340B MDRP Virtual Summit
September 14-18, 2020
Talking Points – RADM Krista M. Pedley

Introduction

- Hello and thank you for the opportunity to address you all today. I first want to recognize the tireless efforts of the industry to combat the COVID-19 pandemic.
- In these unprecedented times, many of you are joining forces to find solutions to the challenges we face and are still able to maintain a commitment to the integrity of the 340B Program. You each play a vital role in this critical work, and for that, I want to say thank you.

340B Program & COVID-19

- I want to take some time to share some of our efforts related to the COVID-19 pandemic. We are thankful for the support and leadership of the Health Resources and Services Administrator, Tom Engels, throughout this pandemic. We do understand that 340B stakeholders are concerned about the evolving impact of the pandemic and the impact on program implementation and compliance.

- This is why we worked quickly to create a new webpage specifically for issues related to the COVID-19 pandemic, which is www.hrsa.gov/opa/COVID-19-resources. The webpage includes several FAQs that clarify flexibilities available to manufacturers and covered entities during the COVID-19 pandemic. We encourage all stakeholders to review the resources on the webpage on a regular basis as we update it with new information on an ongoing basis.

- Right now, bio/pharma industries have a critical role to fulfill and we want to ensure flexibilities to the extent possible. We encourage manufacturers participating in the Program to contact us if they have a specific circumstance where they believe their COVID-19 response may affect compliance in the 340B Program. Manufacturers can contact us at 340Bpricing@hrsa.gobv and we will provide targeted technical assistance that supports the unique situations of each manufacturer.

340B OPAIS Updates

- I want to now highlight some of the new features and enhancements that will soon be made available in the pricing component of the 340B Office of Pharmacy Affairs Information System (or 340B OPAIS).

- One key enhancement will provide manufacturers the opportunity to view notes from the Office of Pharmacy Affairs (OPA) regarding whether reconciled data was accepted or

rejected. This enhancement streamlines the flow of communication between OPA and the manufacturer during the adjudication process.

- Another enhancement enables the system to flag values that are mismatched between the data HRSA receives from CMS and First Databank during the manufacturer reconciliation process. This will ensure manufacturers are aware of any discrepancies and provide appropriate notes for all of the data they wish to submit.

- Additionally, OPA will soon have the ability to send NDC data back within the Pricing Component to a manufacturer for an additional opportunity to clarify a reconciliation. Currently, these requests happen outside of 340B OPAIS via email. When an NDC is returned for more information, a manufacturer will receive an email notification that is system generated to notify them of pending tasks. The back and forth functions will be available until the time of publication of the quarter's data.

- Also, inactive NDCs will no longer be published in the system and only active NDCs will be viewable to avoid confusion.

- Finally, the 340B Prime Vendor will now have the ability to impersonate a manufacturer user in the registration component of 340B OPAIS. This will allow the call center to assist more readily with manufacturer change requests and registrations. The prime vendor will not be able to submit any data in 340B OPAIS on behalf of a manufacturer nor will the prime vendor have access to any information in the pricing component of 340B OPAIS.

- These enhancements will be noticeable for the November pricing upload window that will publish Quarter 1, 2021 ceiling prices. HRSA will provide more education and information related to these new features as we near rollout and will ensure that all stakeholders are apprised of these changes.

<u>Pricing System Updates</u>

- As we move into completing seven full quarters of pricing adjudication, we continue to learn more and more about the about manufacturer reporting practices and CMS reporting requirements. Over the past year, we have captured important trends and learned important lessons in the pricing system.

- Communication between HRSA and our external stakeholders in relation to price reporting and price comparison practices has improved significantly. Manufacturers have expressed their appreciation to submit and verify a published 340B ceiling price that is accessible to authorized covered entities.

- Since implementation of the 340B OPAIS pricing component, HRSA has had a significant reduction in notifications of potential incorrect 340B prices in the market. The increased transparency in 340B pricing is significant for both covered entities and manufacturers. We

continue to use the system internally to monitor manufacturer compliance by performing regular spot checks of prices and any necessary follow-up on pricing errors/discrepancies.

