SUBCHAPTER A. GENERAL PROVISIONS
28 TAC §12.1 AND §§12.3 - 12.6

SUBCHAPTER B. CERTIFICATE OF REGISTRATION FOR INDEPENDENT REVIEW
28 TAC §§12.101 - 12.111

SUBCHAPTER C. GENERAL STANDARDS OF INDEPENDENT REVIEW
28 TAC §§12.201 - 12.208

SUBCHAPTER D. ENFORCEMENT OF INDEPENDENT REVIEW STANDARDS
28 TAC §§12.301 - 12.303

SUBCHAPTER E. FEES AND PAYMENT
28 TAC §§12.401 - 12.406

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

1. INTRODUCTION. The Texas Department of Insurance (TDI) adopts 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). TDI adopts the new section and amendments with changes to the proposed text published in the November 28, 2014, issue of the *Texas Register* (39 TexReg 9310). Two correction of error notices were published in the December 12, 2014, (39 TexReg 9738) and December 19, 2014, (39 TexReg 10083) issues of the *Texas Register* to correct errors in the proposal published in the November 28, 2014, issue of the *Texas Register* (39 TexReg 9310). In response to comments on the proposal, TDI added the phrase “if any” in §12.103(4)(A) to track Insurance Code §4202.004(6)(B). Also in response to comments, TDI deleted “a letter from the Texas Secretary of State” and added “a copy of the Certificate of Formation from the Secretary

of State" in §12.103(8)(a) to reflect the formation and existence requirements of Business Organizations Code §3.001.

In addition to changes made in response to comments and to conform to the agency's current style guidelines, TDI deleted "as of September 1, 2013," in §12.1. TDI deleted "applications for a certificate of registration as an IRO, and for a renewal of a certificate of registration as an IRO" and "April 1, 2015," and added "This chapter is effective on July 7, 2015," and "July 7, 2015" in §12.4 to clarify that all of 28 TAC Chapter 12 is effective on July 7, 2015.

TDI revised §§12.5(20), 12.5(22), 12.101, 12.103, 12.104, 12.107, 12.108, 12.111, 12.206(d)(7), 12.208(f), 12.302(f), 12.401(a), and 12.406 to replace "certified," "renew," and "certification." The term "certification" refers to an issuance of the certificate of registration. For consistency of terminology throughout 28 TAC Chapter 12, TDI removed references to the term "certification," instead referring to a "certificate of registration." As a conforming change, TDI also changed the title of Subchapter B.

TDI deleted "pertaining to" and added "on" in §12.5(15) to conform to current agency writing style. TDI deleted "including" and added "includes" in §12.5(23)(a) to conform to current agency writing style. TDI capitalized deleted "Federal" and added "federal" in §12.5(25)(E)(i) to conform to current agency writing style. TDI deleted "pertaining to" and added "about" in §12.5(32) to conform to current agency writing style.

TDI deleted "where the activities and computer systems described in" and "are maintained, performed, and located" and added "the IRO's primary office" in §12.5(30)

to implement Insurance Code §4202.002(c)(2)(A)(i), which requires the IRO to maintain a physical address in Texas, and Insurance Code §4202.002(c)(2)(A)(iv), which requires the IRO to maintain its primary offices in this state. TDI also made these changes throughout 28 TAC Chapter 12 for consistency. TDI added “in Texas” in §12.5(32) for clarity and to implement Insurance Code §4202.002(c)(2)(A)(i). TDI deleted "pertaining to" and added "about" in §12.5(32) to conform to current agency writing style. TDI made a nonsubstantive correction to punctuation in §12.5(35).

TDI deleted “Certification” and “Organizations” and added “Certificate” and “IROs” in the title of subchapter B to correct the existing title and to comply with current agency writing style. TDI deleted “to” and added “in an IRO application form for” in §12.102(a) to be consistent throughout 28 TAC Chapter 12. TDI made nonsubstantive corrections to punctuation throughout §12.103. TDI deleted "title" and added "chapter" in §12.103(1)(E) to conform to current agency writing style. TDI deleted "title" and added "chapter" in §12.103(1)(E) to conform to current agency writing style. TDI deleted “above” and added “in subparagraph (A)” in §12.103(4)(B) to conform to current agency writing style. TDI moved “for an applicant that is publicly held” from the end to the beginning of §12.103(8)(B) to better track Insurance Code §4202.004(a)(1).

TDI deleted “IRO” and added “applicant” in §12.103(8)(D), §12.103(8)(E), and §12.103(11)(D) to be consistent with existing language. TDI deleted "subchapter" and added "chapter" in §12.103(11) to conform to current agency writing style.

TDI deleted “noted on the application” and added “included on the IRO application form” in §12.103(13)(A) for consistency and to conform to current agency

writing style. TDI made a nonsubstantive amendment to renumber the paragraphs in §12.104 by deleting “4” and adding “3.” TDI replaced “will” with “may” in §12.106(a) to clarify that TDI conducts examinations at its discretion. TDI made a nonsubstantive correction to punctuation in §12.104(2)(B). TDI deleted "or the commissioner's designee" in §12.106(a) because the commissioner's designee is included in the definition of commissioner in §12.5(8). TDI deleted "Prior to" and added "Before" to the title of §12.107 to conform to current agency writing style. TDI added “of” to §12.108(a) to correct a grammatical error. TDI moved “Every two years” to the beginning of the sentence in §12.108(a) to conform to current agency writing style. TDI deleted “not” and added “no” in §12.108(a) to conform to current agency writing style. TDI deleted “responses” and added “responded” in §12.108(e)(2) to correct a grammatical error.

TDI replaced “may” with “must” in §12.110(a) for consistency with §12.102(a), which requires the use of the IRO application form for reporting a material change. TDI also deleted “applicant’s” and added “purchaser’s” in §12.110(a) for consistency. TDI replaced “addresses” with “address” to clarify that the IRO is only required to maintain one physical address under Insurance Code §4202.0029(a)(2)(A). TDI deleted “not” and added “no” in §12.110(a) to conform to current agency writing style. TDI deleted "prior to" and added "before" in §12.110(c) to conform to current agency writing style. TDI deleted “§12.102” and added “§12.103” in §12.111(a) to cite to the correct section about reporting a material change. TDI deleted “not” and added “no” in §12.111(a) to conform to current agency writing style.

TDI deleted "A" and added "a" in §12.201(1) to conform to current agency writing style. TDI deleted "utilize" and added "use" in §12.201(3)(A) to conform to current agency writing style. TDI deleted "utilize" and added "use" in §12.201(4)(A) to conform to current agency writing style. TDI made a nonsubstantive correction to punctuation in §12.202(a). TDI deleted "the" and added "who are" in §12.202(d) to conform to current agency writing style. TDI deleted “by” in §12.202(d) to conform to current agency writing style. TDI made a nonsubstantive change to the requirement in §12.202(d)(1) for readability and clarity. TDI deleted “screening criteria” and added “review criteria” in §12.202(c)(1). Proposed §12.202(c)(1) referred to the term “screening criteria” to describe the criteria used in the IRO’s review process. However, screening criteria applies more appropriately to the utilization review process than the independent review process, while review criteria is more reflective of the independent review process. TDI deleted "prior to" and "being" and added "before" and "is" in §12.202(g)(4) to conform to current agency writing style.

TDI moved language about the definition of control from §12.203(b) to §12.5(9) to clarify that the language applies to the entire chapter, and further defines the term “control.” TDI removed the subsection numbering because there are no longer subsections within §12.203. Also in §12.203, TDI replaced “pursuant to” with “under” to conform to current agency writing style. TDI made a nonsubstantive correction to punctuation in §12.203. TDI added "and Relationships" to the title of §12.204 to correct the existing title. TDI deleted “not” and added “no” in §12.206(b) to conform to current agency writing style. TDI deleted “not” and added “no” in §12.206(c) to conform to

current agency writing style. TDI deleted "prior to" and added "before its" in §12.206(d)(11)(F) to conform to current agency writing style. TDI made nonsubstantive corrections to punctuation throughout §12.208. TDI deleted “as” in §12.302(a) to conform to current agency writing style. TDI deleted “a” and “case” and added “cases” in §12.302(c) to conform to current agency writing style. TDI deleted "prior to" and added "before" in §12.502(f)(1) to conform to current agency writing style.

2. REASONED JUSTIFICATION. The amendments and new section are necessary to implement HB 2645, 83rd Legislature, Regular Session (2013), which amended 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. In addition, TDI has determined that other amendments are necessary to enforce Insurance Code Chapter 4202. The entire adoption order is part of the reasoned justification for the amendments and new section.

Insurance Code §4202.002, concerning adoption of standards for IROs, requires the commissioner to adopt standards and rules for the certification, selection, and operation of IROs that perform independent reviews described by Insurance Code Chapter 4201, Subchapter I; and for the suspension and revocation of the certificate of registration issued to IROs. Insurance Code §4202.002(c) 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 amends Insurance Code §4202.002, in part, to require an IRO to maintain a physical address and a mailing address in this state, to 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 satisfied. Amendments to §12.103(13)(A) provide that an IRO must locate and maintain its primary office at the physical address in this state as noted on its application. Amendments to §12.103(13)(A) further require, as a condition of holding a certificate of registration to conduct the business of independent review in this state, that the physical address of the IRO's primary office be maintained in this state.

New §12.5(30) defines "physical address." The existing definition of "primary office" is redesignated in §12.5(32) and adds the requirement that an IRO "maintain its physical address in Texas." These amendments are necessary to implement Insurance Code §4202.002(c), which requires an IRO to maintain its 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 the IRO to release certain information to TDI.

HB 2645 adds Insurance Code §4202.002(f), which, in part requires the commissioner to adopt standards that require that the IRO's primary office is equipped with a computer system capable of processing requests for independent review, that all

records are maintained electronically, that records are made available to TDI on request, and that independent review offices located in residences are located in a room set aside for business purposes to ensure confidentiality of medical records. Amendments to §12.103(13) add a new subparagraph (B) to require an applicant for an initial or renewal certificate of registration 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. Amendments to §12.103(13)(D) require that if the IRO's primary office is in a residence, dedicated space is set aside for business purposes.

HB 2645 amends Insurance Code §4202.003, which requires each IRO to make the IRO's determination for a life-threatening condition, as defined by Insurance Code §4201.002, no 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 by the eighth day after the date the IRO receives the request that the determination be made.

HB 2645 amends Insurance Code §4202.004, which requires a description of any relationship the applicant or the named individual has with specified entities. It also requires the IRO application form to include information about an applicant's procedures for verifying physician and provider credentials, including the computer processes, electronic databases, and records used, if any, 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 include a description of the applicant's use of communications, records, and computer processes to manage the independent review process. Insurance Code §4202.004 also 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 a certificate of registration. HB 2645 amends Insurance Code §4202.004(g), which requires that the certification be renewed biennially.

HB 2645 amends Insurance Code §4202.005(c), which requires that information about a material change be submitted on a form adopted by the commissioner no later than the 30th day after the date the material change occurs. If the material change is a relocation, §4202.005(c) requires the IRO to inform TDI that the new location is available for inspection by TDI before the date of the relocation, and that an officer of the IRO must attend the inspection on TDI's request. Amendments to §12.5(22) define "IRO application form" to include that the IRO application form must be used to report a material change to TDI. Amendments to §12.102(a) require an IRO to report a material change in an IRO application form by submitting the IRO application form to TDI.

In compliance with new Insurance Code §4202.011, the commissioner appointed an IRO advisory group on July 31, 2014, composed of members as required by Insurance Code §4202.011(a).

TDI has also determined that other amendments are necessary to 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 that the procedures maintain the confidentiality of medical records transmitted to an IRO.

TDI adopts amendments throughout the rule text to correct grammar and punctuation, and to make other nonsubstantive changes to update and conform rule text to the current agency writing style.

TDI posted a concept draft of these rules to its website and held a public stakeholder meeting on November 20, 2013; posted to its website an informal draft of the rules on August 5, 2014; and held a public hearing on the proposed rules on December 15, 2014, under Docket Number 2776. In response to both written comments and comments made at the hearing, TDI made several changes to the proposal, but none of the changes made to the proposed text or form in this adoption materially alter issues raised in the proposal, introduce new subject matter, or affect persons other than those previously on notice.

Section §12.1. Statutory Basis. Section 12.1 changes the existing provisions relating to the statutory basis for the rules in Subchapters A through F to reflect that the adopted rule amendments incorporate the most recent amendments to Insurance Code

Chapter 4202. TDI adopts nonsubstantive amendments to §12.1 to conform to current agency writing style.

Section §12.3. Effects of Chapter. TDI adopts nonsubstantive amendments to §12.3 to conform to current agency writing style.

Section §12.4. Applicability. Section 12.4(b) specifies the applicability of Insurance Code Chapter 4202 to independent review requests filed with TDI before the effective date of the rules. The effective date of July 7, 2015, in §12.4(b) gives IROs time to comply with the amendments and new sections in 28 TAC Chapter 12, and allows time for IROs to complete any remaining reviews assigned to them under the current rules. TDI also adopts nonsubstantive amendments to §12.4 to conform to current agency writing style.

Section 12.5. Definitions. New §12.5(4) adds the definition for "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. This amendment establishes the standardized form for submitting biographical information as required under Insurance Code §4202.004(4).

New §12.5(9) adds the definition of "control." This new definition is necessary to clarify how an IRO may comply with 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 "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 determining whether control exists under §12.203.

Insurance Code §4202.002(a)(1) 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. TDI defined this new term based on its rulemaking authority under Insurance Code §4202.002(a)(1).

New §12.5(22) adds the definition of "IRO application form." The definition is necessary to clarify the form to use to apply for a certificate of registration as an IRO in Texas, for renewal of a certificate of registration, and for reporting a material change to an IRO application for a certificate of registration previously submitted to TDI. Insurance Code §4202.004 requires an organization to submit an application in the form required by the commissioner. This definition also 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 no 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(13)(A), which implements the requirements in Insurance Code §4202.002(c)(2)(A)(i) and (f). 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 the organization's office is located at a physical address in its application for certification. The requirement in new §12.5(30) that the IRO have personnel reasonably available by telephone at least 40 hours per week during normal business hours is an existing requirement in existing §12.207(a).

