Texas Vendor Drug Program – Medicaid MCO Survey

Seeking Input on Proposed Policy: Medicaid/CHIP Formulary, PDL and PA Management Transition

The Health and Human Services Commission's (HHSC) Vendor Drug Program (VDP) currently oversees the outpatient drug benefit for Medicaid fee-for-service (FFS) and Medicaid and Children's Health Insurance Program (CHIP) managed care, including the management of a single program-wide formulary, preferred drug list (PDL), and prior authorization (PA) requirements. Section 533.005 of the Texas Government Code requires Medicaid and CHIP MCOs to exclusively use VDP's formulary, PDL, and PA requirements found in Sec. 531.073 (b), (c), and (g). This statute and the requirement expire on August 31, 2023. Under current law, these statutory requirements will no longer apply, and management of these functions will transfer to each Managed Care Organization (MCO) on September 1, 2023.

In preparation, HHSC is working with the Centers for Medicare and Medicaid Services (CMS) to obtain guidance regarding formulary, PDL, and PA requirements to comply with federal provisions for amount, duration, and scope as required by 42 C.F.R. § 438.210(a)(2). Additionally, HHSC will collaborate with the Texas Department of Insurance on CHIP requirements.

HHSC is seeking public input on the following draft contract requirements for this transition. Stakeholders may submit comments via survey by 5:00 p.m. CT, December 4, 2022. HHSC may propose additional contract requirements based on further guidance or information from CMS and/or TDI.

Required

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5.*Proposed Policy: *

MCO formularies, PDLs, and PAs must be set in accordance with federal regulations. 42 CFR § 438.210 requires MCOs provide services in an amount, duration, and scope that are no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid. The MCO may establish a formulary, PDL, and PAs as

long as they demonstrate coverage consistent with the amount, duration, and scope of the FFS formulary, PDL, and PAs. A beneficiary would receive at least the same medically necessary care with any contracted Medicaid MCO as he or she would in FFS Medicaid.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS applauds Health and Human Services Commission's (HHSC) Vendor Drug Program (VDP) for developing policies which would bring Texas managed care plans standards in alignment with fee-for-service (FFS) Medicaid and with federal regulations. FFS policies and activities have long been standard for covered outpatient prescription drugs and applying these standards to managed care plans demonstrates HHSC's recognition of the need for more oversight and responsibility of the managed care entity to ensure optimal health outcomes for Medicaid beneficiaries.

6.MCOs may establish their own formulary.

Please enter your feedback in the text box provided or indicate if you have no comments.

Allowing MCOs to establish their own formulary creates a patchwork of standards and access barriers for enrolled beneficiaries. It is not uncommon for managed care beneficiaries to switch managed care plans from year to year, and the lack of standardization in formularies across managed care plans could result in continuity of care challenges if coverage varies from one plan to the other. NACDS supports standardization of Medicaid managed care formularies if a MCO decides to establish their own formulary. We believe this will help beneficiaries more effectively navigate and understand their Medicaid managed care plan and ensure cost savings. Community pharmacists have assisted patients over the years with this difficult process and worked with other members on the health care team if changes in therapies are warranted due to plan coverage limitations. We believe the health care provider team and patient relationship should be preserved for the best outcomes and not determined by entities not intrinsically involved with the patients' medication management and the care planning process.

7.The formulary must be the same for all Medicaid programs that the MCO is contracted to provide services for.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS applauds HHSC for considering the standardization of Medicaid managed care and coverage to ensure widespread patient access to needed prescription medications which helps to prevent the need for more costly care. Medicaid beneficiaries can face multiple barriers to understanding their new plan formularies, to determining which of their medications are covered, and to exploring if there are other plans that they should consider enrolling in to meet their needs. Plan formularies that vary greatly often make this process extremely complicated for patients. We agree with HHSC's approach to require all contracted managed care plans to function under a standard formulary. We believe managed care plans should not have the authority to determine unilaterally which medications patients should be taking. It should be up to the healthcare provider team to determine the best course of treatment but given varying formulary limitations and restrictions across managed care plans, unfortunately this is often not the case.

