INTRODUCTION. The Commissioner of Insurance adopts new 28 TAC §35.2, concerning Pharmacy Benefits, on an emergency basis, effective immediately. The emergency adoption is necessary to ensure that enrollees in TDI-regulated plans have access to the medications they need while limiting their exposure to public places during the COVID-19 pandemic.

REASONED JUSTIFICATION. On March 13, 2020, Governor Abbott issued a statewide disaster declaration due to the COVID-19 pandemic. As the governor noted, it is critical to take steps to prepare for, respond to, and mitigate the spread of COVID-19. Negative outcomes from the virus, including hospitalization and death, disproportionately affect older people and those with pre-existing conditions, a population that is more likely than others to take prescription drugs regularly. Enrollees may have a more difficult time seeing their health professionals, both because of fewer available appointments and efforts to avoid exposure. Businesses, including health plans and plan administrators, may experience staffing shortages due to illness, school closures, and quarantine efforts. Further, the global pandemic is disrupting supply chains and manufacturing operations around the world, which may lead to difficulty locating on-formulary or preferred drugs at in-network pharmacies.

The new rule prevents disruptions in access to potentially critical prescription drugs due to difficulty seeing prescribing health professionals or delays in obtaining prior authorization by requiring plans to extend established prior authorization approvals. Routine appointments are often being postponed due to social distancing efforts, and
enrollees may also experience fewer available appointments with their prescribing health professional. Health plans have already inquired about extending certain timelines out of concerns about staffing shortages caused by the pandemic. The intent of the rule is that plans would update their computer systems to reflect a 90-day extension of prior authorization approvals for qualifying prescription drugs in advance of a refill request. The provision ensures that enrollees’ access to maintenance medications is not at risk due to decreased access to their prescribing health professionals or shortages of staff that may be experienced by plan administrators and cause prior authorization delays during the pandemic.

Limiting person-to-person contact is key to slowing the spread of this virus. The new rule limits exposure to public places by limiting trips to the pharmacy and preventing unnecessary physical contact. Under the rule, health benefit plans will be required to cover up to a 90-day additional supply of prescription drugs regardless of when the drug was last dispensed. This applies only to situations in which a prescribing health professional has determined that the additional supply is appropriate. The rule does not affect laws limiting dispensation of certain drug classes or affect a pharmacy's ability to limit dispensation to ensure availability of a drug. In an effort to limit physical exposure, the new rule also prevents plans from requiring signature at the point of delivery of a prescription drug unless the signature is otherwise required by law or refusing payment solely on the grounds that the drug was delivered by a local pharmacy to the enrollee.

The new rule puts protections in place for enrollees who are unable to reasonably locate a prescribed drug due to supply chain issues. Health benefit plans will be required to cover prescription drugs from out-of-network pharmacies at no additional copayment, coinsurance, or other cost sharing when the enrollee cannot reasonably obtain them from an in-network pharmacy. The rule also requires health benefit plans to make alternative
drugs available on-formulary or in the same preferred tier when an on-formulary or preferred drug is unavailable due to shortage or lack of distribution. If the alternative drug is substantially equivalent to the originally-prescribed drug, plans may not require prior authorization for the alternative drug. Health plans may assist enrollees in locating pharmacies to fulfill prescriptions in-network with on-formulary or preferred drugs, but the new rule prohibits health benefit plans from requiring the enrollee to travel more than 30 miles or visit multiple pharmacies.

This emergency rule does not affect the authority of the prescribing health professional and will be in effect for a limited amount of time. The rule relies on the discretion and duty of care of the prescribing health professional to ensure the health and safety of the enrollee and provides for the delivery of prescription drugs that the health professional has determined that the enrollee needs.

An emergency rule is necessary

Pursuant to Government Code §2001.034 and §2001.036(a)(2), the new rule is adopted on an emergency basis and with an immediate effective date because an imminent peril to the public health, safety, or welfare requires adoption on fewer than 30 days' notice.

As noted in Governor Abbott's disaster declaration, COVID-19 poses an imminent threat to the public health and welfare. COVID-19 is spreading at an exponential rate, and it is vital that actions be taken to prepare for, respond to, and mitigate the spread of the virus. The new rule is adopted to ensure that foreseeable problems affecting access to prescription drugs arising from the pandemic do not put the public at risk while limiting enrollee exposure to public places, which is widely recognized as vital to slow the spread
of COVID-19. Therefore, it is vital to the public health and welfare that the new rule goes into effect immediately.