Amendments to the definition of "primary office" in §12.5(32) delete "based upon the totality of the business activities related to independent review performed under this chapter" and add "maintains its physical address in Texas" to implement the requirements in Insurance Code §4202.002(c)(2)(A)(i) and (f). Insurance Code §4202.002(c) requires the commissioner to adopt standards and rules that require an IRO to maintain a physical address in this state. Insurance Code §4202.002(f) 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. TDI clarifies that the primary office cannot be virtual and must be 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 are necessary for TDI staff to conduct on-site examinations that include an examination of the IRO's records as part of its ongoing oversight requirement under Insurance Code §4202.007, and to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

TDI also adopts nonsubstantive amendments to §12.5 to conform to current agency writing style.

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

Section 12.101. Certificate of Registration for Independent Review. Amendments to §12.101 change the heading of the section from "Where to File Application" to "Certificate of Registration for Independent Review" to more accurately reflect the content of the section. TDI also adopts nonsubstantive amendments to §12.101 to conform to current agency writing style.

Section §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). Amendments to §12.102(a) also instruct applicants to use the IRO application form to report a material change to a certificate of registration and require IRO applicants to use the IRO application form prescribed by TDI. These amendments are necessary to implement Insurance Code §4202.005(c), which requires that information about a material change be submitted on a form adopted by the commissioner no later than the 30th day after the date the material change occurs. Insurance Code §4202.005(c) also provides that if the material change is a relocation of the IRO, the IRO must inform TDI that the location is available for inspection by TDI before the date of the relocation, and an IRO officer must attend

the inspection on TDI's request. Amendments to §12.102(c) are necessary to provide the correct Internet and mailing addresses from which an applicant may obtain the form.

TDI also adopts nonsubstantive amendments to §12.102 to conform to current agency writing style.

Section §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 of a certificate of registration. Amendments to §12.103 also delete the reference to Form No. LHL006 to conform to adopted amendments to §12.102.

Amendments to §12.103(1)(C) replace "an authorized representative" with "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 existing §12.201(3). The requirement that a medical director sign the certification ensures that an appropriately qualified individual approves criteria for a higher quality of review. These amendments are necessary to implement Insurance Code §4202.002(b)(3) and (4), which require 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. They are also necessary to implement Insurance Code §4202.007, which requires TDI to maintain oversight of

IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

Amendments to §12.103(1)(D) delete “§12.105(d)” and add “§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). As in the paragraph above, new §12.103(1)(E) is also necessary to implement Insurance Code §4202.002(b)(3) and (4), and §4202.007.

Amendments to §12.103(3) require an officer, director, or owner of the IRO to certify compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12, instead of only an authorized representative. The officer, director, or owner of the IRO must also certify that any party that performs an IRO function through contracts and subcontracts will comply with Insurance Code Chapter 4202 and 28 TAC Chapter 12. The certification must also state that the IRO retains responsibility to ensure 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. As outlined in paragraphs above, these amendments are also necessary to implement Insurance Code §4202.002(b)(3) and (4), and §4202.007.

Amendments to §12.103(4) replace “credentialing” with “their credentials” for clarity and delete “relating to Personnel and Credentialing” to conform to agency writing style. New §12.103(4)(A) and (B) require an IRO applicant to include in the original

application for a certificate of registration 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), which require the IRO application form to include a description of the procedures used by the applicant to verify physician and provider credentials, including the computer processes, electronic databases, and records used, if any, 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. This amendment is necessary to implement Insurance Code §4202.004(a)(8), which requires 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, substantially similar to, or stricter requirements than TDI's certificate of registration in the IRO application form. Section 12.103(7) provides that TDI will maintain evidence of accreditation on file for the applicant, and allows the applicant to request expedited approval of the application for a certificate of registration based on the evidence of accreditation. These amendments are necessary to implement

Insurance Code §4202.004(b), (e) and (f), which establish requirements for 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 the same, substantially similar to, or stricter requirements than TDI's requirements for accreditation. Insurance Code §4202.004(e), in part, requires that an IRO that applies for a certificate of registration to review health care services that is accredited by an organization described Insurance Code §4202.004(b) provide TDI with evidence of the accreditation. Insurance Code §4202.004(e) requires the commissioner to consider the evidence if the accrediting organization publishes and makes available to the commissioner the accrediting organization'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 amended Insurance Code §4202.004(f), in part, to authorize a certified IRO that becomes accredited by certain organizations to provide evidence of that accreditation to TDI and requires that evidence be maintained in TDI's file related to the IRO's certification.

Amendments to redesignated §12.103(8)(A) require the applicant to submit written evidence that the applicant is incorporated in this state, which may include a copy of the Certificate of Formation from the Secretary of State. These amendments are necessary to implement Insurance Code §4202.002(c)(2)(A)(ii), which requires 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, such

as bylaws, because TDI has included more specific requirements about the information necessary for the commissioner to determine whether an applicant is qualified to obtain a certificate of registration as an IRO in amended §12.103.

Amendments to §12.103(8)(B) require the applicant to submit the address and Federal Employer Identification Number (EIN) for each stockholder or owner of more than 5 percent of the applicant's stock or options if the applicant is publicly held. These amendments are necessary under Insurance Code §4202.002, §4202.004, §4202.005, and §4202.007 for TDI staff reviewing IRO applications for certificates of registration, renewals of certificates of registration, and reports of material changes to quickly and efficiently verify the identification information submitted by the applicant in the IRO application form. TDI recognizes that IROs and IRO applicants benefit from a more efficient process.

Amendments to §12.103(8)(D) clarify the contents of the chart of contractual arrangements to include contracts between the applicant and any persons and all subcontracts with other persons to perform any business or daily functions of an IRO. 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 IRO functions, 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) and §4202.007, ensuring that the IRO is responsible 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 also implement Insurance Code §4202.002(a) and are necessary for TDI staff reviewing IRO applications for certificates of registration to quickly and efficiently verify the identification information submitted by the applicant in the IRO application form. TDI recognizes that IROs and IRO applicants benefit from a more efficient process.

Amendments to redesignated §12.103(11) change "Form No. FIN311 (Biographical Affidavit)" to "biographical affidavit" to conform to new §12.5(4). New §12.103(11)(A) requires the applicant to submit fingerprints for each director, officer, executive, owner, or shareholder of the applicant. These amendments are necessary to implement Insurance Code §4202.004(d), which, in part, requires 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 of more than 5 percent of any of the applicant's stock or options, 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, by obtaining information made available to TDI by the DPS, the FBI, and any other criminal justice agency under Government Code Chapter 411. Additionally, 28 TAC §1.501(b)(1)(B) authorizes TDI 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(a) applies to applicants for certificates of 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 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 applicant." These amendments are necessary to implement Insurance Code §4202.004(d).

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), 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. The information required in the sworn statement in amendments to §12.103(13)(A) - (D) is necessary to implement Insurance Code §4202.002(f), which requires the commissioner to adopt standards requiring that: (i) on application for certification, an officer of the IRO attest that the office is located at a physical address; (ii) 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; (iii) all records be maintained electronically and made available to TDI on request; and (iv) 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. This amendment is necessary to implement Insurance Code §4202.002(e), which requires that the standards to ensure the confidentiality of medical records transmitted to an IRO under Insurance Code §4202.002(b)(2) require IROs and utilization review agents (URAs) 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.)(HIPAA) and the regulations and standards adopted under that Act.

TDI also adopts nonsubstantive amendments to §12.103 to conform to current agency writing style.

Section 12.104. Review of Original Application. TDI changed the title of the section from “Review of Application” to “Review of Original Application” to reflect that the content of the section is for review of an original application. New §12.104(1) and §12.104(2)(a) - (c) delete the current 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 URAs in 28 TAC §19.1704(e) and (f), and §19.2004(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 certificates of registration as IROs should be consistent with the process for review of applications for certification or registration of URAs. This change streamlines 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 certificate of registration within 60 days of receipt of a complete original application. This section also provides an applicant the right to waive the 60-day time limit.

New §12.104(2)(A) provides that TDI will send the applicant written notice of any omissions or deficiencies in the original 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 by providing TDI with necessary information more quickly. These amendments 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. They are also necessary to implement Insurance Code §4202.007, which requires TDI to maintain oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12. New

§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 within the time frame provided will result in the application being closed as incomplete and provides that the application fee is not refundable. This amendment is adopted 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, and the requirement in Insurance Code §4202.007 for TDI to maintain oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

TDI also adopts nonsubstantive amendments to §12.104 to conform to current agency writing style.

Section 12.105. Revisions During Review Process. Amendments to §12.202(b) include renumbering subsections. Amendments to §12.105 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 also correct the mailing address where applicants send revisions to TDI. Amendments to redesignated §12.105(b) make a conforming change to delete the requirement that revisions to bylaws be accompanied by a notarized certification

because the requirement to submit bylaws in existing §12.103(8)(A) is also adopted for deletion. Amendments to redesignated §12.105(b) also delete "to be," "all copies of," and the quotes around "red-lined" to conform to current agency writing style. Additionally, amendments to redesignated §12.105(b) delete "or otherwise clearly designated" after "red-lined" to ensure that all revisions submitted to TDI are uniform and easily understood. Amendments to §12.105(d) - (f) delete the requirements for an applicant to report material changes to the application because that information is in new §12.111.

TDI also adopts nonsubstantive amendments to §12.105 to conform to current agency writing style.

Section 12.106. Examinations. TDI adopts an amendment to this section's title from "Qualifying Examinations" to "Examinations" to reflect that this section applies to all IRO examinations. Amendments to §12.106 include reformatting to add subsections. New §12.106(a) also clarifies that the examination will be at the applicant's primary office and is 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. Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

New §12.106(c) deletes "Documents that support the application for the certificate of registration of renewal of the certificate of registration" and adds "The following documents." New §12.106(c)(1)-(8) are documents that an IRO must make available for review during the examinations. 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 Insurance Code §4202.007 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.

TDI also adopts nonsubstantive amendments to §12.106 to conform to current agency writing style.

Section 12.107. Withdrawal of an Original Application Before Granting a Certificate of Registration and Subsequent Renewal Applications. Amendments to §12.107 revise the section title to more accurately reflect the content of the section. TDI also adopts nonsubstantive amendments to §12.107 to conform to current agency writing style.

Section 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. 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 adopted amended §12.102. TDI

adopts amendments to §12.108(b) and the deletion of sections (e) - (g) to remove the requirements about reporting material changes because those requirements are adopted 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 will be unnecessary because TDI will already have this information from either the original application for a certificate of registration or the IRO reporting it as a material change required under new §12.111.

TDI also adopts nonsubstantive amendments to §12.108 to conform to current agency writing style.

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

Adopted §12.110. Effect of Sale or Transfer of Ownership of an Independent Review Organization. Amendments to §12.110 replace existing requirements for the sale of an IRO and the prohibition on transferring an IRO with requirements for the sale or transfer of ownership of an IRO to implement Insurance Code §4202.002(c)(2)(C), as amended. New §12.110(a) requires 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. New §12.110(a)(1) requires the IRO to submit the name of the purchaser and a complete set of fingerprints for each officer, owner, and shareholder of the purchaser. New §12.110(b) provides that TDI will send the IRO written confirmation that the requirements under Insurance Code Chapter 4202

and 28 TAC Chapter 12 have been satisfied before the sale can be completed. These sections are necessary to implement amendments to Insurance Code §4202.002(c)(2)(C), which require an IRO to: (i) notify TDI of an agreement to sell the IRO or shares in the IRO; (ii) no 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 of more than 5 percent of the IRO's stock or options, 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 28 TAC Chapter 12 have been satisfied. Amendments to §12.110 also delete existing requirements for sale of an IRO and the prohibition on transferring an IRO to implement Insurance Code §4202.004, as amended.

New §12.110 (a)(2) requires an IRO to notify TDI of any material changes in its notice of intent to sell or transfer ownership. Insurance Code §4202.005(c) requires the IRO to submit information about a material change to TDI no later than the 30th day after the date the material change occurs. In the case of a sale or transfer of ownership of an IRO, TDI has determined that this rule is necessary under TDI's rulemaking authority in Insurance Code §4202.002(a), the requirement under Insurance Code §4202.007 to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12, and for TDI staff to review all changes about an IRO sale or transfer of ownership at the same time for the sake of

efficiency. The amendments to redesignated §12.110(c) add the phrase “the sale or transfer of ownership” for consistency throughout §12.110.

TDI also adopts nonsubstantive amendments to §12.110 to conform to current agency writing style.

Section 12.111. Regulatory Requirements Subsequent to Certificate of Registration. 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), which, in part, requires that information about a material change be submitted on a form adopted by the commissioner no later than the 30th day after the date the material change occurs. Insurance Code §4202.005 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 TDI’s request.

New §12.111(c), an existing requirement that was formerly in deleted §12.108(f), 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), an existing requirement that was formerly in deleted §12.108(g), requires the IRO to notify TDI within 10 days after it

enters into any new contracts under subsection (c), and requires the notification to include a complete explanation of the circumstances.

TDI also adopts nonsubstantive amendments to §12.111 to conform to current agency writing style.

Adopted §12.201. Independent Review Plan. Amendments to §12.201 delete "a physician" and adds "the IRO's medical director" to clarify that the medical director must review and approve the IRO's independent review plan. Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12. These amendments are necessary because TDI has determined that a physician medical director is best qualified 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. These are standards for which the commissioner must adopt rules under Insurance Code §4202.002(b).

TDI adopts nonsubstantive amendments to §12.201 to conform to current agency writing style.

Adopted §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 workers'

compensation 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 provide the commissioner, in addition to the existing 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) include reformatting to add paragraphs. New §12.202(b)(2) deletes language about 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) add "medical director who is a" before "physician," and add "The medical director functions must include, but are not limited to, conducting." New §12.202(c)(1) - (3) describe the functions of the IRO's medical director. These functions include, but are not limited to, the annual review and approval of review 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. This is an existing requirement moved from §12.202(b)(2). New §12.202(d)(1) - (4) lists the minimum types of credentialing and recredentialing information that the IRO must maintain current and that must be available for review by TDI. Amendments to §12.202(d) also delete existing language about 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)(1) - (8) list the required elements of the certification of independence and qualifications of the reviewer.

