December 4, 2022

Texas Health and Human Services Commission

Cecile Erwin Young, Executive Commissioner

CC: Gabi Simpson (gabi.simposon@hhs.texas.gov)

P.O. Box 13247

Austin, Texas

28711-3247

Dear Commissioner Young,

On behalf of our 33-member companies and the patients throughout the world that we serve, thank you for allowing us to provide stakeholder comments as requested by December 4th. We hope that the information we provide in this letter will be helpful and we welcome any follow up conversations as desired.

As the Health and Human Services Commission (HHSC) is preparing to obtain guidance regarding the Medicaid formulary, Preferred Drug List (PDL) and Prior Authorization (PA) requirements, PhRMA feels strongly that the single formulary and PDL in Texas must remain in place. Over the past few years, the single formulary has protected Texas patients and strengthened the patient/provider relationship, allowing patients to receive the treatments that work best for them. Other states who transitioned from a single formulary to allowing multiple managed care organizations (MCOs) to offer different formularies, have seen problems and some states have even reverted to the single formulary with state budget savings projected by doing so. In fact, in 2020, two states (North Dakota and Wisconsin) reported an intent to change the pharmacy benefit from being administered by several managed care plans back to fee-for-service. In addition, approximately 15 states carved out a portion of their drug benefit from their MCOs, allowing a certain subset of drugs to be administered by a single formulary (Arizona, California, Florida, District of Columbia, Iowa, Indiana, Maryland, Michigan, Mississippi, New Hampshire, New Jersey, Ohio, Oregon, South Carolina, and Washington). Ohio has gone so far as to fully carve out the prescription drug benefit to avoid having any MCO involvement after an investigation revealed drug pricing irregularities by a health plan and its contracted pharmacy benefit manager (PBM) in their formerly carved-in program. Texas has been a leader in ensuring patient access to medicines through a single formulary and because of this protection, providers have more uniformity and predictability, and patients benefit with stability and continuity of care.

There are many scenarios where multiple formularies can be detrimental to patients and result in adverse health outcomes. For example, if there are different formularies, chances are high that if a patient moves to a different region of the state, their new Medicaid plan may not provide preferred coverage for the drug that has previously stabilized them.

Predictability and consistency are important for providers and patients. Furthermore, providers, who are already stretched for time to properly care for their patients, should not have to use precious office resources to initiate voluminous paperwork to appeal or challenge drug coverage so they can get the medicine needed that the single formulary previously covered. Additionally, many providers see Medicaid patients who are covered by different MCOs. In a system with limited network physicians who are already saddled by low reimbursement rates-dealing with multiple formularies will only serve to increase their Medicaid-related administrative burden and potentially push more physicians out of the program.

The life of the patient can be greatly disrupted if a negative health outcome results due to disruption in medication therapy as well. An example of an unintended consequence of medication disruption is for patients with a mental health diagnosis. Often, it takes a minimum of 2 weeks to achieve optimal effects of some medicines, such as antidepressants or antipsychotics. If a patient is forced to switch to a different medicine in a class, they could incur a setback in symptoms, causing issues for their employment and caring for their family.

Troubling scenarios can be avoided if the single formulary remains intact, allowing continued coverage of medicines for patients so they can continue living productive lives. Otherwise, medication disruption, even if for one medicine, can mean a patient’s condition is no longer stable, potentially triggering a domino effect of adverse consequences.

Research has shown that adherence (patients taking medicines as prescribed) provides a tremendous opportunity to save on costs and improve outcomes. When patients are adherent and take medicines as prescribed by their provider, studies have shown that approximately $213B/year could be saved in medical and societal costs, such as averted hospital admissions and emergency room visits from being non-compliant.[[1]](#footnote-1) Medicaid patients, who tend to be a more vulnerable population due to multiple chronic conditions, could experience the greatest disruption and impact from multiple formularies. Adherence and care coordination concepts are truly a win-win because patients and their caregivers/families have a better quality of life, employers have a reduction of absenteeism or presenteeism, and government programs and health plans will save money in avoided costly complications.

