

SUBCHAPTER C. GENERAL STANDARDS OF INDEPENDENT REVIEW
28 TAC §12.206

INTRODUCTION. The Texas Department of Insurance proposes amendments to Title 28, Texas Administrative Code §12.206, concerning notices of determinations made by independent review organizations (IROs). The amendments to §12.206 implement House Bill 1621, 84th Legislature, Regular Session (2015) and SB 680, 85th Legislature, Regular Session (2017).

EXPLANATION. The proposal amends §12.206(b) and §12.206(c) to include new requirements that HB 1621 and SB 680 added to Insurance Code Chapters 1369 and 4202. The amendments are necessary to align the rules with statute and implement HB 1621 and SB 680.

Section 12.206(b). The proposal amends §12.206(b) to include the provision that the time for IROs to give notice of their determination of appeals from adverse determinations of URAs provided in that subsection does not apply to situations described in §12.206(c). The change is needed to clarify the rule and remove any potential conflict between the existing sections.

Section 12.206(c). The proposal amends §12.206(c) to require that IROs notify enrollees of the results of appeals from adverse determinations for prescription drugs or intravenous infusions for which a patient is receiving benefits under the health insurance policy, and reviews of step therapy protocol exception requests, within three days after the IRO receives the information necessary to make the determination. The statutory changes in HB 1621 and SB 680 necessitate amending 28 TAC §12.206 to align the rule with the statutes. Insurance Code §4202.002(b)(5) requires that the Commissioner adopt

standards ensuring the timely notice to an enrollee of the results of an independent review. The Commissioner implemented the statute's notice standards by adopting §12.206 on November 26, 1997.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Debra Diaz-Lara, Director of the Managed Care Quality Assurance Office, has determined that during each year of the first five years the proposed amendment is in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the section, other than that imposed by the statute. This determination was made because the proposed amendment does not add to or decrease state revenues or expenditures, and because local governments are not involved in enforcing or complying with the proposed amendment.

Ms. Diaz-Lara does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. Ms. Diaz-Lara has also determined that for each year of the first five years the proposed amendments are in effect, public benefits are expected as a result of enforcing the proposed amendments. Public benefits resulting from the adoption of the rules will be the implementation of HB 1621 and SB 680. The benefits include conforming §12.206(b) and (c) to current applicable statutory requirements, which will result in consistent notice requirements for IRO determinations and protect consumers by ensuring consistent and efficient regulation.

Ms. Diaz-Lara expects that the proposed amendments will not increase the cost of compliance with Insurance Code §§1369.0546, 4202.002, and 4202.003. Standards for notice of the results of IRO's determination of appeals were previously adopted in 28 TAC §12.206. The legislative changes to §4202.003 require these amendments to conform the

rule to the statute. Insurance Code §4202.002(b)(5) provides that the Commissioner must adopt standards for timely notice of the results of an independent review. The proposed amendments make no changes regarding the determination requirements other than to recognize the new statutory time frame established for determinations involving prescription drugs or intravenous infusions for which a patient is receiving benefits under the health insurance policy and reviews of step therapy protocol exception requests. Therefore, the proposed amendments impose no additional costs on regulated parties.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. The department has determined that the proposed amendments will not have an adverse economic effect or a disproportionate economic impact on small or micro businesses, or on rural communities. As a result, and in accordance with Government Code §2006.002(c), the department is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. The department has determined that the proposed amendments do not impose a cost on regulated persons, so no additional rule amendments or repeals are required under Government Code §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT. The department has determined that for each year of the first five years that the proposed amendments are in effect the proposed rule:

- will not create or eliminate a government program;
- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the department;
- will not require an increase or decrease in fees paid to the department;
- will expand regulation in §12.206 by requiring IROs give notice of their determination of appeals under Insurance Code §4202.003 as amended by HB 1621 and SB 680, as required by Insurance Code §4202.002(b)(5);
- will not repeal an existing regulation;
- will not increase or decrease the number of individuals subject to the rule's applicability; and
- will not positively or adversely affect the Texas economy.

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

REQUEST FOR PUBLIC COMMENT. The department will consider any written comments on the proposal received by the department no later than 5:00 p.m., Central time, on February 25, 2019. Send your comments to ChiefClerk@tdi.texas.gov; or to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. To request a public hearing, submit a written request before the end of the comment period to ChiefClerk@tdi.texas.gov or to the Office of the Chief Clerk, Mail Code 113-2A, Texas Department of Insurance, P.O. Box 149104, Austin, Texas 78714-9104. The request for public hearing must be separate from any comments and received by the department no later than 5:00 p.m., Central time, on February 25, 2019. If

the department holds a public hearing, the department will consider written and oral comments presented at the hearing.

SUBCHAPTER C

28 TAC §12.206

STATUTORY AUTHORITY. Amendments to §12.206 are proposed under Insurance Code §§1369.057, 4202.002, and 36.001.

Insurance Code §1369.057 provides that the Commissioner may adopt rules to implement Insurance Code Chapter 1369, Subchapter B.

Insurance Code §4202.002(b)(5) provides that the Commissioner adopt standards to ensure the timely notice to an enrollee of the results of an independent review.

Insurance Code §36.001 provides that the Commissioner may adopt any rules necessary and appropriate to implement the powers and duties of the department under the Insurance Code and other laws of this state.

CROSS-REFERENCE TO STATUTE. The amendments to §12.206 affect Insurance Code §1369.0546 and §4202.003.

TEXT.

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

(a) (No change.)

(b) For a situation other than a situation described in subsection (c), the [The] notification required by this section must be mailed or otherwise transmitted no later than the earlier of:

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

(c) In the case of a life-threatening condition, the provision of prescription drugs or intravenous infusions for which the patient is receiving benefits under a health insurance policy, or a review of a step therapy protocol exception request under Insurance Code §1369.0546, the notification must be by telephone, and followed by facsimile, email, or other method of transmission no later than the earlier of:

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

(d) - (e) (No change.)

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

Issued in Austin, Texas, on January 11, 2019.

/s/ Norma Garcia

Norma Garcia
General Counsel
Texas Department of Insurance