New §12.202(h) provides that the information required in §12.202 must be available for examination and review by TDI and TDI-DWC personnel on request. New §12.202(i) requires IROs to require providers conducting independent reviews to notify the IROs of any changes in the information in §12.202(d). New §12.202(a)(1), §12.202(a)(2), §12.202(c)(1) - (3), §12.202(d)(1) - (4), and §12.202(g)-(i) and amendments to §12.202(b)(1) and §12.202(c) are necessary to implement Insurance Code §4202.007 and Insurance Code §4202.002(b). Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12. TDI has determined the enhanced personnel and credentialing requirements of amended §12.202 are necessary to ensure the qualifications and independence of each reviewer and the fairness of the procedures used by an IRO in making review determinations, standards for which the commissioner must adopt rules under Insurance Code §4202.002(b).

TDI also adopts nonsubstantive amendments to §12.202 to conform to current agency writing style.

Section §12.203. Conflicts of Interest Prohibited. Amendments to §12.203 delete “is a subsidiary of, or in any way owned or controlled by” and add “has any

ownership interest in or control over the person, or if the person has any ownership interest in or control over a payor" for clarity and to conform to current agency writing style.

Section §12.204. Prohibitions of Certain Activities and Relationships 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). Insurance Code §4202.002(c) requires 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. TDI deletes §12.204(h) because the "December 26, 2010," applicability dates are no longer relevant. Existing §12.204(g) is redesignated as §12.204(h).

TDI also adopts nonsubstantive amendments to §12.204 to conform to current agency writing style.

Section §12.205. Independent Review Organization Contact with and Receipt of Information from Health Care Providers and Patients. Amendments to §12.205(a) delete "preclude" and add "as the initial contract prevent" to clarify an existing requirement. Amendments to §12.205(e) delete "such expense shall be reimbursed by the" and "as expense of independent review" and add "The" and "must

pay these unreimbursed costs to the health care provider" to clarify an existing requirement. TDI also adopts nonsubstantive changes to conform to current agency writing style.

Section §12.206. Notice of Determinations Made by Independent Review Organizations. Amendments to §12.206(c)(1) and new §12.206(c)(2) and (3) require IROs to make a determination on a life-threatening condition within three days after receiving the information necessary to make a determination or, with respect to workers' compensation medical benefits, within eight days after receiving the request to make a determination. These amendments are necessary to implement Insurance Code §4202.003(1), which provides 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 no 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 by the eighth day after the date the IRO receives the request for determination. 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 by 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.

TDI also adopts nonsubstantive amendments to §12.206 to conform to current agency writing style.

Section §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 are necessary to implement Insurance Code §4202.002(a) and (b). They are also necessary for TDI staff to be able to contact the IRO as part of its ongoing oversight of IROs under Insurance Code §4202.007. Moreover, the amendments ensure the IRO is preserving the confidentiality patient records.

TDI also adopts nonsubstantive amendments to §12.207 to conform to current agency writing style.

Section §12.208. Confidentiality. New §12.208(b) prohibits IROs from disclosing patient information protected by HIPPA to implement Insurance Code §4202.002(c)(1)(F). New §12.208(c) adds a reference to HIPAA to implement Insurance Code §4202.002(c)(1)(F). Amendments to redesignated §12.208(h) require IROs to transmit and store records in compliance with HIPAA to implement Insurance Code §4202.002(c)(1)(F). Insurance Code §4202.002(c), in part, requires the commissioner to adopt standards and rules that prohibit publicly disclosing patient information protected by HIPAA 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 HIPAA.

TDI also adopts nonsubstantive amendments to §12.208 to conform to current agency writing style.

Section §12.301. Complaints, Oversight, and Information. TDI adopts nonsubstantive amendments to §12.301 to conform to current agency writing style.

Section §12.302. Administrative Violations. TDI adopts nonsubstantive amendments to §12.302 to conform to current agency writing style.

Section §12.303. Surrender of Certificate of Registration. Amendments to §12.303(a) clarify when an IRO must surrender its certificate of registration. Amendments to §12.303(a) delete “while the organization is under investigation or as part of an agreed order” to implement Insurance Code §4202.002(c)(2)(B) as amended by HB 2645.

Amendments to existing §12.303(b) delete the definition of “investigation” to conform to changes to §4202.002(c)(2)(B), as amended by HB 2645, which deleted the term. Amendments to existing §12.303(c) delete “a certificate of registration that is surrendered under this section is temporarily suspended while the investigation is pending” also to conform to changes to §4202.002(c)(2)(B). Amendments to §12.303 delete existing §12.303(f), which states that §12.4 only applies to IROs licensed on or after December 26, 2010, or IROs with certificates of registration renewed in Texas on or after December 26, 2010, as the applicability of this chapter is addressed in amended §12.4.

TDI also adopts nonsubstantive amendments to §12.303 to conform to current agency writing style.

Section §12.401. Fees. TDI adopts nonsubstantive amendments to §12.401 to conform to agency writing style.

Section §12.402. Classification of Specialty. TDI adopts nonsubstantive amendments to §12.402 to conform to agency writing style.

Section §12.403 Fee Amounts. TDI adopts nonsubstantive amendments to §12.403 to conform to agency writing style.

Section §12.404. Payment of Fees. Amendments to §12.404(c) change the number of days within which URAs 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 URAs or payors to pay IROs. TDI also adopts nonsubstantive amendments to §12.404 to conform to current agency writing style.

Section §12.405. Failure To Pay Invoice. TDI adopts nonsubstantive amendments to §12.405 to conform to agency writing style.

Section §12.406. Application and Renewal of Certificate of Registration 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 an original certificate of registration is necessary because the new fee better reflects the cost to TDI of regulating IROs. The amendment to the fee for the renewal of a certificate of registration is necessary

because the renewal is now every two years instead of every year. TDI clarifies that the net cost of renewal for an IRO will remain the same. TDI clarifies that there is no fee for reporting a material change to a certification as an IRO. These amendments are adopted under TDI's rulemaking authority in Insurance Code §4202.002(a)(1).

TDI also adopts nonsubstantive amendments to §12.406 to conform to current agency writing style.

Section §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 about utilization review.

TDI also adopts nonsubstantive amendments to §12.501 to conform to current agency writing style.

Section §12.502. Random Assignment. TDI adopts nonsubstantive amendments to §12.502(b) to conform to agency writing style.

3. SUMMARY OF COMMENTS AND AGENCY RESPONSE.

General

Comment: Commenters express their support for the proposed amendments.

Agency Response: TDI appreciates the supportive comments.

Comment: A commenter requests that all agency responses in the adopted rules implementing HB 4519 from the December 17, 2010, issue of the *Texas Register* (35 TexReg 11281) be reviewed and that the precedents set in the rulemaking phase of HB 4519 be used in rulemaking for HB 2645.

A commenter states that the proposed rules have an “overly broad” interpretation of HB 2645 and that substantial portions of the proposed sections have no legislative authorization in HB 2645.

Agency Response: TDI declines to make the suggested change. TDI emphasizes that 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. In addition, TDI has determined that other amendments are necessary to enforce Insurance Code Chapter 4202. TDI clarifies that in the December 17, 2010, issue of the *Texas Register*, adopted rules implementing HB 4519 were published (35 TexReg 11281), and reconsideration and application of HB 4519 agency responses would be redundant.

Comment: A commenter requests the commissioner change the deadline for the submission of written comments on the proposed rules and delay the rule proposal public hearing for 30 days. The commenter states that IROs do not have full-time regulatory and advisory attorneys to prepare comments on new rules to determine constitutional issues such as legislative authority. The only option for IROs would be to retain law firms. Small IROs have had no surplus earnings to retain an attorney

because average caseload was down to four per month in 2014. The commenter states that executives of the IROs prepare the comments and need more time. The commenter states that legislators who managed the passing of HB2645 should have additional time to review the proposed new rules to determine whether the rules faithfully implement the legislation that passed by overwhelming majorities in both houses and that was approved by the office of the governor. The commenter further explains that TDI has allowed IROs to comment on two draft proposals before publication of the proposed rules, but that the comments many submitted have not led to dialogue or discussion, and the same rules that were proposed will now be adopted.

Agency Response: TDI declines to provide additional time for submission of comments because TDI provided a reasonable opportunity for all interested persons to submit data, views, or arguments, orally and in writing as required under Government Code §2001.029(a). TDI provided many opportunities for public comment, including a public stakeholder hearing, two advisory group forums, a public hearing on the rule proposal with oral testimony, and both a concept draft and proposed rule comment period.

Comment: A commenter expresses concern that a currently filed bill will jeopardize confidentiality of the IRO panels of reviewers. The commenter states that IROs will no longer be independent if the reviewers' identities are known.

Agency Response: TDI asserts that proposed legislation is outside the scope of the proposed IRO rules.

Section 12.4 Applicability

Comment: A commenter recommends changing the applicability date in one of two ways: (i) at the time of the renewal application in the first renewal period after the publication of the adoption, or (ii) 120 days after the publication of the adoption. The commenter states that at least 120 days may be required to comply with the provisions of the new rules that require IROs to develop software to manage IRO processes, including a system for credentialing verification. The commenter states that while some IROs have software, others do not, and software experts tell the commenter that it may take as long as 180 days to develop and test the new software. The commenter states that it may take IROs a considerable amount of time to contract with medical directors, and with reviewers whose contracts must be changed to disclose that another physician without the same specialization of the reviewer will be auditing their work product.

Agency Response: TDI agrees to change the effective date of the rule, but disagrees with the commenter's suggested change. As explained in the reasoned justification, TDI has determined that the effective date of the adopted rules, which gives stakeholders until July 7, 2015, is sufficient. Based on this effective date, TDI also clarifies that existing IROs have an obligation to update their applications, but their submission of updated information does not change their existing renewal date. TDI asserts that IROs that have been granted a renewal of a certificate of registration before the effective date of this rule must report any material change, which will include new

requirements of §12.103, no later than the 30th day after the date on which the change takes effect under Insurance Code §4202.005(c).

TDI deleted the phrase “applications for a certificate of registration as an IRO, and for a renewal of a certificate of registration as an IRO” in adopted §12.4 to clarify that IROs must comply with the adopted amendments on the effective date of the rule. However, all independent reviews filed with TDI before the effective date of the rule are subject to the rules in effect at the time the independent review was filed with TDI.

TDI clarifies that amended §12.103(4)(A) and (B) does not require IROs to develop software to manage IRO processes. But amended §12.103(4)(A)and (B) does require an IRO to include in its original application the 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, if any, and the credentialing software used by the applicant for managing the processes, databases, and records. An extension of the effective date is not necessary for an IRO to develop and test the new software, because an IRO is not required to purchase new software under the proposed rules.

TDI clarifies that the new and amended rules neither require the IRO to change its contracts with reviewers nor require an IRO to disclose to reviewers that the medical director will perform quality assurance audits.

Section 12.5. Definitions

Comment: A commenter states the definition of “adverse determination” should be amended to highlight that a determination that a health care service is experimental or investigational is not an adverse determination for purposes of health care provided under workers’ compensation insurance. Section 12.5(1) should be amended to be consistent with the definition of adverse determination for utilization review in §19.2003(b)(1) and state specifically that a determination that a health care service is experimental or investigational is not an adverse determination for purposes of health care provided under workers’ compensation insurance. The commenter recommends that the definition of “adverse determination” include the sentence, “For purposes of workers’ compensation, a determination that health care services are experimental or investigational does not constitute an adverse determination.” The commenter states that the definition of “independent review” in amended §12.5(19) should be modified by removing the language after adverse determination. The commenter states this would permit the same definition of the phrase for both workers’ compensation and group health, without continuing the misstatement that a determination that proposed health care is experimental or investigational is a basis for denial in workers’ compensation. The commenter states the changes to both §12.5(1) and §12.5(19) provide precision and clarity as to the meaning of the rules.

Agency Response: TDI declines to make the suggested change. TDI did not propose amendments to the existing definition of “adverse determination” because existing §12.6(b), in part, provides that IROs and personnel conducting independent reviews must comply with Labor Code Title 5 and applicable TDI-DWC rules. For workers’

compensation, in the event of a conflict between 28 TAC Chapter 12 and the Labor Code, the Labor Code controls. It is TDI's and TDI-DWC's position that, based on Labor Code §408.021, an injured employee under both network and nonnetwork coverage is entitled to all medically necessary health care services, including experimental and investigational health care services. Labor Code §408.021 entitles an injured employee, under both network and nonnetwork coverage, to health care reasonably required by the nature of the injury as and when needed.

Additionally, under §12.206(d)(15), the IRO's review outcome in the notice of determination must clearly state whether 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.

Comment: A commenter welcomes the replacement of the term "stored" with "maintained and accessible" in proposed §12.5(32) because most micro businesses, and businesses in general in the current technological environment, store their records in secure remote servers, accessible from their office computers. These records are "maintained and accessible" and managed by the computer in the office of the business. This contrasts with the past technological environment where business records were stored in file cabinets in physical offices.

Commenters also state that a short inspection of the computer system at the office of an IRO would allow TDI to verify both that an IRO has a physical office in the state and that the required records are "maintained and accessible" from the IRO's

computer. A commenter states that the same records could be accessed by IRO staff at a computer at the TDI offices, which would allow TDI to hold examinations in a government office rather than in the home offices of small, micro businesses.

Agency Response: TDI appreciates the supportive comment but does not agree that TDI can access the IRO's computer from the TDI offices. Remotely accessing the IRO's records would require TDI to expend additional resources obtaining a system capable of such access and potentially jeopardize both the IRO's and TDI's security as well as patients' and reviewers' confidentiality.

