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May 11, 2021

Lisa Smith  
MO HealthNet Division  
P.O. Box 6500  
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Dear Ms. Smith:

On behalf of its 340B qualifying hospital members, the Missouri Hospital Association submits the following comments concerning the proposed Medicaid state plan amendment on 340B drug reimbursement posted for public review by the Missouri Department of Social Services on April 12, 2021.

Reducing Physician Administered Drug Reimbursement to Actual Acquisition Cost

Federal law directs state Medicaid programs to reimburse 340B drugs dispensed in retail and specialty pharmacy setting at actual acquisition cost. However, this requirement does not extend to physician administered drugs, meaning the state agency has no duty to pursue, nor CMS the authority to compel Medicaid physician administered drugs to be reimbursed at actual acquisition cost. MO HealthNet projects that the reduction in retail and specialty pharmacy reimbursement under this plan amendment will cut 340B hospital reimbursement more than \$18 million. Imposing further reductions by cutting reimbursement for physician administered drugs unnecessarily removes an additional \$18 million from Missouri's health care safety net. These reductions are particularly ill-timed because hospitals are struggling to regain financial footing in the new health care economy reshaped by COVID-19. Ironically, the very hospitals that were the state's front line in the fight against the disease are those that will be hurt most by diminished reimbursement. The pandemic has brought into clear focus the detrimental consequences of the government's inadequate investment in public health. It is with this perspective that we question the wisdom of further divestment in the health care safety net wrought by the proposed plan amendment.

Submission of Actual Acquisition Costs

Our objections to the change to 340B physician administered drug reimbursement notwithstanding, the requirement that hospitals bill their actual acquisition cost for physician administered drugs fails to recognize the practical reality of hospital pharmaceutical procurement. Besides being overly burdensome, the policy is arguably arbitrary and capricious. The (literal) actual cost to acquire a 340B drug is a function of facts which may not be fully known or knowable at the time the drug is administered or the claim for reimbursement submitted. As such, a hospital in good faith could submit a claim that fully complies with the proposed rule, but which would not be accurate days or weeks later when the final accounting of all 340B purchases is available. Such complexity and variability greatly increase the risk that the validity of an individual claim would be unfairly questioned in an audit. If CMS is to allow the state to pursue this path, it should require actual acquisition cost claims submissions to be based on factors that are known or knowable at the time the drug is administered to promote efficient, timely and accurate reimbursement.

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However, the plan would be vastly improved if the state agency abandoned the requirement that providers submit actual acquisition costs, and simply set reimbursement at the 340B ceiling price irrespective of hospitals' charges. This design would greatly simplify the administration of 340B reimbursement for both the state and for providers and establish a policy that is well-defined, easily enforced, and readily auditable, and thus be far superior to the methodology put forth by the state agency.

#### Projected Cost of Compliance

The proposed state plan amendment includes a statement of the reimbursement reductions to 340B hospitals (i.e., savings to the state). The state's estimate does not include the substantial costs hospitals will incur to comply with the provisions of the plan amendment.

In particular, the cost to discern the literal acquisition cost of certain drugs will require significant administrative effort. Although not directly addressed in the plan amendment, the state agency's intention to use the JG and TB modifiers to identify 340B claims submitted to it will require major changes to hospital systems and retraining for staff because the purpose and logic will be different from what these modifiers signify for Medicare claims.

The costs hospitals will incur to comply with the state plan amendment are relevant to and informative of the adequacy of reimbursement established by the amendment and therefore must be considered.

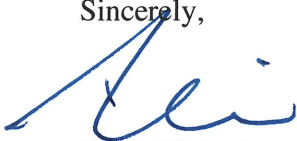
#### Effective Date

The proposed plan amendment is to be effective July 1, 2021. A July 1 effective date allows no time for hospitals to change policy, systems, and practices to comply with the new requirements. Further, the July 1 effective date does not allow the state agency sufficient time to promulgate the rules required to enforce the provisions of the plan amendment.

The effective date of the state plan amendment should be extended to a date that affords hospitals a fair opportunity to change their operations to comply with it and which allows the state agency the time it needs to promulgate the rules required by state law to effectuate this major program change.

Thank you for the opportunity to comment on the proposed state plan amendment.

Sincerely,



Brian Kinkade  
Vice President of Children's Health and Medicaid Advocacy

bk/dd