Texas Association of Health Plans
1001 Congress Ave., Suite 300
Austin, Texas 78701
P: 512.476.2091
www.tahp.org

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HHSC Vendor Drug Program,

As the statewide trade association representing health insurers, HMOs, Medicaid managed care, and other health plans that serve over 20 million Texans, the Texas Association of Health Plans (TAHP) is committed to ensuring that Texas families and employers have access to affordable, comprehensive, and high-quality coverage. We are writing today to express our concern regarding the implementation of HB 3286, specifically the draft policy relating to temporary non-preferred status of new-to-market drugs that have been added to the Texas Medicaid formulary.

HB 3286 changed the process for new-to-market drugs to ensure that patients were not put on drugs for which they eventually would not qualify. The legislation achieved this goal by requiring that new-to-market drugs have an automatic non-preferred status. Importantly, this provision fits into an overarching aim to avoid instances of patients being removed from drugs when they are stable. Part of this goal was to ensure that a patient takes a preferred drug first—when appropriate and available—until the Drug Utilization Review (DUR) Board determines if the newly introduced drug will go on the Preferred Drug List (PDL).

This proposed policy would require a Prior Authorization (PA), which will be approved for 180 days. However, in order to satisfy the PA requirements, the prescription would merely need to be FDA-approved for the diagnosis, the appropriate dosage for the member's age and indication, and not be contraindicated. These PA requirements are far less stringent than the requirements for non-preferred drugs, as they do not include a requirement for patients to first try a preferred drug, or show an allergy or contraindication to a preferred drug, as is standard for all other non-preferred drugs. The impact will be that patients continue to be taken off these new-to-market drugs when they are stable, after they are designated as non-preferred by the DUR Board.

At least two other states have a temporary non-preferred status with a PA process that requires a patient to try a preferred drug first. For example, Louisiana places all new drugs into a non-preferred status and requires treatment failure, an intolerable side effect, a contraindication, or no alternative preferred drug to satisfy the prior authorization requirements. Likewise, Ohio requires "medical necessity beyond convenience for why the patient cannot be changed to a

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preferred drug (i.e., allergies, drug-drug interactions, contraindications, or intolerances)" or an inadequate clinical response to a preferred drug.

The PA requirements in this draft policy are vastly different from what was expected when the bill was passed. In fact, within HB 3286, the legislature detailed its expectations for "allowing exceptions to the preferred drug list." Tex. Gov. Code 533.071, which now applies to all non-preferred drugs, spells out those expectations. This proposal, if adopted as drafted, would set a completely new, and dramatically lower, standard for "exceptions to the preferred drug list." These exceptions to the PDL do not align with statute, nor do they align with requirements that were in place for any drug before or after the passage of HB 3286. Again, members would meet these PA standards, then likely fail the PA after DUR Board review, as they would not be able to meet the standard non-preferred criteria. This would effectively continue the *status quo* and render the changes in HB 3286 meaningless.

To address these issues, we recommend that the agency adopt prior authorization criteria that aligns with the criteria in HB 3286 for all non-preferred drugs. Given that at least Louisiana and Ohio policies have similar requirements, we do not expect any issues with approval of the State Plan Amendment. We recommend the following language:

2. Prescribers may obtain coverage of a temporary non-preferred drug by requesting a PDL prior authorization for members who meet the exception criteria listed below:

- *A. Temporary non-preferred drug is necessary for the treatment of stage 4 advanced metastatic cancer and associated conditions;*
- *B. The drug required under the Preferred Drug List is:*
  - *1. Contraindicated;*
  - *2. Will likely cause an adverse reaction of physical or mental harm to the patient; or*
  - *3. Is expected to be ineffective based on the known clinical characteristics of the recipient and the know characteristics of the prescription drug regimen; or*
- *C. The recipient previously discontinued taking the preferred drug at any point in their clinical history and for any length of time due to ineffectiveness, diminished effect, or adverse event(s).*

Assuming this change is made, we would also encourage the agency to lengthen the prior authorization to 365 days to align with other non-preferred drugs. If an enrollee will have to meet the standard requirements for a non-preferred drug prior to DUR Board review, it follows that they will likely be able to meet the requirements after DUR Board review. These changes will

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meet the goal of HB 3286 by reducing instances of patients being taken off drugs, while also decreasing the number of prior authorizations providers and patients are required to satisfy.

We appreciate the opportunity to comment on this proposal. Please contact us if you have any questions or concerns.

Sincerely,

Jamie Dudensing, RN
CEO
Texas Association of Health Plans