In addition, TDI does not agree with the commenter's recommendation that TDI could hold examinations in TDI's offices. Existing §12.106(c) requires that documents that support the application for certificate of registration or renewal must be available for inspection at the primary office of the IRO. In addition to examining records, TDI staff must go on-site to determine continuing compliance with Insurance Code Chapter 4202. Under amended §12.106(c), TDI specifies that documents must be available for review during an examination at the IRO's primary office located in Texas, including information required in the original application for a certificate of registration. TDI will conduct an on-site examination at the applicant's primary office to ensure compliance with TDI's rules, including amended §12.106, §12.208, and §12.103(13), existing §12.204(c), and in the case of an office located in a residence, verifying that the office is located in a room set aside for IRO business.

Section 12.103. Information Required in Original Application for Certificate of Registration.

Comment: A commenter recommends clarifying in §12.103(1)(B) that the summary of review criteria and review procedures that will be used to determine the experimental and investigational nature of health care will have no application for IROs performing review of health care provided in workers' compensation. The commenter suggests adding "provided outside of workers' compensation" to the end of existing §12.103(1)(B).

Agency Response: TDI declines to make the suggested change. TDI clarifies that existing §12.6(b), in part, provides that IROs and personnel conducting independent reviews for workers' compensation must comply with Labor Code Title 5 and applicable TDI-DWC rules. In the event of a conflict between 28 TAC Chapter 12 and the Labor Code, the Labor Code controls. It is TDI's and TDI-DWC's position that based on Labor Code §408.021, an injured employee under both network and nonnetwork coverage is entitled to all medically necessary health care services, including experimental and investigational health care services. Labor Code §408.021 entitles an injured employee, under both network and nonnetwork coverage, to health care reasonably required by the nature of the injury as and when needed. Under §12.206(d)(15), the IRO's review outcome in the notice of determination must clearly state whether 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.

Comment: A commenter that is an accreditation board asks TDI to state whether its accreditation standards for IROs are substantially similar to TDI's requirements.

Agency Response: TDI will consider an organization's accreditation standards at the time an IRO applicant submits an application for or renewal of a certificate of registration.

Comment: A commenter requests that new §12.103(8)(A) state "the applicant shall submit written evidence in the form of a copy of the Certificate of Formation issued by the Texas Secretary of State, and nothing in this rule shall be taken to mean that the applicant must submit any additional 'letter' or other documentation from the secretary of state."

Agency Response: TDI agrees to amend §12.103, but disagrees with the suggested language. TDI deleted the phrase "a letter from the Texas Secretary of State" and added the phrase "a copy of the Certificate of Formation from the Texas Secretary of State" in §12.103(8) to reflect the formation and existence requirements of Business Organizations Code §3.001.

Comment: A commenter disagrees with TDI's proposed deletion of existing §12.103(8)(A), requiring an IRO to submit documentary evidence including the applicant's bylaws, rules, and regulations in the IRO application. The commenter requests that §12.103(8)(A) require an IRO to provide:

(A) Written evidence that the applicant is doing business in this state in accordance with the Business Organizations Code, which may include:

(i) a letter from the Secretary of State indicating the entity has filed the appropriate information to conduct business in this state; and

(ii) 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.

Agency Response: TDI declines to make the suggested change. New §12.103(12) requires the IRO applicant to submit to TDI documentation from the comptroller demonstrating the applicant's good standing and the right to transact business in Texas. Insurance Code §4202.002(c)(2)(A)(ii) requires an IRO to be incorporated in this state. TDI deleted the phrase "a letter from the Texas Secretary of State" and added the phrase "a copy of the Certificate of Formation from the Texas Secretary of State" in new §12.103(8)(A) to reflect the formation and existence requirements of Business Organizations Code §3.001. TDI deleted language requiring the applicant to submit documents relating to its internal affairs, such as bylaws, because TDI has included more specific requirements about the information necessary for the commissioner to determine whether an applicant is qualified to obtain a certificate of registration as an IRO in amended §12.103.

Comment: A commenter states that new §12.103(8)(E) has no legislative authorization, is not in HB 2645, and is not in Insurance Code §4200.002(a) or any other section of the Insurance Code. Insurance Code §4200.002(a) requires IROs to submit a list of any contractors, and a list follows of the types of businesses, all of which are in the health care industry. The commenter suggests TDI make it clear that IROs must submit a list of contractors in the medical industry where there might be a conflict of interest, but this is not a demand for lists of contracts for any and all contractors, especially if not in the medical industry or if the contractor is not involved in processing cases and does not have access to medical records.

A commenter requests that TDI continue the same practice that has been in place for over a decade, requiring IROs to submit lists of contractors in the health insurance industry. If the contractor has access to medical records, the contractor must sign a business associate agreement, as per HB 2645. A commenter states that until 2014, IROs were not required to submit either copies of contracts or lists.

Agency Response: TDI declines to make the suggested change. TDI clarifies that Insurance Code Chapter 4202 does not contain a requirement that IROs submit to TDI only a list of health care industry contracts. Insurance Code Chapter 4202 gives the commissioner the authority to adopt standards and rules for the certification, selection, and operation of IROs. Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance. TDI's oversight of IROs includes oversight of contracts and subcontracts with third parties who perform any IRO functions on behalf of the IRO. TDI staff must determine compliance with all

requirements of Insurance Code Chapter 4202, including processing the independent review requests that TDI assigns to the IRO, maintaining confidentiality, and credentialing of reviewers. To do so, TDI staff must be aware of all parties performing IRO functions.

TDI clarifies that new §12.103(8)(E) is necessary to implement Insurance Code §4202.002(a) and Insurance Code §4202.007, to ensure that IROs retain responsibility for compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

Section 12.104. Review of Original Application.

Comment: A commenter states that the existing 30-day time frame for an applicant to correct omissions or deficiencies in the application should be retained unless TDI publishes and makes available to applicants a guide to application for a certificate of registration as an IRO, in which case the proposed 15-day requirement would be sufficient. At one time before HB 4519, TDI published such a guide, but no such guide has been available since 2009. The commenter states that a guide would streamline the application and renewal process, and any audit or examination process. The commenter states that a guide would make TDI's understanding of the IRO process clear, and how to be successful and avoid lengthy disputes with IROs that have been certified as IROs.

Agency Response: TDI declines to make the suggested change. TDI clarifies that the requirement in new §12.104(2)(B) that an applicant correct omissions or deficiencies in the application within 15 days of the date of TDI's latest notice of omissions or

deficiencies only applies to original applications for certificates of registration, and does not apply to renewals, audits, or examinations. TDI determined that 15 days is a sufficient amount of time for applicants to respond to TDI's notice of omissions and deficiencies.

Additionally, new §12.104(2)(B) provides that an applicant may request additional time, not to exceed 30 days, in writing to correct omissions or deficiencies.

TDI is not aware of any guide that TDI published for use by IRO applicants. The current and past application forms (LHL006) include and have included instructions for applicants. TDI has also prepared a Frequently Asked Questions page for IROs, available on TDI's website at www.tdi.texas.gov/hmo/irofaqs.html.

Section 12.106. Examinations.

Comment: A commenter commends TDI for establishing that the commissioner or the commissioner's designee will conduct an on-site examination of the IRO applicant's primary office. The commenter agrees that an on-site examination is the most effective mechanism for ensuring compliance with the requirements to be certified as an IRO.

Agency Response: TDI appreciates the supportive comment.

Comment: A commenter states that HB 2645 does not directly address examinations, either before or after certification, but it does address computer systems required at the office of the IRO, and the required use of electronic records by IRO. A commenter recommended that HB 2645 include a provision that IROs move to computer systems

and electronic systems in the hope that TDI would see how these provisions would streamline the examination and certification process by making a form of eRegulation possible. The commenter states that in TDI's adopted rules in November 2010, implementing HB 4519, TDI declares that on-site examinations of IROs are necessary in order to examine the books and records of the IRO, which at that time were usually in file cabinets at the IROs primary office in Texas. The commenter states that HB 2645 requires IROs to maintain electronic records that are accessible from the computer systems in the IRO's offices.

A commenter states that proposed amended §12.106 was not required by HB 2645 and is not addressed in the Insurance Code. The commenter requests that TDI amend §12.106 to state:

"Prior to Certification: Prior to issuing a Certification, TDI will conduct an onsite 'Inspection' of the executive office of the IRO to verify that the IRO has a physical office, and that it is equipped with a computer system where records are maintained and accessible. In the case of home offices maintained by IROs that are not large enough to accommodate all the staff of the IRO and staff of TDI, 'Examinations' will be held at an office of TDI. At the inspection, an officer of the IRO and a the person who operates the computer of the IRO will be required to be present, and TDI regulators will be given a demonstration of the computer system to demonstrate how it operates and that records of the IRO are accessible from the computer system. At Time of Change of Address: TDI will have the option of conducting an 'inspection' at any time the IRO notifies TDI of

a change of address, and that inspection shall be similar to the one conducted prior to Certification."

A commenter states that according to the proposed sections, all 41 currently certified IROs are small businesses as defined by federal and state law, and as such, government agencies must take this into account in the regulation process. A commenter states that substantial numbers of these small businesses are micro businesses. A commenter states that the offices of almost all IROs are in the homes of the officers of the IROs, and that HB 2645 acknowledges this by stating that IRO offices exist in residences, and that space must be set aside for them. As a practical matter, the IRO offices in residences cannot accommodate over one person, usually the officer of the IRO. In this space, an IRO officer can use his or her computer and usually a cell phone to communicate with staff members, who use computers in their homes, and, if necessary, communicate with URAs and TDI.

A commenter states that between 2010 and 2014, TDI conducted 18 examinations. For some of them, TDI held the examination in an office of TDI. In others, the examinations were held in the offices of attorneys. A commenter states that some of the examinations were required in IRO offices in residences, in which cases the IROs showed the computer systems to TDI regulators, and were required to use the living rooms or kitchens of the residences where IRO offices are located. During the home examinations, TDI regulators often had to leave the meetings to call in to regulators at TDI offices. The commenter states that the letter announcing the examinations demanded that IROs make conference phone systems available for the

exams, and assume liability if TDI officials were harmed during the visits. During those exams that were held at homes, the same questions about operations were addressed as at exams held at TDI offices, and there is no compelling requirement for exams to be held in homes, especially if an “inspection” has already occurred.

A commenter states that there should be a code, and that it should limit the regulated government agency to an inspection at a time before certification and to an inspection in the event the regulated entity changes offices. Commenters state that TDI should conduct examinations before the time of certification at an office of TDI, and that an officer of the IRO as well as a staff member who is a specialist in the computer operations of the IRO be required to be present at the examination. Commenters state all examinations should be held at TDI offices, and not in home offices. By holding the examination at TDI, TDI may have present as many regulators as they may deem necessary. The commenter states that this is simply practical. TDI is set up for examinations. Home offices are not set up for examinations. The commenter states that this is a reasonable accommodation to micro businesses that do not have conference room facilities.

Agency Response: TDI clarifies that new §12.106(c) includes a list of documents that an IRO must make available for review during an on-site examination by TDI. 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. Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

Comment: A commenter states that in some instances an owner of a corporation that is an IRO may want to elect an "officer" of the entity to operate the entity, and in those instances, the elected officer should be present at an examination, but not the owner. In the case of a public company, a commenter asks if TDI interprets this provision to mean that all shareholders, who are in fact "owners" be present at the exam.

Agency Response: TDI declines to delete the requirement that the IRO owner appear at an on-site examination under new §12.106(d). IRO owners are responsible for compliance with all IRO requirements and are responsible for ensuring that officers, employed staff, and contracting parties comply with all requirements.

New §12.106(d) implements Insurance Code §4202.002(a) and is 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. Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12.

Comment: A commenter states that with regard to medical directors, it is not practical to have physicians in active practice present at examinations because they have

patients to care for and operations to perform. The commenter states that at no point in the entire history of exams has a medical director been present, so the safety and health of the people of Texas is not endangered by the medical director not being present. The commenter states that, should TDI examiners have questions that they believe only medical directors can answer, these can be submitted in writing, and answered in writing.

Agency Response: TDI declines to make the suggested change. Insurance Code §4202.002(a) mandates that the commissioner adopt standards and rules for the certification, selection, and operation of IROs to perform independent review and the suspension and revocation of the certification of registration issued to IROs. It is important for the regulation of IROs conducting independent reviews in this state under the adopted rules that the medical director be available for on-site examinations. TDI would incur substantial costs in conducting on-site audits if the necessary records or information were not available. TDI staff must be able to determine, through direct questioning and the immediate production of records, if the medical director is following the criteria and review procedures provided to TDI in the IRO application form under new §12.103(1)(E) for the quality assurance audits of decisions required under new §12.202(c)(2). TDI must be able to determine if there is a material change to review procedures that must be reported to TDI under Insurance Code §4202.005 and new §12.111(a). The medical director must also be present for TDI to determine that the medical director is performing the annual quality assurance audits of at least 25 percent of all assignments required under new §12.202(c)(3). Quality assurance audits are

necessary to ensure that authorized reviewers with the same or similar specialties are being appropriately assigned to cases, as required by Insurance Code §4201.457 and Labor Code §§408.0043 - 408.0045.

TDI notifies the IRO before conducting the on-site examination and coordinates with the IRO to set the examination date and time unless TDI determines that immediate on-site auditing is necessary.

Section 12.108. Renewal of Certificate of Registration

Comment: A commenter requests that TDI revise the definition of "material change" to include "A material change shall include a change in ownership of shares, or of an officer, director, or executive of an IRO, or of the review criteria presented at the time of the certification."

Agency Response: TDI declines to make the suggested change because the suggested definition is overly narrow. New §12.111 requires the IRO to report to TDI any material changes to the information submitted in the IRO application form. TDI clarifies that a change in ownership of shares, a change of an officer, director, or executive of an IRO, and of the review criteria, are material changes that must be reported to TDI, but that list is not exhaustive.

§12.202. Personnel and Credentialing.