Under Government Code §2001.034, this emergency rule may not be in effect for longer than 120 days, with the possibility for a 60-day extension.

**STATUTORY AUTHORITY.** The new rule is adopted on an emergency basis with an immediate effective date under Insurance Code §§36.001, 1369.005, and 1369.057; and Government Code §2001.034 and §2001.036(a)(2).

Insurance Code §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.

Insurance Code §1369.005 provides that the Commissioner may adopt rules as necessary to implement Insurance Code Chapter 1369, Subchapter A, concerning Coverage of Prescription Drugs in General.

Insurance Code §1369.057 provides that the Commissioner may adopt rules as necessary to implement Insurance Code Chapter 1369, Subchapter B, concerning Coverage of Prescription Drugs Specified by Drug Formulary.

Government Code §2001.034 provides that a state agency may adopt an emergency rule without prior notice or hearing if the agency finds that an imminent peril to the public health, safety, or welfare requires adoption of a rule on fewer than 30 days' notice.

Government Code §2001.036(a)(2) provides that if a state agency finds that an expedited effective date is necessary because of imminent peril to the public health, safety, or welfare, and subject to applicable constitutional or statutory provisions, a rule
is effective immediately on filing with the secretary of state, or on a stated date less than 20 days after the filing date.

TEXT.

SUBCHAPTER A. COVID-19 EMERGENCY RULES
28 TAC §35.2

§35.2. Pharmacy Benefits.

(a) This section applies as follows:

(1) This section applies to a health benefit plan as specified in Insurance Code §1369.052 and §1369.053.

(2) This section does not apply to a workers’ compensation insurance policy.

(3) A health benefit plan subject to this section must ensure compliance with this section even if it has contracted with another entity for purposes of administering the plan's pharmacy benefits.

(4) The requirements of this section apply only to a prescription drug delivered on or after the effective date of this section and before this emergency rule is rescinded or expires by operation of law.

(5) Nothing in this section is to be construed as affecting the authority of the prescribing health professional.

(b) Words and terms defined in Insurance Code Chapter 1369 have the same meaning when used in this section.

(c) A health benefit plan must extend established prior authorization approvals for 90 days. This subsection applies only to drugs prescribed under the authority of a licensed health professional, excluding controlled substances as defined in the Texas Controlled Substances Act.
(d) A health benefit plan must authorize payment for an additional one-time 90-day supply of any drug that is covered or required to be covered and as prescribed under the authority of a licensed health professional for an enrollee, regardless of the date on which the prescription has most recently been filled. This section does not affect laws limiting dispensation of certain drug classes.

(e) An enrollee is liable for copayments, coinsurance, or other cost sharing as if a prescription drug is dispensed in-network, when no reasonably available in-network pharmacy is able to timely dispense a prescription drug prescribed under the authority of a prescribing health professional. The health benefit plan may direct the enrollee to a particular mail-order pharmacy or an in-network pharmacy that can timely dispense the prescription drug but may not require the enrollee to travel more than 30 miles one-way or visit multiple pharmacies.

(f) A health benefit plan must make alternative drugs available on-formulary or in the same preferred tier when an on-formulary or preferred drug is unavailable due to shortage or lack of distribution. The health benefit plan may not require prior authorization for the alternative drug if it has the same active ingredients and yields the same therapeutic effect as the originally-prescribed drug. The health benefit plan may direct the enrollee to another pharmacy or a particular mail-order pharmacy that can timely dispense the prescription drug but may not require the enrollee to travel more than 30 miles one-way or visit multiple pharmacies.

(g) A health benefit plan may not require an enrollee's signature at the point of delivery of a prescription drug unless the signature is otherwise required by law. This subsection may not be construed to prohibit a health benefit plan from requiring a prescription drug to be delivered to and orally acknowledged by an adult.
(h) A health benefit plan may not refuse or reduce payment for a prescription drug based solely on the grounds that the prescription drug was delivered by a local pharmacy to the enrollee. This subsection does not mandate coverage for prescription drugs delivered through United Parcel Service, FedEx, the United States Postal Service, or other such delivery company. The health benefit plan is not responsible for any delivery fees.

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

Issued at Austin, Texas, on April 1, 2020.

James Person, General Counsel
Texas Department of Insurance

The Commissioner adopts new §35.2 on an emergency basis, effective immediately.

Commissioner's Order No. 2020-6305