



Department
of Health

340B Advisory Group

Meeting # 3

September 16, 2020

Agenda

- Advisory Group Timeline and Meeting #2 Recap
- Deeper Dialogue on the 340B Data Shared In Prior Meetings
- Initial Ideas Proposed for the Reinvestment of 340B Savings and Alignment with Advisory Group Charge
- Next Steps

Advisory Group Timeline and Meeting #2 Recap

Advisory Group Timeline

July 13th

- Announce 340B Advisory Group Membership



August 26th - Meeting 2

- Review group feedback and options for policy proposals
- Discuss potential recommendations that align with Advisory Group goals and objectives



Today



TBD - Meeting 4

- Further Discussion to discuss Advisory Group Recommendations



August 5th - Meeting 1

- Overview of Advisory Group timeline, process and charge
- Background on the 340B program and Federal/State requirements regarding FFS reimbursement of 340B claims
- Presentation of relevant 340B data in Medicaid
- Brainstorming/discussion of ideas

September 16th - Meeting 3

- Review any recommendations
- Discuss modifications and identify recommendations that align with Advisory Group goals
- Open discussion and next steps on implementation of pharmacy carve out

Meeting #2 Recap

- DOH outlined the savings associated with the 340B program as part of the FFS Pharmacy Carve Out, including the reinvestment of 340B savings (\$102 million) to Covered Entities in State Fiscal Year (SFY) 2021-22.
 - *The recommendations from the 340B Advisory Group will help determine the method by which the \$102 million is reinvested directly to Covered Entities.*
- 340B Advisory Members shared preliminary thoughts on recommendations for reinvesting 340B Savings
- DOH requested a short concept paper for recommendations from Advisory Group member(s) for discussion at the 3rd meeting

Deeper Dialogue on the 340B Data Shared In Prior Meetings

Initial Ideas Proposed for the Reinvestment of 340B Savings and Alignment with Advisory Group Charge

Advisory Group Charge

- The State and the legislature recognize that the 340B program is important to many safety net providers throughout the State. As such, the State Fiscal Year 2021-22 (April 1, 2021 – March 30, 2022) budget savings assume the transition of 340B reimbursement from the current reimbursement in Managed Care to the FFS reimbursement rate.
- In helping accomplish this goal, the 340B Advisory Group is charged with making recommendations to achieve savings on 340B eligible drugs in the FFS program

Recommendations that Advance Must:

- ✓ Achieve savings associated with 340B eligible claims starting in State Fiscal Year 2021-22
- ✓ Comply with federal requirements for pharmacy reimbursement of 340B eligible claims, per the Center for Medicare and Medicaid Services (CMS) Covered Outpatient Drug rule
- ✓ Be operationalized in a way that is practical for providers and is systemically supported
- ✓ Consider the viability of the most vulnerable safety net providers
- ✓ Ensure that consumers have continued access to medications

Initial Ideas for Reinvestment of 340B Savings to Covered Entities

Advisory Group members shared several concepts for reinvestment of 340B savings, including:

- 1. Reinvesting 340B Savings directly to Covered Entities through an existing or a new Medicaid funding pool**
- 2. Narrowing the network of pharmacies or providers to achieve savings while retaining 340B dollars for providers**
- 3. Explore a Federal Waiver**

(3a) Pursue a Federal Waiver to reinvest the savings achieved through the pharmacy carve out and 340B as basis for reinvesting savings directly to safety net providers; and

(3b) Pursue a Federal Waiver to seek modification of the FFS Reimbursement requirement of acquisition cost plus a professional dispensing fee for 340B eligible claims.