Comment: A commenter appreciates TDI's requirement that personnel conducting reviews provide the same or similar specialty health, or workers' compensation health

care, services. The commenter recommends that proposed §12.202 be further clarified by adding the phrase “with same licensure.” The commenter states that only physicians have the requisite education, training, and experience to evaluate other physicians. The commenter recommends that TDI revise §12.202(a)(1) by replacing the phrase “the same or similar specialty health services” with the phrase “health services in the same or similar specialty with same licensure.” The commenter recommends that §12.202(a)(2) be revised by replacing the phrase “the same of similar specialty workers’ compensation health care services” with the phrase “workers’ compensation health care services in the same or similar specialty with same licensure.”

A commenter prefers all physicians conducting independent reviews and all medical directors to be licensed in Texas but acknowledges that Insurance Code §4201.152 provides that in the non-workers’-compensation setting that the physician need only be licensed to practice medicine by a state licensing agency in the United States.

Agency Response: TDI appreciates the supportive comment, but declines to make the suggested change. New §12.202(a)(1) and (2) are necessary to implement Insurance Code §4202.007 and §4202.002(b). Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of IROs to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12. TDI has determined the enhanced personnel and credentialing requirements of amended §12.202 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—all standards for which the commissioner must adopt rules under Insurance Code §4202.002(b).

In addition, Labor Code §413.031(e-2) requires a doctor performing an independent review for health care provided in the workers' compensation system to be licensed to practice in this state.

Comment: A commenter states that the cost section of the proposed rules provides that there is evidence that medical directors make an average of $69 an hour, but it is probable that this is the hourly for full-time medical directors, and micro IROs cannot employ full-time medical directors. The commenter states that the proposed rules do not address how an IRO could write a contract with a physician according to these terms and exactly where the IRO finds revenue for an additional $6900 in costs. The commenter states that the proposed rules ignore the APA's recommendations on fees, and offers no increase in fees. The commenter notes that under Government Code §2006.002(c-1), an agency must consider, 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. The commenter states that for well over a decade, indeed, since the first IRO laws were passed in 1997, TDI has not acted as if it believes that health, safety, and environmental and economic welfare of the people of Texas requires that medical directors of IROs take on the additional duties that regulators now believe they must have. The commenter states that there is no doubt that there would be an "adverse

impact on small businesses," which only have gross revenues of $2,600 per month and could not afford the additional $6900 to pay for a physician auditing existing cases, even if a physician would take the position, which is doubtful. A commenter asks where the $6900 is to come from for the additional duties of medical directors. The argument that an increase would lead to fewer requests by patients for appeals is weak: patients do not pay for independent reviews.

A commenter states that in all of the legislation related to IROs, only the physician preparing the review report has ever been given the authority to audit the work of members of the IRO panel of physicians. This requirement would be extremely expensive, as physicians who agree to serve as medical directors usually do so pro bono.

A commenter states that the proposed rules do not provide a new method for compensating the medical director for new duties, specifically the establishment and oversight of an internal audit. IROs have contracts with their medical directors, and the new published rules would require IROs to change the contracts in a way that would be unacceptable to medical professionals who have the credentials to serve as medical directors.

Agency Response: TDI estimated in the proposed rules that the annual quality assurance audits may take a medical director approximately 80 hours per year to complete. The median hourly rate of $86.58 for a medical director was taken from the Texas Workforce Commission website and the estimated cost of compliance for an IRO per year in the proposed rules was $6926.40.

TDI has complied with Government Code §2006.002, which requires the agency to reduce the adverse economic effects on small and micro businesses if doing so is legal and feasible considering the purpose of the statute under which the rule is to be adopted. TDI prepared an economic impact statement estimating the number of small and micro businesses subject to the proposed rule, projecting the economic impact of the rule on these entities, and describing the alternative methods of achieving the purpose of the proposed rule.

TDI also prepared a regulatory flexibility analysis that included consideration of alternative methods of achieving the purpose of the proposed rule. TDI estimated in the proposal that all of the approximately 41 IROs with certificates of registration in Texas are small or micro businesses. Making the rules inapplicable to such a large number of IROs would effectively negate the provisions and in most cases, the rule would not serve its intended purposes. Requiring such a small number of IROs to comply with the rules would result in an unfair competitive market and unfair loss of income for a few IROs. Additionally, proposed §12.103(8)(E) provides a requirement of what IRO contracts must include. TDI asserts that an IRO must determine the best means of compliance with proposed §12.202(c), including the allocation of costs.

Comment: A commenter states that prior to the proposed rules, regulators were careful to use the word “physician,” and to use the title medical director as seldom as possible. A commenter states that there is no legislation in the history of independent

review where the term “medical director” is used, and there is no provision in the Insurance Code that defines the duties of the medical director.

A commenter states in actual practice, no regulator who monitors or examines IROs has ever required anything but an advisory role for people with the title “medical director” in an IRO—while this issue arose in lengthy compliance examinations of 18 IRO members of AAIRO, at no point did TDI ever insist that a physician with the title medical director have any duties other than advising the CEO of the IRO, upon the request of the CEO.

Agency Response: TDI has rulemaking authority under Insurance Code §4202.002(a)(1), requiring the commissioner to adopt “standards and rules for . . . the certification, selection, and operation of independent review organizations,” to define the functions of the medical director. Existing §12.202(a) already exempts medical directors from the active practice requirement, and existing §12.205(a) addresses medical directors’ ability to contact medical providers and patients. As part of implementing Insurance Code §4202.002(a)(1), IRO medical directors perform annual quality assurance audits of at least 25 percent of all independent review decisions under new §12.202(c)(2) to ensure that IROs meet the existing independent review plan requirements of §12.201. These requirements include using medically acceptable review criteria based on medical and scientific evidence under §12.201(3)(A), and using review criteria that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers under §12.201(3)(B).

New §12.202(a)(1) and (2) implement Insurance Code §4201.457 and Labor Code §§408.0043 - 408.0045, requiring personnel conducting independent reviews to hold an unrestricted license, an administrative license, or otherwise be authorized to provide the same or similar specialty health services or workers' compensation health care services, respectively. The requirement that medical directors perform an annual quality assurance audit of at least 25 percent of all assignments under §12.202(c)(3) is necessary to ensure that authorized reviewers with the same or similar specialties are being appropriately assigned to cases, as required by Insurance Code §4201.457 and Labor Code §§408.0043-408.0045.

Comment: A commenter notes that in the financial world, one must be a certified public accountant to conduct an "audit," and there is no equivalent of a CPA in the medical field. A commenter points to a dictionary definition of the word "audit" as "an official examination and verification of accounts or records . . ." The commenter asks how one physician can "audit" the medical opinion of another physician. By asking a physician to conduct an "audit," this rule is asking the physician to, in effect, provide an opinion that the notice of decision about medical necessity meets the standards of an "official examination," but this is impossible because no such auditing standards exist today.

A commenter states that the proposed rules introduce a fundamental change, one that requires the IROs to employ physicians of any specialty to review and audit the medical opinions of other physicians who are specialists. A commenter asks what the

value would be in a cardiologist medical director, for example, auditing the review report of a neurosurgery or pain medicine specialist.

A commenter states that if the new rules were limited to implementing HB 2645, the current timing would be sufficient, but the new rules introduce provisions that neither HB 2645 nor any prior legislation envisioned. A commenter states that many of the new rules will disrupt the established independent review process in a fundamental way by authorizing a new power for IROs and IRO medical directors, including the power to conduct audits of the decisions of physicians who serve on the medical panels of IROs.

A commenter states that many of the new proposed rules, especially those that require IROs to cause the physicians that serve as their medical directors to conduct an entirely new level of review called audits, have no legislative mandate and that the proposed sections may constitute an unconstitutional assertion.

A commenter states that new rules require the IRO and the IRO's medical director to write additional standards for a "compliance audit" which are not defined in the proposed rules. The commenter states that the proposed rules also require the IRO's medical director to, in effect, take on any duties that TDI might, in the future, proclaim to be the medical director's duties.

A commenter states that these new rules will require dramatic and unprecedented change in the role of the IRO medical director who, in the entire history of IROs, has been a part-time role only and limited to providing defined advisory services to officers of IROs.

Agency Response: TDI emphasizes that the amendments and new section are necessary to implement HB 2645, which amends Insurance Code Chapter 4202, relating to the certification and operation of IROs in Texas. In addition, TDI has determined that other amendments are necessary to enforce Insurance Code Chapter 4202.

Insurance Code §4202.002(a)(1) mandates that the commissioner adopt standards and rules for the certification, selection, and operation of IROs to perform independent review. As part of implementing these requirements, TDI requires each IRO to develop an independent review plan under §12.201 that includes the review criteria used by the IRO in conducting independent review. The requirement that medical directors perform annual quality assurance audits of at least 25 percent of all IRO decisions under new §12.202(c)(2) is necessary to ensure that IROs meet the existing independent review criteria plan requirements of §12.201. These requirements include using medically acceptable review criteria based on medical and scientific evidence under §12.201(3)(A) and using review criteria that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers under §12.201(3)(B). The requirement that medical directors perform an annual quality assurance audit of at least 25 percent of all assignments under new §12.202(c)(3) is necessary to ensure that authorized reviewers with the same or similar specialties are being appropriately assigned to cases, as required by Insurance Code §4201.457 and Labor Code §§408.0043-408.0045.

TDI clarifies that the audits listed in new §12.202(c)(2) and (3) are not "compliance audits" but are "quality assurance audits." TDI clarifies that the quality assurance audits described in §12.202(c) are not examinations and clarifies that audits do not consist of medical directors approving the medical opinions of the physician reviewers. New §12.202(c)(1) and (2) implement Insurance Code §4201.457 and Labor Code §§408.0043-408.0045, requiring personnel conducting independent reviews to hold an unrestricted license, an administrative license, or otherwise be authorized to provide the same or similar specialty health services or workers' compensation health care services, respectively. The requirement that medical directors perform an annual quality assurance audit of at least 25 percent of all assignments under new §12.202(c)(3) is necessary to ensure that authorized reviewers with the same or similar specialties are being appropriately assigned to cases, as required by Insurance Code §4201.457 and Labor Code §§408.0043-408.0045.

TDI also has rulemaking authority under Insurance Code §36.001 and §4202.002(a)(1) to adopt rules to implement Insurance Code Chapter 4202.

Comment: A commenter requests that TDI strike all of the provisions in the proposed rule relating to increasing the duties of the medical director.

Agency Response: TDI declines to make the suggested change.

Comment: A commenter is concerned with the liability of the medical director. The commenter states that, as long as physicians act as advisors to the CEOs of IROs in advisory positions only, there is absolutely no question of legal liability. But once TDI

publishes the name of an IRO and the name of the IRO's medical director, and when the new rules written by TDI regulators are published that state an IRO's medical director is engaged in "auditing," and thus approving the opinions of other physicians, then the possibility of adverse litigation opens for any physician who has agreed to serve as medical director.

A commenter states that the very foundation of the IRO review system, which protects the identity of physicians involved in the independent review process, would be violated by the medical director audits because the name of the medical director would be in the public domain.

Agency Response: TDI clarifies that although amended §12.202(c) requires IROs to provide quality assurance reports to TDI when requested, amended §12.202(c) neither requires IROs to inform involved parties and the public about the audits, nor requires publication of the audit results. The identities of IRO reviewers remain confidential under Insurance Code §4202.009. Under Insurance Code §4202.010, an IRO is not liable for damages arising from the review determination made by the IRO unless an IRO's act or omission is made in bad faith or involves gross negligence.

TDI further clarifies that audits do not consist of medical directors approving the medical opinions of the physician reviewers. Under §12.202(c)(2), the medical director conducts quality assurance audits of independent review decisions to ensure the reviewer complied both the IRO's independent review plan and all requirements under Insurance Code Chapter 4202, 28 TAC Chapter 12, and other applicable statutory or regulatory requirements. Under §12.202(c)(3), the medical director conducts quality

assurance audits of assignments to ensure authorized reviewers with the same or similar specialties are being appropriately assigned to cases, as required by Insurance Code §4201.457 and Labor Code §§408.0043 - 408.0045.

Comment: A commenter states the economic impact and flexibility section of the rule proposal acknowledges the adverse impact. TDI does not give a justification for the conclusion, except that TDI considers it "necessary" for the efficient operation of the regulating IROs.

Commenters state that IROs will not be able to find and contract with physicians who will serve as medical directors under the proposed rules. The commenters state that when IROs seek to renegotiate the contracts with their medical directors to include the functions in the proposed rules, the medical directors will not sign the contracts. The commenters state that was not considered by the proposed rule and could have an adverse impact on patients seeking independent review in the entire state of Texas.

A commenter questions what physician would agree to add 100 hours of audit time, and act as "auditors" of other physicians, according to auditing standards that TDI has not provided. The commenter also questions whether the physicians who are reviewers would agree to a change in their contracts, with the disclosure that the medical directors will be required to audit their work product.

Agency Response: TDI carefully considered the fiscal impact of the rule requirements and provided an analysis with the proposed rule. TDI disagrees that the proposed rules have an adverse impact on patients, and asserts that the rules have positive impacts on

patients. For example, performing the annual quality assurance audits of assignments under new §12.202(c)(3) helps to ensure patient cases are reviewed by appropriate health care providers with the same or similar specialties, as required by Insurance Code §4201.457 and Labor Code §§408.0043 - 408.0045. The requirement that medical directors perform annual quality assurance audits of at least 25 percent of all IRO decisions under new §12.202(c)(2) ensures reviewers are using medically acceptable review criteria based on medical and scientific evidence, as required under existing §12.201(3)(A), and using review criteria that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, and other health care providers, as required under existing §12.201(3)(B).

TDI clarifies that the proposed rules do not require an IRO to disclose to reviewers that the medical director will perform quality assurance audits. The overhead costs will vary for each IRO based on the IRO's business model and expenses, and TDI asserts that an IRO will determine the best means of compliance with proposed §12.202(c)(1) - (3), including allocation of costs.

Comment: A commenter states that it is clear in HB 2645 that the word "director" refers to a person who is a member of the board of directors of a corporation, and not to a physician with the title "medical director." The commenter requests that TDI state clearly that "director" in the Insurance Code and in the Administrative Code refers to a

person who is a member of the board of directors of the IRO and who is not physician with the title medical director.