- We continue to welcome your feedback on system improvements or on the user interface with the system. We will continue to enhance features as work is prioritized.

Program Integrity

- Now, I would like to spend time ensuring that you have the most up-to-date information related to program compliance – for manufacturers and covered entities.

- HRSA completed an evaluation of its audit process and other program integrity efforts as they relate to HRSA's ability to enforce and require corrective action in a Program that is primarily administered by guidance. HRSA's enforcement ability is limited, as guidance does not provide HRSA appropriate enforcement capability.

- We place the highest priority on the integrity of the 340B Program and continues to enforce the statute to the greatest extent possible.

- The Agency's audit process currently consists of reviews of the statutorily required program integrity elements, including eligibility, diversion and duplicate discount prohibitions. Though HRSA believes that its program policies are sound, HRSA is unable to enforce guidance unless there is a clear violation of the 340B statute. Therefore, we evaluate each audit and any non-compliance on a case-by-case basis to determine potential findings and violations of the statute. HRSA posts its audit findings on our public website where you can see the changes in audit findings that have occurred due to our l of enforcement capability.

- HRSA's limited enforcement capability is why we have requested regulatory authority in the President's Budget each year since FY 2017. Binding and enforceable regulations for all aspects of the 340B Program would provide HRSA the ability to more clearly define and enforce policy and would significantly strengthen HRSA's oversight of the Program.

- For manufacturers, in accordance with the statute, HRSA is required to collect information from manufacturers to verify the accuracy of 340B ceiling prices, and then make ceiling prices available to covered entities. Manufacturers should also ensure their information on the HRSA website is up-to-date and accurate. This information will assist covered entities that need to contact a manufacturer. It will also help HRSA to ensure it has the appropriate contact information to prepare for users that will be authorized to enter data into the pricing system.

- HRSA reviews and follows up on all allegations brought to its attention regarding manufacturer compliance; particularly that manufacturers are not charging covered entities at or below the 340B ceiling prices, and ensuring that manufacturers are treating 340B entities

as they do other customers. HRSA works with all parties involved to resolve the matters and ensure compliance.

- HRSA also has statutory authority to audit manufacturers, and HRSA conducted its first audit of manufacturers in FY 2015. The results of all finalized audits are posted on our website. As of August 14, 2020, HRSA finalized 24 audits of manufacturers (with one additional audit conducted with the assistance of the Office of the Inspector General – OIG) and plans to finalize two more audits in FY 2020. Finalized audit results are posted on our website.

Closing

- While we continue to provide oversight of the Program, our goal is to also provide the utmost flexibility, to the fullest extent possible to all stakeholders participating in the Program during this pandemic, while maintaining program integrity. We value and appreciate the work that is done to fight this pandemic. We are asking manufacturers to reach out to us if you have questions or concerns, as we want to hear from you about what is working and what we can do better to support all 340B stakeholders during this challenging time.

- I want to emphasize the importance of the stakeholders working with each other and the importance of transparency. We encourage all stakeholders, especially covered entities and manufacturers, to work in good faith on areas of concern as these efforts create the necessary transparency for the parties to resolve issues.

- We have continued to be proactive in our communication and outreach with stakeholders to enhance program compliance, relay the latest information about the program, and provide continuing education on the 340B Program. We have worked with our partners to identify gaps in resources and have subsequently developed an array of educational tools and resources for 340B Program stakeholders to support participants in implementing and maintaining a compliant 340B Program. Whether that displays on our website, in webinars, or working with the 340B Prime Vendor Program, education and communication remain our top priorities.

- We are here to work with you and I would encourage you to stay informed of the latest information by monitoring our website, including the COVID-19 Resources page, and working with other stakeholder groups to stay abreast of the latest information.

- I want to wish you a successful conference, and I look forward to continuing our work together on this important program.