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Submitted via survey

TAHP Responses to VDP Formulary Carve-In Survey

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.

(3985 characters) We continue to maintain HHSC's interpretation of 42 CFR § 438.210 reflects a misunderstanding of the federal regulation. Requiring MCOs to mirror FFS PA requirements and criteria does not align with CMS' interpretation of its regulations and fundamentally contradicts the concept and purpose of managed care. A key benefit of managed care is that it allows MCOs to use their expertise and experience to apply PA requirements for certain services and develop the specific clinical standards and criteria that best meet the needs of their Medicaid members.

CMS has made it abundantly clear in its regulations that it does not consider applying PAs to be a limitation on the amount, duration, and scope of a service. 42 CFR §440.230 requires a sufficient amount, duration, and scope of a service, but CMS clarifies in Subsection (d) that an agency "may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." In other words, while the amount, duration, and scope of a service cannot be arbitrarily limited, CMS acknowledges that PA requirements may be implemented without violating the rule.

CMS also made its intent clear in its responses to comments on the 2016 Final Rule amending the federal regulation at issue, regarding service authorizations and appeals. CMS responded to a commenter, saying "We do not believe it appropriate for us to set the utilization management standards and/or authorization criteria for managed care plans. The provisions in § 438.210(a) and (b) do provide a sufficient level of detail and will provide adequate consistency across

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states. We believe states and managed care plans have the expertise and experience to develop the specific standards and criteria that best meet the needs of their program."

Other states also do not interpret the federal regulations as requiring the standardization of PAs and medical necessity criteria. In fact, 48 states, including Texas, allow managed care plans to develop their own criteria. According to a NASHP policy brief on state strategies, only two states have actively adopted a policy to standardize medical necessity clinical criteria/guidelines for EPSDT services, and this was a deliberative state policy choice rather than a state Medicaid agency's interpretation of the federal requirements.

The courts have also not required this change. In Coleman et. al. v. Wilson, at issue was whether the MCO was properly applying clinical standards, not whether those clinical standards must identically match the FFS program. In that case, the plaintiff argued, and the court held, that care was being denied without medical justification. Likewise, in the resolution passed after the case, the Texas Legislature stated very clearly that the agency had been "discriminating among similarly situated Medicaid recipients on the basis of categorical restrictions that are not based upon prevailing clinical standards." Neither this case nor the resolution that followed requires MCOs to adopt the medical necessity conditions provided for in the FFS program—MCOs are merely required to use prevailing clinical standards, as they currently do, pursuant to Insurance Code §4201.153(b).

The Texas Legislature has also expressly rejected this policy. HB 2453 (86R) would have required HHSC to align treatments and conditions subject to PA to create uniformity among Medicaid managed care plans. The Legislature did not pass that bill, and instead passed SB 1207, which was very similar but excluded the uniformity requirement. Not only has the Legislature not passed a bill that would support these changes, but they rejected the idea just two sessions ago.

Simply put, this new interpretation is bad public policy. We recommend the policy read "MCO services must be set in accordance with federal regulation 42 CFR § 438.210. The MCO may establish services as long as they demonstrate coverage consistent with the amount, duration, and scope of FFS services."

6. MCOs may establish their own formulary.

We agree that MCOs no longer have to employ the state's Medicaid or CHIP formularies, as well as PDL and PA procedures after Aug. 31, 2023.

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

None

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.

Without an express statement that an MCO's formulary does not have to include all drugs that are in the MDRP, we believe this policy will lead to confusion. We suggest the addition of the following after the first sentence: "An MCO is not required to include all drugs that are in the MDRP in the MCO's formulary."

We also recommend a statement clarifying that PAs are not limited to drugs on the MDRP but not on the formulary, and that PAs may also be required of drugs on an MCO's formulary. We recommend conclusion with the following sentence: "This does not limit an MCO from requiring a PA for drugs that are on the MCO's formulary."

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

HHSC intends to require MCOs to cover all drugs that are in the MDRP, as indicated in the above draft policy. This policy appears to be redundant and unnecessary. As the UMCC is already an astonishing 600 pages, TAHP encourages HHSC to be as precise and concise as possible when implementing new policies. If the intent of this draft policy is not simply a restatement of the previous draft policy, further clarification is needed.

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.

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This policy is needlessly restrictive. Interpreting the proposed formulary policies by HHSC as a whole, HHSC is restricting MCO formularies to only the drugs included in the MDRP, with a single exception for children under 20. HHSC has made no other exceptions–making MCO formularies more restrictive than the state's formulary.

Currently, when the state's PDL changes, MCOs frequently honor requests from members and their providers to override restrictions when information is provided that changing medications has the potential to decompensate/destabilize a member's condition. This policy allows patients to continue receiving medications that are working for them. If an MCO lacks the flexibility to allow for consideration of an exception for medications that are medically appropriate and clinically sound, MCOs will be required to take Texans off medications they are stable on. We encourage HHSC to consider an exception for medications that are medically appropriate and clinically sound, regardless of age.