Agency Response: TDI clarifies that a medical director under amended §12.202(c) may qualify as an officer, director, manager, executive, or supervisor of an IRO under Insurance Code §4202.002(c)(1)(E), as amended by HB 2645, under certain limited circumstances. Specifically, a medical director may qualify as an officer, director, manager, executive, or supervisor of an IRO under Insurance Code §4202.002(c)(1)(E) if the medical director has the right to control the IRO or has similar responsibilities. A medical director performs annual quality assurance audits of decisions and assignments under new §12.202(c)(2) and (3), performs annual review and approval of review criteria under new §12.202(c)(1), certifies that review criteria and review procedures applied in review determinations are established with input from appropriate health care providers and approved by physicians under §12.103(1)(C), and is available during on-site examinations under §12.106(d). TDI clarifies that these functions alone would not rise to the level of controlling the IRO or having similar responsibilities to an officer, director, manager, executive, or supervisor of an IRO under Insurance Code §4202.002(c)(1)(E).

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

Comment: Two commenters recommend deleting “subparagraph (A)” and replacing it with “paragraph (2)” in §12.206(c).

Agency Response: TDI appreciates the comment and has already made the correction, published in the December 19, 2014, issue of the *Texas Register* (39 TexReg 10083).

Comment: A commenter recommends that existing §12.206(d)(12) be amended to require the exact professional specialty of the provider and the IRO reviewer be included in the notice of determination to clearly demonstrate that the specialty match requirement is met.

Agency Response: TDI declines to make the suggested change. Existing §12.206(d) provides a comprehensive list of the data elements that an IRO is required to include in its notification of determination. The list incorporates data elements identified by TDI as necessary to ensure that the review has been performed in compliance with the requirements of 28 TAC Chapter 12.

Insurance Code §4202.009 requires information that reveals the identity of a physician or other individual health care provider who makes a review determination for an IRO to be confidential.

Comment: A commenter states that the phrase “as applicable” in existing §12.206(d)(15) acknowledges the difference that an experimental or investigational treatment has in workers’ compensation, but the commenter would prefer to see a more explicit statement. The commenter recommends that the phrase “in non-workers’-compensation cases” be added to existing §12.206

Agency Response: TDI declines to make the suggested change. TDI did not propose substantive amendments to existing §12.206(d)(15) because existing §12.6(b), in part, provides that IROs and personnel conducting independent reviews must comply with Labor Code Title 5 and applicable TDI-DWC rules. In the event of a conflict between 28 TAC Chapter 12 and the Labor Code, the Labor Code controls. It is TDI's and TDI-DWC's position that based on Labor Code §408.021, an injured employee under both network and nonnetwork coverage is entitled to all medically necessary health care services, including experimental and investigational health care services. Labor Code §408.021 entitles an injured employee, under both network and nonnetwork coverage, to health care reasonably required by the nature of the injury as and when needed.

§12.207. Independent Review Organization Telephone Access.

Comment: A commenter states that proposed §12.207 requires an IRO's phone system to be "dedicated," which is a telephone system intended primarily for use in the IRO business. A commenter states that the new rules appear to envision that a person who works for the IROs will be sitting by this dedicated landline "during normal business hours." A commenter states that neither HB 2645 nor any prior law or code requires such a dedicated landline. The commenter states that in actual practice telephones of any kind, and especially "dedicated" landlines are simply not used by businesses because email is far more effective. A commenter states that a dedicated landline would not improve communications and could decrease the efficiency of the system.

According to commenter, IROs have phone systems that comply with current code, and does not see why installing a landline will improve communications.

A commenter states that electronic phone providers such as Skype link their services to computers by sending an email every time a caller leaves a message. A commenter states that Skype should be sufficient to meet the communications requirements of small or micro business entities such as IROs. The commenter states that use of computers and computer-enabled phone systems such as Skype make it possible to ensure communications, and that all phone messages that are left on Skype are connected to the computer, making it unnecessary for a person to be present at a physical office 40 hours a week and answer phones installed in that office. The commenter states that IROs now receive an average of one case and two calls a week, so it would be entirely unreasonable to have a rule requiring a person to be present in an office 40 hours a week.

The commenter reminds regulators that IROs are small micro or businesses that use computer-assisted phone services, and are not present in their physical offices 40 hours a week.

Agency Response: TDI clarifies that the proposed rules do not require IROs to maintain a “landline.” However, IROs must have a telephone system solely dedicated to its IRO business. In addition, the requirement that IROs have a telephone system as well as appropriate personnel reasonably available by telephone at least 40 hours per week is a requirement under existing §12.207, and all IROs should be in compliance.

§12.208. Confidentiality.

Comment: A commenter states that if a patient believes his or her rights to confidentiality have been violated, there are provisions in the HIPAA federal legislation for reporting a violation to federal authorities, who are experienced in handling violations under this code. Commenters also request that an officer, director, or owner of an IRO seeking to comply with this provision declare and assert to TDI that the IRO works on a best-effort basis to ensure that all its electronic systems comply with HIPAA for handling electronic records. Further, in the event that a patient believes that there has been a HIPAA violation and reports the violation to federal authorities, the IRO will work with federal authorities to address the violation. Commenters state that this clarification is necessary in the event that TDI regulators were to interpret this provision of HB 2645 as a requirement that TDI enforce federal regulations. The commenter states that in practical terms, TDI would refer any patient who asked to the federal authorities charged with enforcing HIPAA violations, and from that point, the IRO would have to attempt to show that HIPAA standards were being enforced.

Agency Response: TDI declines to make the suggested change. HB 2645 amends Insurance Code §4202.002(c) to require compliance with the Health Insurance Portability and Accountability Act of 1996. TDI asserts that an IRO is required to comply with Texas regulations, in addition to the federal requirements involving confidentiality. TDI will continue to investigate any violations of state or federal laws by an IRO to ensure compliance with the requirements to protect confidentiality.

§12.403. Fee Amounts.

Comment: Commenters state that at the July 15, 2010, rule proposal public hearing, TDI staff stated that the decision to not recommend a fee increase at that time was not made lightly, noting that they were aware that fees had not been increased since 1997. At that meeting, TDI staff's justification was that "significant concern from stakeholders that raising the fees would act as a disincentive to enrollees, injured employees, and providers to seek a review on a denied service and would increase the total cost to the system for health care." To date, thousands of cases have gone through the IRO review process. That fact alone seems to alleviate the concerns stated by TDI staff four years ago. It is clear that people continue to seek IRO reviews.

A commenter states that the proposed rules threaten the future of the IRO business in Texas and could lead to the closure of IROs. The commenter states that no profession has the same pay rate today as it did 17 years ago. The commenter states that costs increase and so should compensation. A commenter provides three economic indicators as good alternatives for providing a reasonable fee increase. The first indicator is the Bureau of Labor Statistics consumer price index inflation calculator, which shows that the buying power of $460 in 1997 would equal $680.49 today and the buying power of $650 in 1997 would equal $961.57 today. The second indicator is Social Security Administration's cost-of-living adjustments, which show automatic percentage increases by year, totaling 43.4% since 1997. The third indicator is the Centers for Disease Control and Prevention's National Center for Health Statistics, which tracks medical consumer price index indicators. The commenter explains that the

consumer price index for medical care components shows an increase in the cost of medical care and physician services. The commenter states that comparing the numbers for 2000 to 2012 shows a 66% increase under medical care services and a 42% increase under physician services. The commenter states proposed rule §12.401(b) provides that "fees for independent review must be determined by TDI and shall reflect in general the market value of services rendered." The commenter adds that, given the provided indicators and the rule's specificity to reflecting the market value of services rendered, the fees that IROs are paid should go up. The commenter states the proposed rules place new mandates on an IRO's medical director, who will require increased compensation for the increased work requirements.

A commenter states TDI's website contains a Texas Medical Association (TMA) posting stating that an increase in the IRO fee will discourage applicants for the IRO process. The commenter explains that TMA represents the medical community and an applicant for the IRO process is the doctor or the patient, but the patient must ask for the IRO through his treating doctor. The commenter states there is no inhibiting effect to the potential requesting patient caused by the IRO fee. The commenter states that the inhibiting effect of the current unadjusted fee creates an inhibition on the IRO to recruit and maintain its reviewer panel, many who are members of TMA. The commenter urges TDI to tell TMA that neither the patient nor the requesting health care provider pays the IRO fee. Rather, the carrier or URA pays the IRO fee.

A commenter states that, in the majority of cases, the insurance carrier or its URA pays the IRO fee and not the patient or the treating practitioner. The commenter

explains the patient or practitioner in retrospective workers' compensation cases pays the IRO when the IRO's review upholds the carrier's denial of services. The commenter states between 2013 and 2014, out of 100 cases received by its IRO, only one was a retrospective workers' compensation case and its IRO disagreed with the denial. The commenter questions TMA's concept that this discourages all IRO applications and states if it does, then the system does not work; but the system has worked.

A commenter states that for 10 years, TDI has repeatedly announced that it is reviewing the fees paid to IROs but there is no proposal for a fee increase. The commenter adds that many Texas IROs have difficulty finding reviewers to conduct the work necessary to perform an IRO within existing fee structures. The commenter states that TDI acknowledges the proposed rules will impose new costs on IROs. The commenter asks why TDI did not propose an increase in fees paid to IROs at this time. The commenter states most IROs are micro businesses, with fewer than five employees and only $2600 a month in revenues. Even with a substantial fee increase, the commenter doubts there could be sufficient revenue to pay for the increased duties demanded in the new proposed rules. The commenter states that IROs are requesting a fee increase to cover new regulatory costs and because, for 15 years, there has been no cost-of-business increase. The commenter states that TDI's cost evaluation should be based on surveys of costs of operating IROs, and that physicians should be surveyed to determine if they would work on audits for $69 an hour. The commenter further states that TDI should develop information on how much the computer systems required by HB 2645 will cost. This is relevant to TDI's decision not to increase fees.

A commenter submitted analyses showing that if cost-of-living and cost-of-business increases are considered, costs that the Administrative Procedures Act and all Texas agencies are required to follow, fees would increase to $950. The commenter states that HB 2645 will substantially increase the cost of operating an IRO. The commenter explains computer systems and software custom designed to meet TDI rules and regulations are expensive, perhaps running as much as $20,000, or IROs may incur up to $1,000 a month for the servers that are accessed by the computers in each office. The commenter states HB 2645 now requires that IROs process some cases in less than five days, which is very expensive and requires paying reviewers more. The commenter states with the expansion of the number of specialties now required by TDI, the cost of paying reviewers has increased, and in some case doubled. The commenter refers to analyses and requests that the commissioner or the Inspector General ask TDI department staff experienced in finance to review the costs of these new regulations and to set new fees, or that TDI retain an independent consultant to look at the issue.

A commenter states stakeholders requested a fee increase four years ago. The commenter states that the cost of living has gone up, the cost of postage has nearly doubled, and the cost of gasoline has tripled. The commenter states that the current fee amount restricts IRO's ability to pay reviewers. The commenter adds that reviewers and potential reviewers decline review requests because the fee is not high enough. The commenter states that by not increasing the IRO fee, the whole program is

jeopardized and Texas can become the leader in the demise of IROs, as opposed to 17 years ago, when it was the leader in establishing them.

Agency Response: TDI declines to increase the current fee amounts paid to IROs at this time. TDI requested details at all IRO public meetings on how IRO fees impacted IRO business and why increases were needed. TDI did not receive specific information on the operating costs of IROs to support a change to the current fee structure. TDI asserts that although these rules potentially increase costs, they are nevertheless necessary to implement HB 2645, make other changes necessary for clarity and effective implementation of Insurance Code Chapter 4202, and improve the regulatory framework for IROs. TDI has determined that the benefit of requiring medical directors to review and approve review criteria and perform quality assurance audits of at least 25 percent of all decisions and assignments outweighs the fact that it may be burdensome or add cost.

Existing §12.401(b) provides that fees for independent review must be determined by TDI and should reflect, in general, the market value of services. TDI sought but did not receive specific information about the current market value of performing independent reviews, and determined that the current fee amounts reflect, in general, the current market value of these services when compared to other states. TDI reviewed other states' processes and fee methodologies. The review indicated that Texas charges a higher fee for regular reviews performed by a doctor of medicine or doctor of osteopathy. TDI determined that other states' processes are similar in concept, but no other state was identical to Texas. California contracts with one or

more IROs to conduct a review. California permits the administrative director of an IRO to establish a reasonable, per-case reimbursement schedule to pay costs of IRO reviews and the cost of administrating the IRO system. These costs may vary depending on the type of medical condition under review and other relevant factors. California Labor Code §4610.6(l). In 2014, the cost for a regular review performed by a MD or DO in California was $550.00, and for regular reviews performed by a reviewer other than a MD or DO the cost was $475.00. 8 California Code of Regulations §9792.10.8. Tennessee and North Carolina have external review programs that do not apply to workers' compensation cases. However, these states do have separate appeals processes for workers' compensation cases. For example, Tennessee charges $250 for the utilization review appeal for the administration of the appeals process. Tennessee Code Annotated 50-6-204(j)(5). North Carolina permits independent review organizations to submit proposals for the commissioner to determine if the organization will be selected to conduct external reviews. North Carolina General Statutes 58-50-94. Wisconsin's independent review process permits IROs to establish reasonable fees by submitting fee schedules to the commissioner for approval. 632.835(4)(ap). Wisconsin Statutes. Washington developed a maximum fee schedule for independent reviews in 2006 that IROs are required to use. Revised Code of Washington 43.70.235(8). Similar to Texas IROs, Washington IROs have a fee schedule that remains unchanged. TDI remains diligent in the regulation of IROs and may revisit the fee structure in the future.

TDI clarifies that the commenter is referencing a Workcompcentral article dated August 8, 2014, titled "TDI Posts Informal Draft of Revised IRO Rules" that summarized TMA's comment about TDI's informal draft IRO rules. TDI clarifies that the proposed rules do not expand the number of specialties. However, §12.202(d)(3) provides, in part, that an IRO may obtain verification from an applicable specialty board to comply with the requirement of retaining credentialing and recredentialing information, such as current board certification available for review at TDI's request. TDI complied with Government Code §2001.024(a)(5)(B), which requires TDI to include a note about the probable economic cost to persons required to comply with the rule. TDI clarifies that the computer system costs are a result of legislative enactment of HB 2645 and not a result of the proposal, enforcement, or administration of this adoption. TDI declines to retain a consultant to review the issue of fees paid to IROs for independent review.

