The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

May 4, 2023

Ms. Sally Kozak, MHA, RN
Deputy Secretary / State Medicaid Director
Department of Health and Human Services
Office of Medical Assistance Programs
515 Health & Welfare Building
Harrisburg, PA 17120

Via email to c-bstarr@pa.gov

Re: Hospital Concerns About the DHS Proposal for the 340B Drug Pricing Program – Dispensing 340B Purchased Drugs and Implmenting a 340B Drug Exclusion List

Dear Sally:

On behalf of Pennsylvania's 340B member hospitals, health systems, and other health care organizations, The Hospital and Healthsystem Association of Pennsylvania (HAP) welcomes the opportunity to comment on the Department's proposals for dispensing 340B purchased drugs in the Medicaid program and implementing a 340B Drug Exclusion List.

The hospital community also applauds the Department of Human Services (DHS) for seeking input on the implementation of a 340B Drug Exclusion List for the Medicaid Program, and convening a stakeholder group for robust discussion and information gathering in order to enable DHS to craft a dispensing process that complies with all federal requirements, while also considering the impact on Covered Entities (CE) that serve the most vulnerable populations in Pennsylvania.

While we appreciate the steps that DHS has taken to date, we are concerned that operational issues with the chosen solution will have a negative impact on the 340B Program providers and recipients.

This communication will detail hospital CE concerns and propose alternatives for your consideration before a solution is finalized.

Challenges with the DHS 340B Indicator Proposal for Dispensing 340B Purchased Drugs in the Pennsylvania Medicaid program

For managed care contract pharmacies, DHS is proposing that the billing provider identify 340B-purchased drug claims by including the NCPDP Telecommunication Standard's 340B indicator code on all applicable drug claims. This is operationally very difficult for pharmacies because they would need to identify 340B claims *at point of sale* in order to add the 340B indicator on the claim before it is submitted.

Most 340B contract pharmacy arrangements work on a retrospective basis, where a contract pharmacy sends billed claims to a third-party who matches those claims with a CEs eligible patient and prescriber lists to determine eligibility. Through a virtual inventory process, eligible drugs are then replenished at 340B prices. Since the claims are identified as 340B eligible *after the point of sale*, pharmacies would need to create and implement a new process, dedicate resources and training to rebilling all 340B claims to add the 340B indicator. This duplicate work would be operationally challenging, increase costs, and thereby reduce the 340B savings.

A related concern is with the timeframe allowed to complete the rebilling process; it is currently listed at 30 days. Hospitals are concerned that this is not long enough and the time required for rebilling would need to be at least 45-60 days.

Additionally, there is uncertainty about whether the large chain pharmacies would be willing to adopt a 340B indicator process. There is at least one example where that was tried in the past and those pharmacies elected to stop supporting the 340B program rather than adding the indicator.

Prior to implementing any program change, there should be 100 percent clarity on what the chain pharmacies will and will not do in order to properly gauge and account for the impact on Medicaid enrollees.

Finally, the DHS proposed effective date for implementing a 340B indicator process has been identified as July 1, 2023. Hospitals are concerned that this date does not allow enough time to complete the necessary education, training, and system changes required to operationalize whatever solution is finalized. As a result, hospitals respectfully request that the implementation date be moved to October 1, 2023, or later.

HAP Members Recommend a File Submission Appraoach

For contract pharmacy claims, hospitals recommend that DHS adopt the file submission process discussed with stakeholders during the 340B Workgroup meetings.

CEs would submit quarterly files of 340B claims to either DHS, the MCO, or a third-party designee. DHS would then exclude these claims from the rebate files. Many CEs are already submitting regular 340B claims data files as part of their various 340B processes and have become proficient at doing so.

The retroactive 340B claims file submission process used in Oregon could again serve as a model for Pennsylvania. In Oregon, the 340B entities that elect to carve-in Medicaid managed care submit claims data to the state that allows it to retroactively identify which claims were filled with 340B drugs and remove those claims from its rebate submissions. The required data fields for the Oregon method include: Medicaid ID, dispense date, NDC, Rx number, billing provider NPI, and prescribing provider NPI.

When Pennsylvania DHS did its pilot several years ago for contract pharmacy 340B Medicaid managed care, the Internal Control Number (ICN) field was problematic for matching. With the Oregon model, it has been reported that the ICN is not required since other data elements available to all parties are included in the claim submissions to the State instead.