However, we understand the issue of whether or not to maintain the single formulary is a legislative decision. In light of that fact, we would like to thank the HHSC for undertaking a thoughtful and inclusive process to seek public input on draft contract requirements that will ultimately impact the millions of Texans who currently receive prescription drug benefits through Texas Medicaid.

In current statute many patient protections exist beyond PA requirements and protected classes. Each of these statutory protections was put in place through the tireless work of a variety of advocates, careful consideration by the legislature, multiple votes by each legislative body and ultimately the blessing of the Governor. Each was determined by the legislative and executive branch to be an important safeguard to ensure the beneficiaries of the Texas Medicaid program have access to the medically necessary care they need. We appreciate the effort to ensure many of the patient protections that currently exist in Texas Medicaid are transferred to the multiple-formulary scheme, but we believe much more must be required.

Existing protections include extensive transparency requirements for the committee developing the state’s drug list. While the state may transition to an MCO developed formulary, each dollar spent on prescription drugs in the Medicaid program is still a tax dollar levied from the public. The public deserves the same transparency and ability to provide input on drug benefit changes whether implemented by the state or by an MCO. In addition, the contract provision requiring the maintenance of written documentation of the rationale for the decisions made regarding drug list development should be strengthened by requiring that documentation be made publicly available. Draft contract provisions do consider that MCOs should follow certain federal regulations by requiring them to follow 45 CFR § 156.122(3)(i) and (ii) related to Pharmacy and Therapeutics (P&T) Committee membership standards and meeting standards but Subdivision (iii) related to formulary drug list establishment and management is equally important and should be followed as well.

Other protections currently included in statute should also be carried over through the transition including timeliness requirements for prior authorization, requirements to make newly approved drugs available to patients at least until the next meeting of the P&T Committee/Drug and Utilization Review (DUR) Board, appeals processes, and prohibitions against working with pharmacy benefit managers who have been convicted of certain offenses and abuses.

Other concerns with the draft contract provisions include:

* Specific promotion of the use of step therapy and fail first approach.
	+ Provisions related to drug tiering do not specify that MCOs should consider net cost when determining tiers.
* No specific restrictions exist for therapeutic substitutions.
* No transparency regarding pharmaceutical drug manufacturer negotiations, PBM profits and rebate amount secured through negotiations with drug manufacturers which could be used to offset MCO rate increases.
* Contract provisions do not prohibit “white bagging” of drugs, particularly “specialty drugs”.
* No limitation in frequency of formulary and preferred drug class changes or similar protections for continuity of care which could be as brief as 60 days according to draft provisions.
* Oversight of MCO formulary, PDL and PA requirements are lacking and should be conducted with each change made by the plans or at least quarterly to ensure compliance with all contract provisions.
* MCOs should be required to report supplemental rebate amounts to HHSC regularly.

In summary, multiple formularies only add to provider and patient confusion, especially when it is already difficult to navigate healthcare. Time demands and pressures on providers are increasing. Getting timely access to the medicine their provider wants them to have is paramount. Therefore, the Texas single formulary should remain in place. However, if the legislature does give direction for HHSC to put in place a regulatory structure with MCO-developed drug lists, it is crucial to keep in mind: 1) the legislatively established patient protections that currently exist in statute should be maintained in the Medicaid program, regardless of who determines the drug list, and 2) Medicaid will always be a taxpayer funded program and those who administer the program should remain transparent, be open to public input and always operate with the best interest of their beneficiaries in mind.

PhRMA and its member companies look forward to continued engagement with the HHSC. Thank you for your consideration of our comments related to the request for stakeholder input on the single formulary issue.

Sincerely,

Brynna Clark, JD, Senior Director, PhRMA State Government Affairs

bclark@phrma.org; 202-294-2998

Sharon Lamberton, MS, RN, Deputy Vice President, PhRMA State Policy

slamberton@phrma.org; 202-306-2465

1. Su W, Lockwood C; IHS Markit. Comparing health outcome differences due to drug access: a model in non-small cell lung cancer. (http://cdn.ihs.com/www/prot/pdf/0119/IHSM\_NSCLC%20HTA%20model%20white%20paper\_18Jan2019r.pdf). Published December 13, 2018. [↑](#footnote-ref-1)