Comment: Two commenters state that current IRO fees are more than adequate. The commenters recommend lowering IRO fees. The commenters state that there are 41 IROs approved to operate in Texas and that access to dispute resolution is adequate for the needs of the Texas workers' compensation system. A commenter references the "13th edition of Workers Compensation Research Institute (WCRI), Monitoring the Impact of Reforms and Recession in Texas: CompScope Benchmarks" and states that unusually high fees in Texas for independent review contribute to the high medical cost containment expenses and high disparity cost compared to other states. A commenter states that raising the current IRO fee would unnecessarily increase workers'

compensation costs for Texas employers while departing from recent legislative and regulatory progress in curbing unnecessary costs.

A commenter states in nonnetwork workers' compensation retrospective medical necessity disputes, it is the party requesting the independent review that must initially pay the IRO fees. The commenter explains if the requesting party prevails at the IRO level, the responding party must reimburse the IRO payment. The commenter explains that in situations where either the health care provider or facility requests the independent review but does not prevail, the health care provider or facility is responsible for the IRO fees. The commenter adds that increasing the IRO reimbursement rates could adversely impact health care providers and facilities without helping the injured worker or the Texas employer. A commenter states that increased fees would have a significant impact on workers' compensation insurance carriers who are required to pay the IRO fee, win or lose, when the dispute involves health care rendered within a health care network or health care that requires preauthorization.

A commenter includes an analysis of the cost impact increased fees would have using present day tier fee values of $961.57 and $680.49, respectively, as submitted by IROs at the rule proposal public hearing, and IRO case review data obtained from a TDI through an open records request. The commenter states that, depending on the number of IRO case reviews completed, the cost impact would range from an increase of $1,004,323.34 to $631,158.49 per calendar year for tier one and tier two fees. The commenter referred to the rule proposal public hearing on December 15, 2014, and states that in a nonnetwork workers' compensation retrospective case, to say that

doctors and health care providers would not be impacted by an increase in IRO fees is contrary to the IRO outcome numbers in records produced by TDI from the open records request.

The commenter states that, according to the data obtained from TDI by an open records request, doctors and health care providers were the nonprevailing party in the majority of nonnetwork workers' compensation retrospective review disputes. The commenter states that in 2012 and 2013 health care providers failed to prevail in 1,445 and 938 disputes, respectively. The commenter states that if IRO fees are raised to the level IROs referenced in their testimony, doctors, other health care providers, and insurance carriers would pay significantly more for IRO retrospective reviews. The commenter states if doctors and health care providers view an increase in IRO fees as a financial barrier to pursuing medical dispute resolution and do not request an IRO case review, they may stop treating injured employees due to their inability to access an affordable medical dispute resolution process.

Three commenters state the fee for an independent review in California is $195 and the fee for an independent review in Tennessee is $224. A commenter states that California and Tennessee have processes in place similar to Texas' IRO process and both have lower fees than Texas. The commenter states that California uses a process called independent medical review (IMR) to resolve disputes about the medical treatment of injured employees. The commenter states that the Division of Workers' Compensation is required to contract with one or more independent medical review organizations (IMROs) to conduct IMR on its behalf, and the costs of an IMR are paid

by employers. The commenter states that IMRs are based on the nature of the medical treatment dispute and the number of medical professionals needed to resolve the dispute, and are significantly lower than the cost to resolve a dispute through litigation. Two commenters state that California's reimbursement rate for a standard IMR involving nonpharmacy-only claims is $420, while the reimbursement rate for pharmacy-only claims is $390. The commenter states that the fee is calculated as amount charged per utilization review request assignment that potentially has from one to five determinations associated with the request. The average fee charged by utilization review organizations and peer review organizations during 2012 ranged from $99 to a high of $5,110.

The commenter states that Tennessee uses a process called utilization review appeal to resolve disputes about the medical treatment of injured employees. The commenter states that Tennessee contracts with an outside entity, an IRO, to review appeals and issue a decisions about the medical necessity of disputed health care. The commenter states that an employer or insurance carrier pays the $250 utilization appeal fee. The commenter states that the majority of other workers' compensation jurisdictions use one or more processes to resolve medical necessity disputes that may include independent medical examination, a review by the state's workers' compensation regulatory agency, mediation, and administrative hearings to determine appropriateness or medical necessity of treatment. The commenter adds that Wisconsin uses tiebreak medical examinations paid for by the insurance carrier. The commenter adds that Florida uses an administrative hearing review process. The

commenter adds that North Carolina uses an informal dispute resolution and limited intervention process to resolve medical disputes. The commenter states that California, Tennessee, and Texas are the only states that use an IRO process for the resolution of workers' compensation medical necessity disputes. The commenter states that some jurisdictions use an IRO-like process for group health medical necessity disputes.

A commenter states that a new fee of $1,500 for IRO reviews associated with life-threatening medical conditions is unnecessary for Texas workers' compensation claims since preauthorization is not required for health care associated with life-threatening medical conditions.

Agency Response: TDI declines to decrease the current fee amounts paid to IROs at this time. TDI requested details at all IRO public meetings on how IRO fees impacted IRO business and why increases were needed. TDI did not receive specific information on the operating costs of IROs to support a change to the current fee structure. IROs currently charge fee amounts on a two-tier payment system based on specialty classifications. Texas Administrative Code §12.403 provides that tier one fees are $650.00 and tier two fees are $460.00. TDI reviewed other states processes and fee methodologies, and determined that Texas allows a higher fee for regular reviews performed by a doctor of medicine or doctor of osteopathy.

TDI agrees, in part, that other jurisdictions use one or more processes to resolve medical necessity disputes. Some jurisdictions have different processes for workers' compensation and group health medical necessity disputes. As discussed earlier in

responses to the comment requesting fees be increased, TDI determined that other states' processes are similar in concept but no other state was identical to Texas. TDI asserts that there is no statutory requirement that TDI establish a separate fee for life-threatening cases. TDI remains diligent in the regulation of IROs and may revisit the fee structure in the future.

§12.404. Payment of Fees.

Comment: A commenter recommends amending proposed §12.404(a) to clarify that an IRO may not bill the utilization review agent or payor until the notice of determination is transmitted. The commenter states it is common practice for an IRO to send an invoice to a utilization review agent or payor before the independent review is completed or the notice of determination is transmitted. The commenter states that premature billing can result in the issuance of inappropriate payments when a request for independent review is later withdrawn or reassigned. The commenter suggests requiring IROs to bill utilization review agents or payors, as appropriate, directly for fees for independent review on or after the date the notice of determination required by §12.206 of this chapter is transmitted.

Agency Response: TDI declines to make the suggested change. Title 28 TAC §133.308(q) requires the payor to remit payment within 15 days after the receipt of an invoice from an IRO. If the commenter has concerns about premature billing or the issuance of inappropriate payments, the commenter can file a complaint, and TDI will consider whether the IRO has violated the Insurance Code, Labor Code, or TDI-DWC

rules. Further, TDI has general authority to assess administrative penalties and does not need a specific penalty it can assess an IRO for recovery of overpayments made by a carrier or URA.

§12.406. Application and Renewal of Certificate of Registration Fees.

Comment: Two commenters express concern that increasing the fees TDI charges, while also creating more work for IROs at the existing fee amounts, will lead to fewer IROs in Texas. Two commenters express concern that fewer IROs will lead to a rise in health care costs because disputes will be settled in the courtroom and not through the IRO process.

Agency Response: TDI clarifies that proposed §12.406 provides an increase from $800 to $1000 for an IROs original application for a certificate of registration, and that this better reflects TDI's cost of regulating IROs. TDI clarifies that the net cost of renewal for an IRO will remain the same. The change from $200 to $400 in proposed §12.406 was necessary because renewals are every two years instead of every year.

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

For: Texas Occupational Therapy Association; American Insurance Association; and the Insurance Council of Texas.

For with changes: Property Casualty Insurers and Texas Mutual Insurance Company

Neither for nor against, with recommended changes: One individual; Envoy Medical Systems, LP; URAC; the State Office of Risk Management; Texas Medical Association; Medtronic Inc.; and the Office of Injured Employee Counsel.

Against: Two individuals and AAIRO.

5. STATUTORY AUTHORITY. TDI adopts the amendments and new section under Insurance Code §§4202.002, 4202.003, 4202.004, 4202.005, 4202.007, 4202.008, 4202.013, and 36.001. Insurance Code §4202.002(a) provides that the commissioner must 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 non-life-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) provides that the commissioner 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 Government Code Chapter 411. Insurance Code §4202.004(e), in part, requires that an application for certification for review of health care services requires an IRO accredited by an organization described in 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 publishes and makes available to the commissioner the organization's requirements for and methods used in the accreditation process, and authorizes an IRO applicant 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 the 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 about a material change to the IRO on a form adopted by the commissioner no 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 that an officer attend the inspection on TDI's request. Insurance Code §4202.007 requires the commissioner to provide ongoing oversight of the IRO to ensure continued compliance with Insurance Code Chapter 4202 and 28 TAC Chapter 12. 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 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.

6. TEXT.

SUBCHAPTER A. GENERAL PROVISIONS

§12.1. Statutory Basis. This chapter implements Insurance Code Chapter 4202.

§12.3. Effect of Chapter. This chapter governs the performance of appropriate statutory and regulatory functions and is not to be construed as limiting the exercise of statutory authority by the commissioner of 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 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.

(b) This chapter is effective on July 7, 2015. Unless otherwise provided, this chapter applies to all requests for independent review filed with the department on or after July 7, 2015. All independent reviews filed with the department before July 7, 2015, will 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 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) of this paragraph are not available, case-series; or

(D) if subparagraphs (A), (B), and (C) of this paragraph 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) Case Series--An evaluation of a series of patients with a particular outcome, without the use of a control group.

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

(8) Commissioner--The commissioner of 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. 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 under 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.

(10) Department--Texas Department of Insurance.

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

(12) 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) 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) 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 not yet broadly accepted as the prevailing standard of care.

(15) Expert opinion--A belief or an interpretation by a specialist with experience in a specific area about the scientific evidence on a particular service, intervention, or therapy.

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

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

(20) Independent review organization or IRO--An entity that is granted a certificate of registration by the commissioner to conduct independent reviews under the authority of Insurance Code Chapter 4202. An IRO must have the capacity for independent review of all specialty classifications and subspecialties contained in the two-tiered structure of specialty classifications set out in §12.402 of this chapter.

(21) Independent review plan--The review criteria and review procedures.

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

(23) Legal holiday--A holiday:

(A) as provided in Government Code §662.003(a), includes 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.

(24) 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) 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 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 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 Labor Code §408.028 and §413.011, including Chapter 134 of this title and Chapter 137 of this title; or

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

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

(27) 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 Labor Code Title 5.

(28) 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 Insurance Code §4201.054, to persons treated by a health care provider in this state under a policy, plan, or contract.

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

(30) Physical address--Location of the IRO's primary office 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) Physician--A licensed doctor of medicine or a doctor of osteopathy.

(32) Primary office--The place where an IRO maintains its physical address in Texas, and where its books and records about independent reviews assigned by the department are maintained and accessible.

(33) 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) Randomized clinical trial--A controlled, prospective study of patients who 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) Review criteria--The written policies, medical protocols, previous decisions, and guidelines used by the IRO 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) TDI-DWC--The Texas Department of Insurance, Division of Workers' Compensation.

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

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

§12.6. Independent Review of Adverse Determinations of Health Care Provided Under Labor Code Title 5 or Insurance Code Chapter 1305.

(a) Review of the medical necessity or appropriateness of a health care service provided under Labor Code Chapter 408 or Chapter 413 must 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 Labor Code Title 5 or Insurance Code Chapter 1305:

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

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

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

SUBCHAPTER B. CERTIFICATE OF REGISTRATION FOR INDEPENDENT REVIEW ORGANIZATIONS

§12.101. Certificate of Registration for Independent Review. An application for a certificate of registration and for renewal of a certificate of registration as an IRO and associated fees 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.

(a) Applicants must submit the IRO application form for an original application for, renewal of, and reporting a material change in an IRO application form for a certificate of registration as an IRO in this state in the format prescribed by the department.

(b) The commissioner adopts the biographical affidavit by reference to be used as an attachment to the IRO application form.

(c) The forms are available at www.tdi.texas.gov/forms. Applicants may also obtain the forms from the Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104.

§12.103. Information Required in Original Application for Certificate of Registration. The IRO application form requires information that is necessary for the commissioner to determine whether an applicant is qualified for a certificate of registration as an IRO under Insurance Code §4202.004, including:

(1) a summary of the independent review plan that meets the requirements of §12.201 of this chapter, which 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 that the 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 §12.201(3) of this chapter;

(D) procedures ensuring that the information regarding the reviewing physicians and providers is updated under §12.111(a) of this chapter 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 chapter.