With some renewed attention to making this approach work, Pennsylvania hospitals believe it would be a better solution than the modifier process DHS is currently proposing. We stand ready to continue the conversation at DHS' earliest convenience.

DHS Should Add Specific Language to HealthChoices PH Agreements to Guard Against Reimbursement Reductions Based on the Presence of a 340B Indicator

If DHS ultimately requires submission of a 340B claims indicator, which is not the hospital-preferred solution, at minimum, CEs would like DHS' commitment to protecting 340B savings, to include enforcement action to ensure that reimbursement price discrimination for 340B products does not result from the addition of a 340B indicator. Legislation had been proposed in the previous session that would have provided this protection.

Other states have passed legislation or taken other steps to protecting covered entities from this price discrimination. DHS moving forward with this proposal, without appropriate protections for covered entities, will result in pharmacy benefit managers and other market intermediaries benefitting heavily in the 340B discount, a discount intended for covered entities to stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services.

There is model language that has been used in other states to protect CEs from PBMs or third-parties using the indicator to reduce reimbursement.

For your convenience, **HAP is suggesting draft language for the Pharmacy Services section under Program Requirements for the HealthChoices Agreement is provided below:**

(A) No entity, including but not limited to a pharmaceutical manufacturer, shall deny, prohibit, condition, or otherwise limit the dispensing of drugs from a Pennsylvania-based pharmacy that receives drugs purchased under a contract pharmacy arrangement with a covered entity authorized to participate in the 340B program.

(B) No entity, including but not limited to a pharmaceutical manufacturer, may prohibit a Pennsylvania-based pharmacy from contracting or participating with a covered entity authorized to participate in the 340B program by denying access to drugs that are manufactured by any pharmaceutical manufacturer based on 340B participation

HAP also recommends the following additions to the Definitions section of the Health Choices Agreement:

(A) "A covered entity authorized to participate in the 340B program" means the same as "covered entity" as defined under Section 340B of the federal Public Health Service Act.

(B) "Pharmacy" means the same as defined in the Pennsylvania Pharmacy Act of 1961.

(C) "Dispensing" shall include a Pennsylvania-based pharmacy's entire distribution process from ordering drugs through the sale of those drugs, including ordering, purchasing, delivering, receipt, sale, and any other aspect that an entity may seek to deny, prohibit, condition, or otherwise limit.

Implementing a 340B Drug Exclusion List in the Pennsylvania Medicaid Program

Hospitals are concerned about the proposal to eliminate the ability of CEs to purchase certain high-cost drugs (Hemgenix, Kymriah, Luxturna, Zolgensma, Zynteglo) using 340B pricing. Not only are these products extremely expensive to purchase at wholesale acquisition cost (WAC), but they are also generally intended and procured for a single-patient and are time-intensive to operationalize given the need to closely coordinate approval, procurement, and administration for each patient.

Additionally, there are significant pharmacy costs and risks related to storage and preparation of these therapies that are not billed directly. As a result, CEs assume significant financial risk with these drugs. The assumption of this risk is only possible with the current 340B pricing.

Many studies have shown that the hospital community in Pennsylvania is under unprecedented financial strain as a result of the COVID-19 pandemic. Medicaid reimbursement has been significantly less than the cost of care for these patients for many years. Now is not the time to add to those challenges by making Medicaid program changes that take funding away from hospitals.

Given the important role of these 340B therapies for extremely complex patients and for the reasons noted above, **HAP recommends that DHS refrain from implementing a 340B Drug Exclusion List in the Pennsylvania Medicaid Program.**

Conclusion

Thank you again for the opportunity to comment on the Department's proposals to implement a 340B Exclusion List and a process for dispensing 340B purchased drugs in the Medicaid program.

HAP and the hospital community recognize the complexity of these efforts and strongly urge DHS to take additional time to ensure that the chosen solutions comply with federal law while still providing hospitals and other CEs the maximum benefit that they so greatly need during these financially challenging times. They are committed to serving 340B patients and look forward to a productive partnership with you to support this important program.

Please contact me if you have any questions.

Sincerely,

Jolene H. Calla, Esq.
Vice President, Health Care Finance and Insurance