8.Section 1927(d) of the Social Security Act and 42 CFR § 438.3 require MCOs to cover all drugs that are in the Medicaid Drug Rebate Program (MDRP), also known as covered outpatient drugs. If a drug is in the MDRP but not included in the MCO's formulary, the MCO must cover the drug for the member through a PA.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS appreciates HHSC's thoughtfulness in requiring MCOs to cover all outpatient drugs in the MDRP, including those not included in the MCO's formulary. In covering all covered outpatient drugs, it is appropriate for those drugs to be reimbursed at a comprehensive rate that takes into account the true cost to acquire and dispense prescription drugs to beneficiaries. Often, contracts between MCOs and pharmacies do not include the most basic information, such as the methodology for how pharmacies are reimbursed after dispensing a patient's medication(s). Even with written contractual agreements, MCOs may reduce reimbursement without notification. This can place TX retail/community pharmacies in the position of dispensing drugs at a financial loss. We believe that HHSC's policy should go a step further to require that Medicaid managed care reimbursements rates are set at an adequate level to ensure sufficient beneficiary access to pharmacy provider care and services. Managed care plans should be required to include in all contracts transparent drug pricing methodologies, routinely updated drug pricing, prompt payment to pharmacies, and allowing pharmacies to contest changes in their reimbursement. These requirements are

necessary to help level the playing field between MCOs and neighborhood pharmacies and would help promote continued pharmacy participation, thus helping to ensure continued access and optimal health outcomes for Medicaid beneficiaries.

9.MCOs may add additional drugs that are not on the Texas Medicaid VDP FFS formulary if that drug is in the MDRP.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS has no concerns with MCOs adding additional drugs to the formulary. However, in doing so, NACDS urges HHSC to require MCOs that add any additional drugs from the MDRP that are not on the Texas Medicaid VDP FFS formulary to ensure fair and adequate payment in a timely manner to community pharmacies for acquiring and dispensing the prescription drug or the OTC product to Medicaid beneficiaries.

10.MCOs cannot include drugs on the formulary or otherwise provide coverage of a drug that is not in the MDRP. However, MCOs must provide coverage for all medically necessary drugs for members ages 20 and under even if the drug is not in the MDRP. MCOs must approve these requests through special request from the prescriber, as required by 1905(r) of the Social Security Act. MCOs must establish a process to receive and approve these requests.

Please enter your feedback in the text box provided or indicate if you have no comments.

No comment.

11.MCOs must utilize a pharmacy and therapeutics (P&T) committee and/or a Drug Utilization Review (DUR) Board. The committees may work in tandem or independent of the other, if all committee requirements for both committee types are met:

1. A P&T committee must maintain written documentation of the rationale for all decisions regarding the drug list development and revisions. The committee must follow the membership and meeting standards specified in 45 CFR § 156.122(3)(i) and (ii).

2. The DUR Board must comply with the requirements described in 42 CFR § 456, Subpart K, and 42 U.S. Code § 1396r–8 as if such requirements applied to the MCO instead of the State.

3. The MCO must implement and maintain a process to ensure that its formulary is reviewed and updated, no less than bi-annually, by the MCO's Pharmacy and Therapeutics committee and/or Drug Utilization Review board.

Please enter your feedback in the text box provided or indicate if you have no comments.

As the state considers requiring MCOs to utilize a pharmacy and therapeutics (P&T) committee and/or a Drug Utilization Review (DUR) Board, it is imperative for MCOs to also ensure that these processes do not serve as an unintended barrier to patient access and comport with federal regulations related to the formulary standards and management (e.g., amount duration).

12.The MCO's CHIP formulary must be based on their Medicaid formulary. The CHIP formulary must cover the same drugs and may only exclude drugs that are not covered under CHIP. Exclusions include contraceptive medications prescribed only for the purpose of primary and preventive reproductive health care, and medications for weight loss or gain.

Please enter your feedback in the text box provided or indicate if you have no comments.

No comment.

13.MCOs must provide access to certain products (e.g., limited home health supplies, vitamins, minerals, and vaccines) identified on the VDP formulary. MCOs must include at least one product on the MCO's formulary for each product group or class listed on the Texas Medicaid VDP formulary and provide access to the other options through a PA. MCOs may develop a preferred list of products.

Please enter your feedback in the text box provided or indicate if you have no comments.