Idea 1: Reinvesting 340B Savings directly to Covered Entities through an existing or a new Medicaid funding pool

- The proposal to reinvest 340B savings through a new or existing supplemental payment pool is an established pathway that other states are exploring and/or implementing (e.g., California)
- The idea seemingly aligns with several guiding principles for Advisory Group recommendations:
 - ✓ *Achieves saving associated with 340B eligible claims starting in State Fiscal Year 2021-22 (assuming approval from CMS for Federal Financial Participation)*
 - ✓ *Feasibility of implementation for providers and DOH*
 - ✓ *Complies with federal requirements for pharmacy reimbursement (as this requires no change to the FFS reimbursement model)*
 - ✓ *Ensure that consumers have continued access to medications*
- Questions to be further explored:
 - *Provider eligibility in the pool and the allocation methodology to ensure that such approach considers the viability of the most vulnerable safety net providers*

Idea 2: Narrowing the network of pharmacies or providers to achieve savings while retaining 340B dollars for providers

- The idea to narrow the network of providers or pharmacies to achieve 340B savings is a proposal that other state Medicaid programs have implemented (albeit in a Managed Care environment).
 - *Most Medicaid Programs prohibit Contract Pharmacies in Managed Care*
- The idea aligns with some guiding principles for Advisory Group recommendations, including:
 - ✓ *Feasibility of implementation for providers and DOH*
 - ✓ *Complies with federal requirements for pharmacy reimbursement (assuming this requires no change to the FFS reimbursement model)*
- Questions to be further explored:
 - *How does this approach align with the transition of the pharmacy benefit to FFS ?*
 - *How would this approach create savings associated with 340B eligible claims starting in SFY 2021-22?*
 - *Are there any thoughts on how this approach would ensure that Medicaid consumers will have continued access to medications?*
 - *Does this approach consider the viability of the most vulnerable safety net providers, such as 340B providers that do not operate an in-house pharmacy program ?*

Idea 3a: Pursue a Federal Waiver to reinvest the savings achieved through the FFS Pharmacy Carve Out to support 340B Covered Entities

- The concept to pursue a Federal Waiver to reinvest savings from the FFS Pharmacy Carve Out to 340B Covered Entities could be feasible under the 1115 Waiver Authority, however DOH is not aware of any other State that has pursued or received approval for this type of waiver.
- Assuming CMS is willing to explore this type of demonstration, the concept would align with the Advisory Group principles to: consider the viability of the most vulnerable safety net providers and ensure that consumers have continued access to medications
- Questions to be further explored:
 - *How does this approach achieve saving associated with 340B eligible claims starting in SFY 2021-22 ?*
 - *How could this idea be structured in a way that implementation is both feasible and practical for providers and DOH?*
 - *Does this approach attempt to modify the federal requirements for FFS pharmacy reimbursement of 340B drugs?*
 - *How will this idea ensure that consumers have continued access to medications and consider the viability of the most vulnerable safety net providers ?*

Idea 3b: Pursue a Federal Waiver to seek modification of the FFS Reimbursement requirement of acquisition cost plus a professional dispensing fee for 340B eligible claims

- Similar to Idea 3(a), the concept to pursue a Federal Waiver to modify the CMS requirements to reimburse FFS 340B claims at acquisition cost plus a professional dispensing fee could be feasible, however DOH is not aware of any other State that has pursued or received approval for this type of waiver.
- Assuming CMS is willing to explore this type of demonstration, the concept would align with the Advisory Group principles to:
 - ✓ *Complies with federal requirements for pharmacy reimbursement*
 - ✓ *Considers the viability of the most vulnerable safety net providers; and*
 - ✓ *Ensure that consumers have continued access to medications*
- Questions to be further explored:
 - *How does this approach achieve saving associated with 340B eligible claims starting in SFY 2021-22?*
 - *How could this idea be structured in a way that implementation is both feasible and practical for providers and DOH ?*

Discussion

- Please share any additional feedback or details that should be considered for the idea's described on the previous four slides
- Please share any new ideas that have not yet been discussed with the Advisory Group

Next Steps

Next Steps

- In response to feedback from Advisory Group members, DOH will schedule an additional Advisory Group meeting to allow members more time to develop and discuss policy recommendations regarding the reinvestment of 340B savings.
- DOH staff continue to be available to provide technical assistance or feedback regarding the development of concept papers or recommendations.

Questions?