Further, it is not uncommon for a drug to not yet be rebate eligible. In these instances, MCOs contact VDP to let them know that the drug is an omission to the formulary. VDP then contacts the manufacturer to request the manufacturer begin the process to obtain rebate eligibility status. MCOs ultimately report the drug on their FSR. We encourage a policy that also addresses this scenario, regardless of age.

Finally, a reimbursement policy for coverage of drugs not on the MDRP, regardless of age, should be clearly outlined. Current, MCOs are able to provide coverage for drugs not on the formulary without reimbursement. The draft policy fails to take into consideration this scenario.

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.**

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TAHP requests additional policy language that allows a P&T committee to be comprised of members that are out of state. Federal requirements already establish membership standards to ensure the needs of Medicaid members are appropriately addressed. Because the federal requirements are silent on the location of committee members and a majority of states already allow MCOs to manage their own formularies, many health plans already utilize their own multi-state P&T committees. Continued utilization of existing P&T committees will result in continued uniformity, experienced P&T committees, and cost savings to the state.

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.

Where exclusions will be included in policy, TAHP requests HHSC include all exclusions clearly outlined, and not just limited examples. Specificity in policy better promotes MCO compliance and understanding of the agency's expectations to ensure members' needs are met.

While we agree an MCO's CHIP formulary should be no less inclusive than an MCO's Medicaid formulary, other than the exclusion of drugs not covered under CHIP, the policy is silent as to whether the CHIP formulary may be more inclusive than an MCO's Medicaid formulary.

Further, clarification on the handling of Hepatitis C medication is requested.

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.

Similar to the above request, where phrases like "certain products" are used, TAHP requests HHSC include all products clearly outlined, and not just limited examples. Specificity in policy better promotes MCO compliance and understanding of the agency's expectations to ensure members' needs are met.

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Further, we request an exception process for DME to be provided through pharmacies that are not registered/licensed as DME providers, but where a timely alternative to the DME delivery is not available. Allowing the MCOs to determine our own preferred product lists for pharmacies to be able to bill the pharmacy benefit would give members better and quicker access to products like CGM products and Nebulizers. Some products may have lifetime quantity limits allow members to only receive on device in their lifetime, but devices may not last a lifetime and require a replacement. A reasonable quantity limit could be established by the MCOs (ie. 1 device in 3 years or 1 device in 5 years). This would also allow MCO's to approve products via a PA process if members have hit their quantity limit.

Specialty pharmacies/pharmacies have the ability to bill the pharmacy benefit for drug products like albuterol solutions or inhaled antibiotics, but these products require nebulizing devices to deliver the drug. This requires the pharmacy to have a DME license and bill to the medical benefit. Specialty nebulizing devices may require PA. Overall, this is a very abrasive process for providers and members. We use nebulizers as an example since there are a very select group of pharmacies that have a DME license to bill medical benefits. Unfortunately, under current practice, pharmacies will not register if they don't have the business to support this service.

If the MCOs are given the freedom to determine their own preferred product list as well as the drug list, we can align coverage for inhaled drug products and the devices that deliver these drugs.

Additionally, this can address FWA in the DME space. Using continuous glucose monitors as an example, one plan has found that there is high FWA with regards to billing for E1399 which results in a higher than necessary reimbursement. The way to address this is to allow the monitors to be covered as pharmacy benefits rather than medical benefits.

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.

We encourage further clarification to ensure this policy is no more restrictive than current policy. Bi-annual rereview of every PA type is not currently a practice.

The policy should also be expanded to include current policy regarding new drugs on the market available for coverage. Currently, these drugs are added as open status and not rated. Without

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a policy such as this, children who are receiving open status medications could be denied therapies after Aug. 31, 2023.

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

None

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).

We request the addition of clinical PA requirements, even when the drug is non-preferred.

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.

None

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.

We encourage elimination of this policy, as it runs counter to draft policy that MCOs manage their own formulary. If MCOs are managing the formulary, they should be able to manage their own specialty drug list, which can be used to contract the network.

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.

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We agree with this policy, however, MCOs should have the ability to appeal clinical and PDL PA requirements that are overly burdensome to members and providers. We request the establishment of criteria for non-risk drugs; an escalation, evaluation, and exception process; and outline for reimbursement.

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).

We request further clarification on the type of file expected to be used.

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.

This policy should be clarified so that MCOs are not required to explicitly list all non-preferred medicines that require a PA, but rather generally inform providers that the medicines not listed on the PDL may be subject to a PA.

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 clarify if this is business or calendar days.

MCOs are also interested in whether HHSC intends to establish the consistency by which an MCO's formulary may be reviewed by the MCO.

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.

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None

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.

We request clarification that the readiness review applies only once at initial implementation and encourage a timeline for implementation.

We also request a timeline for VDP's annual review and approval to ensure MCOs are not delayed in implementing formulary changes.

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

We appreciate this opportunity to provide feedback on draft policies and hope there will be multiple opportunities to provide feedback on policies. We look forward to more robust discussion in the months leading up to implementation.