Community pharmacy teams continue to play a central, supporting role in the nation's initiative to improve health outcomes and vaccinate priority populations, and the broader public, including children, to stop the spread of COVID-19 and other vaccine preventable diseases. Pandemic interventions by pharmacy personnel have averted more than 1 million deaths, more than 8 million hospitalizations, and $450 billion in healthcare costs. More than 280 million COVID-19 vaccinations have been provided by pharmacies to date. In fact, pharmacists have served an essential role in connecting the public to

comprehensive vaccination services and other pharmacy care services. The experience of the COVID-19 pandemic only amplified the importance of leveraging pharmacy providers in this capacity. NACDS urges HHSC to require MCOs to implement timely, fair, and adequate reimbursement at the pharmacy and patient level for all managed care claims, including the cost and administration of vaccines and other pharmacy care delivery services such as dispensing of over-the counter (OTC) drugs offered by pharmacists. The overall cost to dispense an OTC should be the same as a prescription drug since they are prepared in the same quality manner. These recommendations would help TX pharmacies facilitate quality vaccination delivery, ensure timely dispensing, and improve access to preventive care for families.

14.The MCO must implement and maintain a process to ensure that its PDL and PAs are reviewed and updated no less than bi-annually by the MCO's Pharmacy and Therapeutics committee and/or Drug Utilization Review Board.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS agrees with the requirement to regularly review and update the PDL and PAs adopted by MCOs. In addition to ensuring adequate review, NACDS urges HHSC to go another step further in their policy and require MCOs to implement fair and adequate reimbursement at the pharmacy and patient level for covered prescription drugs on the MCO's PDL and those with PAs. Pharmacy reimbursement that is below the costs to acquire and dispense prescription drugs threatens viability of neighborhood pharmacies to provide convenient access to care in Texas. These are minimum and necessary requirements that go beyond the formulary level and have direct patient impact. Community pharmacies provide comprehensive and reliable care access points and patient-centered services, in addition to traditional dispensing roles, to advance the health and wellness of communities nationwide. Pharmacy access is especially critical for vulnerable and underserved populations.

15.A drug that is not included in the MCO's PDL may be subject to PA.

Please enter your feedback in the text box provided or indicate if you have no comments.

Please see response to question #5.

16.An MCO may choose to implement a tiered formulary which divides drugs into groups usually based on cost. MCOs may require members to try lower tier drugs before using higher tier drugs. For drugs in a higher tier, the only additional PDL PA the MCO can add is a requirement for the member to fail the lower tier drug(s).

Please enter your feedback in the text box provided or indicate if you have no comments.

Community pharmacies understand the premise of creating tiered formulary structures. In creating tiered formularies, we strongly urge the state to ensure that these tiered formularies do not create unintended barriers to patient access. To optimize the benefits of tiering formularies and PDLs, it is essential that the MCO also provide methods for patients to have access to other drugs that are not on the formulary or PDL through an effective and timely PA process that does not unnecessarily delay access and jeopardize patient continuity of care. Additionally, NACDS urges HHSC to go another step further in their tiered formulary policymaking and require MCOs to implement fair and adequate reimbursement at the pharmacy and patient level for covered tiers. Pharmacy reimbursement of tiered drugs typically fall below the costs to acquire and dispense prescription drugs which places undue pressure on the future sustainability of pharmacies to continue providing medication and pharmacy care services to communities in Texas.

17.The MCO may not require a PA for any drug exempted from PA requirements by state and federal law, including antiretroviral drugs. The MCO may not require a PDL PA for drugs in a Health and Human Services (HHSC) designated protected classes identified in Chapter 16 of the UMCM. HHSC protected classes include anticonvulsants, antihemophilic, antineoplastic (i.e., anti-cancer), antiretroviral (i.e., anti-HIV), medication assisted treatment drugs, medications used to treat multiple sclerosis and medications used to treat sickle cell.

Please enter your feedback in the text box provided or indicate if you have no comments.

No comment.

18.The MCO must adhere to the VDP Specialty Drug List for specialty drugs provided through selective specialty pharmacy contracts. The MCO's policies and procedures must comply with Texas Administrative Code, Title 1, Part 1, Part 15 § 353.905 and § 354.1853 and include processes for notifying Network Pharmacy Providers.

NACDS supports requiring that MCOs' policies and procedures comply with relevant sections of the Texas Administrative Code in a manner that helps to preserve beneficiaries' convenient access to life-saving specialty medications with as minimal burden as possible.

