. Fees for independent review will[~~shall~~] be based on a two-tiered[~~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 of their subspecialties[~~ thereof~~].

§12.403. Fee Amounts.

(a) Fees to be paid to IROs[~~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 must[~~shall~~] be filed with the department no later than five working days from the IRO's[~~independent review organization's~~] receipt of notice from the department that the initial notification of decision is incomplete.

§12.404. Payment of Fees.

(a) IROs must[~~independent review organizations shall~~] bill utilization review agents or payors, as appropriate, directly for fees for independent review.

(b) IROs[~~independent review organizations~~] may also bill utilization review agents or payors, as appropriate, for copy expenses related to reviews[~~review~~] as set out[~~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, must[~~shall~~] pay IROs[~~independent review organizations~~] directly within 15[~~30~~] days of receipt of invoice. For workers' compensation network and nonnetwork[~~non-network~~] disputes, the IRO[~~independent review organization~~] fees must[~~shall~~] be paid under[~~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 IRO[~~independent review organization~~] within 15[~~30~~] days of receipt is[~~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 under[~~in accordance with~~] §12.302 of this chapter[~~ (relating to Administrative Violations)~~].

§12.406. Certification and Renewal Fees. The fee[~~Fees~~] to be paid to the department for the original application for a certificate of registration as an IRO[~~independent review organization~~] is $1000[~~$800~~]. The fee for renewal of a certificate of registration is $400[~~$200~~]. There is no fee for reporting a material change to a certification as an IRO.

SUBCHAPTER F. RANDOM ASSIGNMENT OF INDEPENDENT REVIEW ORGANIZATIONS

§12.501. Requests for Independent Review. Requests for independent review must[~~shall~~] be made to the department on behalf of the patient by the utilization review agent under[~~pursuant to the~~] Insurance Code Chapter 4201, Subchapter I and Chapter 19, Subchapters[~~Subchapter~~] R and U 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)~~];[~~,~~] Chapter 134 of this title;[~~,~~] or by a health insurance carrier, health maintenance organization, or managed care entity under[~~pursuant to the~~] Civil Practice and Remedies Code §88.003(c).

§12.502. Random Assignment.

(a) The department will[~~shall~~]randomly assign each request for independent review to an IRO[~~independent review organization~~] and will[~~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 IRO[~~independent review organization~~], the patient or a representative of the patient, and the provider of record of the[~~such~~] assignment.

(b) The department will[~~shall~~] screen payors and utilization review agents for potential conflicts of interest with the IRO[~~independent review organization~~] before making an assignment to the IRO[~~independent review organization~~]. The

IRO must[~~independent review organization shall~~]screen its physicians and other providers conducting independent review for potential conflicts of interest. The department has[~~shall have~~] the discretion to determine whether conflicts exist.

(c) IROs[~~independent review organizations~~] will[~~shall~~] be added to the list from which random assignments for independent reviews[~~review~~] are made in order of the date of issuance of the certificate of registration by the department.

(d) The department will randomly assign IROs[~~Random assignment shall be made~~] chronologically from the list of IROs[~~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 IRO[~~independent review organization~~] moves the IRO[~~independent review organization~~] receiving the assignment to the bottom of the assignment list.

(f) Independent reviews will not be assigned:

(1) to an IRO[~~independent review organization~~] during the 30 days prior to the anniversary date of the issuance of the IRO's[~~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 IRO[~~independent review organization~~] has surrendered its certificate of registration under[~~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 IRO[~~independent review organization~~] to the bottom of the assignment list. The IRO[~~Such independent review organization~~] retains its chronological position until selected for independent review.

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

Issued at Austin, Texas, on November 10, 2014.

Sara Waitt
General Counsel
Texas Department of Insurance