(2) copies of policies and procedures that 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;

(3) a certification, signed by an officer, director, or owner of the IRO, that the IRO and any party that performs an IRO function through contracts and subcontracts will comply with 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 and a completed profile for each physician and provider, as described in §12.202 of this chapter that must include:

(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, if any, used to make the verification; and

(B) the credentialing software used by the applicant for managing the processes, databases, and records described in subparagraph (A) of this paragraph;

(5) a description of hours of operation and how the IRO may be contacted after hours and during weekends and holidays, as set out in §12.207 of this chapter;

(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 a certificate of registration. Evidence of accreditation will be maintained in the department's file for the IRO applicant, and the applicant may request expedited approval of the certificate of registration with evidence of accreditation from a nationally recognized accrediting organization;

(8) the organizational information, documents, and all amendments that must include:

(A) written evidence that the applicant is incorporated in this state, which may include a copy of the Certificate of Formation from the Texas Secretary of State;

(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 percent of any stock or options;

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

(D) a chart showing contractual arrangements of the applicant, including all contracts between the applicant 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 applicant. 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 applicant is responsible for ensuring that all contracted and subcontracted functions are performed under Insurance Code Chapter 4202 and this chapter, subject to the applicant's oversight and monitoring;

(iii) a provision that the applicant retains ultimate responsibility for compliance; and

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

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

(10) 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) biographical information about officers, directors, and executives, including information requested in the biographical affidavit as required in §12.102(b) of this chapter:

(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) the applicant must submit the name and biographical information for each director, officer, and executive of the applicant and of any entity listed under paragraph (10) of this section and a description of any relationship the named individual has that represents revenue equal to or greater than 5 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; or

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

(C) 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 percent or more interest;

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

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

(13) for an application for a certificate of registration or renewal of a certificate of registration as an IRO in this state made on or after July 7, 2015, a sworn statement from an officer of the organization that:

(A) the applicant's primary office included on the IRO application form is located and maintained at a physical address in this state. As a condition of holding a certificate of registration to conduct the business of independent review in this

state, an IRO 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) the percentage of the applicant's revenues that are anticipated to be derived from independent reviews conducted; and

(15) 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 certificate of registration. The department will send a certificate of registration to an entity that is granted a certificate of registration. The applicant may waive the time limit described in this paragraph.

(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.

(3) The department will maintain a charter file that will 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.

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 addressed to: Texas Department of Insurance, Mail Code 103-6A, P.O. Box 149104, Austin, Texas 78714-9104. If a page is revised, the revised page submitted by the applicant must contain the changed item or information red-lined.

§12.106. Examinations.

(a) The commissioner may conduct an on-site examination at the applicant's primary office as a requirement of applying for a certificate of registration.

(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 must be available for review during an examination at the primary office of the IRO 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 Before Granting a Certificate of Registration and Subsequent Renewal Applications.

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

(b) On the department's receipt of a request to withdraw an application under this section, the application will 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) Every two years, the commissioner will renew the certificate of registration of each organization that meets the standards as an IRO.

(b) An IRO must apply for renewal of its certificate of registration every two years, no later than the anniversary date of the issuance of the registration. The IRO application form must be used for this purpose. The IRO application form may be obtained from the department's website and from the address listed in §12.102(c) of this chapter. The completed IRO application form, 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.

(c) An IRO may continue to operate under its certificate of registration after a completed application form and renewal fee have been received by the department and until the renewal is finally denied or granted by the department. However, independent reviews will not be assigned to an IRO during the 30 days before the anniversary date of the issuance of the IRO'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 not received before 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 must complete and submit a new application for certificate of registration.

(e) Until the certificate of registration renewal application process is complete or the certificate of registration expires, an IRO must:

(1) continue to perform its duties in compliance with 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 §12.208 of this chapter; and

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

§12.109. Appeal of Denial of Application or Renewal. If an original or renewal application is denied under this chapter, the applicant or registrant may appeal the denial under the provisions of Chapter 1, Subchapter A of this title and 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, no later than 60 days before the date of the sale or transfer of ownership. The IRO must 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 purchaser'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 address, 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.

(c) An IRO must continue to perform all duties before the date the sale or transfer of ownership of the IRO is finalized. Notification of the impending sale of an IRO does not negate the IRO's obligation to continue to perform its duties in compliance with Insurance Code Chapters 1305 and 4202, Labor Code Title 5, and applicable department and TDI-DWC rules.

§12.111. Regulatory Requirements Subsequent to a Certificate of Registration.

(a) The IRO must report any material changes to the information required in the IRO application form required by §12.103 and §12.108 of this chapter, including changes relating to physicians and providers performing independent review, no 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 be conducted under 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. The independent review plan must include the following components:

(1) a description of the elements of review that the IRO provides;

(2) written procedures for:

(A) notification of the IRO's determinations provided to the patient or a representative of the patient, the patient's provider of record, and the utilization review agent, under §12.206 of this chapter;

(B) review, including:

(i) any form used during the review process;

(ii) time frames that must be met during the review;

(C) accessing appropriate specialty review;

(D) contacting and receiving information from health care providers under §12.205 of this chapter;

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

(A) based on medical and scientific evidence and use 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 and Chapter 137 of this title for health care provided under 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 the commissioner can carry out the commissioner's lawful duties under the Insurance Code;

(4) independent review determinations that:

(A) use 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 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 to perform independent reviews must be appropriately trained, qualified, and, if applicable, currently licensed, registered, or certified. These personnel must be currently involved in an active practice. An exception to the active practice requirement is the medical director of the IRO. 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 be nurses, physician assistants, or health care providers qualified to provide the service requested by the provider. This provision must 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 is required to provide to the commissioner:

(1) the name, 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) written procedures used to determine whether physicians or other health care providers used by the IRO are licensed, qualified, in good standing, and appropriately trained.

(c) An IRO must 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 review 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 personnel who are either employed 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) verification obtained from the applicable state licensing board that licensure, certification, or registration is 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.

(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 that performs independent review of a health care service provided under Labor Code Title 5 or Insurance Code Chapter 1305 must comply with the licensing and professional specialty requirements for personnel performing independent review as provided by Labor Code §§408.0043 - 408.0045 and 413.031; Insurance Code §1305.355; and Chapters 133 and 180 of this title.

(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 before it is 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 person is not eligible for a certificate of registration 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. The department will have the discretion to determine whether any other conflicts exist.

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

(a) An IRO must 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 in this chapter or Texas law.

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

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

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

(2) This prohibition does not extend to the use of subcontractor services or personnel employed by or under contract with the IRO 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) An individual or entity may not own more than one IRO.

(f) An individual may not own stock in more than one IRO.

(g) An individual may not serve on the board of more than one IRO.

(h) An individual who has served on the board of an IRO that has had its certificate of registration revoked for cause may not serve on the board of another IRO earlier than the fifth anniversary of the date the revocation occurred.

§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 seeking routine information or data. In no event will the designation of an individual or individuals as the initial contact prevent an IRO 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.

(b) An IRO may not engage in unnecessary or unreasonably repetitive contacts with the health care provider or patient and must 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 responsible for timely delivering to and ensuring receipt by the IRO of any written narrative supplied by the patient in compliance with Insurance Code Chapter 4201 and Chapters 19 and 133 of this title. However, in instances of a life-threatening condition, the IRO must contact the patient or patient's representative, and provider directly.

(d) An IRO must notify the department if, within three working days of receipt of the independent review assignment, the IRO 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 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. A health care provider's charge for providing medical information to an IRO must not exceed the cost of copying set by TDI-

DWC rules at §134.120 of this title for records, and may not include any costs that are otherwise recouped as a part of the charge for health care. 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.

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

(g) When conducting independent review, the IRO must 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 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 notify the patient or patient's representative, 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 no later than the earlier of:

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

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

(c) In the case of a life-threatening condition, the notification must be by telephone, and followed by facsimile, email, or other method of transmission no later than the earlier of:

(1) the third day after the date the IRO 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, the eighth day after the date the IRO receives the request that the determination be made; or

(3) a review of health care service other than a service described by paragraph (2) of this subsection, the third day after the date the IRO receives the request that the determination be made.

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

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

(7) the name and certificate of registration number of the IRO;

(8) a description of the services in dispute;

(9) a complete list of the information provided to the IRO 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 before its referral to the IRO, 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 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 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 to make the determination;

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

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

(21) notice of applicable appeal rights under Insurance Code Chapter 1305 and 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 on the department's website at tdi.texas.gov/forms.

§12.207. Independent Review Organization Telephone Access.

(a) An IRO must have appropriate personnel reasonably available by telephone at least 40 hours per week during normal business hours in both Central and Mountain time zones.

(b) An IRO must have a dedicated telephone system capable of accepting or recording or providing instructions to incoming callers related to independent review during other-than-normal business hours, and must respond to calls no later than one working day from the date the call was received.

§12.208. Confidentiality.

(a) An IRO must preserve the confidentiality of individual medical records, personal information, and any proprietary information provided by payors. Personal information includes 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) An IRO may not disclose or publish individual medical records or other confidential information about a patient without the prior written consent of the patient or as otherwise provided by law, including the Health Insurance Portability and Accountability Act of 1996, if applicable. An IRO may provide confidential information to a provider who is under contract with the IRO for the sole purpose of performing or assisting with independent review. Information provided to a provider who is under contract to perform a review must remain confidential.

(d) The IRO may not publish data identifying 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.

(e) All payor, patient, physician, and provider data must be maintained by the IRO in a confidential manner that prevents unauthorized disclosure to third parties. Nothing in this chapter allows an IRO to take actions that violate state or federal statutes or regulations concerning confidentiality of patient records.

(f) To ensure confidentiality, an IRO must, when contacting a utilization review agent, a physician’s or provider’s office, or a hospital, provide its certificate of registration number and the caller’s name and professional qualifications to the provider or the provider’s named independent review representative.

(g) The IRO’s procedures must specify that specific information exchanged for the purpose of conducting a review will be considered confidential, be used by the IRO solely for the purposes of independent review, and may be shared by the IRO only with

a provider who is under contract with the IRO to perform an independent review. The IRO's plan must specify the procedures in place to ensure confidentiality and must acknowledge that the IRO 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 confidential.

(h) Medical records and patient-specific information must be maintained by the IRO 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) Information generated and obtained by the IRO in the course of the review must be retained for at least four years. This requirement is not negated by the suspension or surrender of the IRO's certificate of registration or the failure to renew the certificate of registration.

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

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

(c) The department may use the authority of Insurance Code §38.001 to make inquiries of any IRO.

(d) This chapter does not limit the ability of the commissioner of workers' compensation or TDI-DWC to make inquiries, conduct audits, or receive and investigate complaints against IROs or personnel employed by or under contract with IROs to perform independent review to determine compliance with or violations of 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 Insurance Code Chapters 1305 or 4202; any provision of Labor Code Chapters 408, 409, or 413; or this chapter or Chapters 19, 133, 134, 140, or 180 of this title, respectively, the department will notify the IRO of the alleged violation and may compel the production of any and all documents or other information necessary to determine whether or not a violation has taken place.

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

(c) Proceedings under this chapter are contested cases for the purpose of Government Code Chapter 2001.

(d) If the commissioner determines that an IRO or a person conducting independent reviews has violated or is violating any provision of Insurance Code Chapter 4202 or this chapter, the commissioner may:

(1) impose sanctions under Insurance Code Chapter 82;

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

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

(e) If the IRO 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 Insurance Code Chapters 82, 83, or 84.

(f) The commission of fraudulent or deceptive acts or omissions in obtaining, attempting to obtain, or using a certificate of registration or designation as an IRO is a violation of Insurance Code Chapter 4202.

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

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

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

§12.303. Surrender of Certificate of Registration.

(a) Under Insurance Code §4202.002(c)(2)(B) an IRO that enters into an agreed order with the department that includes surrendering its certificate of registration, must surrender the organization's certificate of registration immediately on the request of the department.

(b) Independent reviews will not be assigned to an IRO during a surrender of the IRO's certificate of registration.

(c) Surrender of an IRO's certificate of registration does not negate the requirement in §12.208(i) of this subchapter that an IRO must retain information generated and obtained by the IRO in the course of a review for at least four years or the obligation to complete all independent reviews assigned to the IRO before its the surrender of the certificate of registration.

SUBCHAPTER E. FEES AND PAYMENT

§12.401. Fees.

(a) The commissioner will establish, administer, and enforce the application and renewal of certificate of registration 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 be determined by the commissioner, and will reflect in general the market value of services rendered.

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

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

(2) Tier two fees will be for 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.

§12.403. Fee Amounts.

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

§12.404. Payment of Fees.

(a) IROs must bill utilization review agents or payors, as appropriate, directly for fees for independent review.

(b) IROs may also bill utilization review agents or payors, as appropriate, for copy expenses related to reviews as set out in §12.205 of this chapter.

(c) Utilization review agents or payors, as appropriate, must pay IROs directly within 15 days of receipt of invoice. For workers' compensation network and nonnetwork disputes, the IRO fees must be paid under §133.308 of this title.

(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 within 15 days of receipt is a violation of §12.404(c) of this subchapter and subject to enforcement action and penalty under §12.302 of this chapter.

§12.406. Application and Renewal of Certificate of Registration Fees. The fee to be paid to the department for the original application for a certificate of registration as an IRO is $1000. The fee for renewal of a certificate of registration is $400. There is no fee for reporting a material change to a certificate of registration as an IRO.

SUBCHAPTER F. RANDOM ASSIGNMENT OF INDEPENDENT REVIEW ORGANIZATIONS

§12.501. Requests for Independent Review. Requests for independent review must be made to the department on behalf of the patient by the utilization review agent under Insurance Code Chapter 4201, Subchapter I and Chapter 19, Subchapters R and U of this title; Chapter 10 of this title; Chapter 133 of this title; Chapter 134 of this title; or by a health insurance carrier, health maintenance organization, or managed care entity under Civil Practice and Remedies Code §88.003(c).

§12.502. Random Assignment.

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

(b) The department will screen payors and utilization review agents for potential conflicts of interest with the IRO before making an assignment to the IRO. The IRO must screen its physicians and other providers conducting independent review for potential conflicts of interest. The department has the discretion to determine whether conflicts exist.

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

(d) The department will randomly assign IROs chronologically from the list of IROs, with ultimate assignment to the first in line with no apparent conflicts of interest.

(e) Assignment of an independent review to an IRO moves the IRO receiving the assignment to the bottom of the assignment list.

(f) Independent reviews will not be assigned:

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

(2) during the time that an IRO has surrendered its certificate of registration under §12.303 of this chapter and Insurance Code §4202.002(c)(2)(B).

(g) Nonselection for presence of conflicts of interest does not move the IRO to the bottom of the assignment list. The IRO retains its chronological position until selected for independent review.

CERTIFICATION. This agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on April 22, 2015.

Sara Waitt
General Counsel
Texas Department of Insurance

The commissioner adopts 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, and 12.501 - 12.502, and new §12.111.

David Mattax
Commissioner of Insurance

COMMISSIONER'S ORDER NO. **3927**