To preserve patients' ability to receive prescription services from their local neighborhood pharmacies, PBMs should accurately classify specialty drugs. Prescription drugs should not be classified as "specialty drugs" based solely on the cost of the drug or other criteria used to limit patient access to these drugs. The inclusion of a particular drug as a "specialty drug" should focus on clinical aspects of drugs and should include only medications that require complex and extended patient education or counseling; requires intensive monitoring; requires clinical oversight; or requires product support services. Moreover, patients should have the freedom and option to fill prescriptions for specialty drugs at the neighborhood or specialty pharmacy of their choice, rather than being steered to receive those medications only by mail.

19.HHSC will continue to cover the cost of drugs excluded from the capitation rate through non-risk payments to MCOs. MCOs must cover all non-risk drugs and to adhere to any required HHSC PDL or clinical PA requirements as noted in Chapter 16 of the UMCM.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS urges HHSC to require MCOs to implement fair and adequate reimbursement at the pharmacy and patient level for non-risks drugs and the MCO's PDL and those with PAs. At minimum, MCOs should be required to cover baseline costs (ingredient cost and dispending cost) to community pharmacies to help ensure community pharmacies remain a reliable access point for the broader public--particularly the vulnerable Medicaid population.

20.The MCO must publish and maintain its current formulary, PDL, and PA criteria on the MCO's website in an easy to access, searchable, machine readable file and format and without a requirement for the member to enter credentials to view the information. MCOs must make a printed version available to Members upon request pursuant to 42 CFR 438.10(i).

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS applauds HHSC for requiring transparency and these quality assurance measures of the MCO's formulary and PDL for health care providers, including community pharmacies, to help best serve Medicaid beneficiaries of Texas. In addition to ensuring transparency and accessibility for providers it is essential that such information is also patient friendly and easy to navigate to ensure patient access to such information.

21.The MCO must make available a service that provides the MCO's formulary and PDL details, at no charge, that health care providers may use on the internet and easily access from handheld devices that they use at the point of care. The directory will inform prescribers about all non-preferred medicines that require PA.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS applauds HHSC for requiring transparency of the MCO's formulary and PDL for health care providers, including community pharmacies, at no charge to help best serve Medicaid beneficiaries.

22.The MCO must have a process in place to notify members, prescribers, and participating pharmacies of any formulary deletions and new PA requirements at least 60 days in advance of the effective date of the change. At minimum, this process must include a notification of changes that is posted to the MCOs website where members, prescribers, and pharmacies can easily access the information.

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS applauds HHSC for requiring early notifications to health care providers, including participating pharmacies, of changes or deletions in the MCO's formulary and PDL.

23.MCOs must send VDP the link to the MCO's formulary, PDL, and PA requirements and keep this link updated. VDP will compile and include the links in a single document available to prescribers, members, and pharmacies on the VDP website.

Please enter your feedback in the text box provided or indicate if you have no comments.

No comment.

24.VDP will review MCO's formulary, PDL, and PA policies and procedures at readiness. MCOs may not implement the formulary, PDL, or PA requirements until VDP provides approval to the MCO.

VDP will review each MCO's formulary, PDL, and PA requirements for compliance at least once annually.

MCOs must provide VDP with a current copy of the formulary, PDL, and PA requirements upon request.

/*VDP will release more specifics as readiness requirements are developed. /

Please enter your feedback in the text box provided or indicate if you have no comments.

NACDS appreciates HHSC's transparency and quality assurance guardrails outlined above for MCOs. We also urge HHSC to consider the adoption of MCO policies that prevent anti-claw backs (recouping payment back from pharmacies), implement rate floors, and maintain robust access to pharmacy network providers. Moreover, we believe it's critical to require MCOs to create an appeals pathway for pharmacies to dispute unfair and inadequate MCO payments to pharmacies.

Allowing pharmacies, the right to an appeal before suspension of payment or recouping alleged overpayments lessens this financial burden to pharmacies as well as allows pharmacies the ability to dispute any findings that may have resulted from administrative error. MCOs should also be required to pay interest for late payments. We believe these are necessary requirements to ensure oversight and transparency in the complicated health care system.

MCOs that suspend or recoup payment to pharmacy providers without allowing pharmacies the right to appeal any findings will pose a real threat to pharmacies continued financial viability and, in turn, to the ability of low-income patients to access prescription drugs and pharmacy services.

25.If you have any additional comments, please provide them in the text box provided.

NACDS thanks the HHSC for the opportunity to share our perspectives on this matter. For questions or further discussion, please contact NACDS' Mary Staples, Director, State Government Affairs at mstaples@nacds.org.