



Current Federal 340B Issues

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As the 340B program continues to grow, Congress has taken an interest in how the program is run and how program integrity is assured. And, some in Congress have expressed concerns with 340B program oversight and structure. NAPH appreciates congressional interest in the program to ensure it is transparent and efficient. The association has been a strong advocate for the 340B program and will continue to work with Congress to ensure the program continues to help providers fulfill their safety net mission. In particular, we hope to work with Congress to ensure HRSA has the tools and resources it needs to oversee this complicated program.

Transparency of the Program

NAPH strongly supports greater transparency in HRSA's oversight of 340B – particularly transparency in the pricing of eligible drugs and efforts to ensure drugs are used in the appropriate setting. We urge Congress to give HRSA the appropriate resources to ensure transparency throughout the program. Any additional regulation implemented by HRSA should recognize the regulatory burdens already placed on hospital accountability.

Regulatory Oversight

Some policy makers have expressed concern about HRSA's oversight of the 340B program. NAPH agrees that the agency could provide better oversight, including issuing guidance through rulemaking procedures that include a notice and comment period.

Program Intent

Some have questioned the original intent of the 340B program and whether the program was intended to support individual patients or safety net providers. It is clear, however, that the intent of the 340B program was to provide savings to a diverse group of safety net providers (covered entities). In turn, these savings benefit patients treated by the provider. The Congressional record clearly indicates that Congress saw this as a discount applied to hospitals, otherwise a drug discount program that “followed the patient” would not have limited where a patient could access their prescriptions.

Patient Definition

HRSA has never issued formal guidance on who constitutes a “patient” for 340B program purposes. NAPH welcomes greater clarity from HRSA about the definition of a patient. We do not believe that HRSA should take any steps to significantly limit the definition of a patient from that which has been current practice.

Contract Pharmacies

Contract pharmacy arrangements were created to expand access to discounted drugs for low-income patients, and have been highly successful at doing so. Before these arrangements were available, 340B entities were limited to only one 340B pharmacy. For many NAPH member hospitals and health systems with large outpatient networks, this acted as a barrier to patients trying to obtain needed prescription drugs. The rule effectively required patients at an off-campus clinic to travel to the main hospital pharmacy - often a significant distance - to access discounted drugs. NAPH supports the development of guidance from HRSA on how to effectively manage contract pharmacies, but it must be done through the regular rulemaking process.

340B and Drug Shortages

Despite some claims to the contrary, there is no compelling evidence that the 340B program is in any way associated with drug shortages. The FDA has never found a connection between the 340B program and drug shortages. 340B drugs account for a minimal amount of the drugs sold throughout the country and, therefore have a minimal impact on the market. Because they account for such a small part of national drug sales, the sale of 340B drugs would not affect pricing in a way that could create a drug shortage. Further, most drug shortages are on generic injectable that are largely used on the inpatient side and therefore not 340B eligible. In addition, most generic drugs have prices that are at or lower than 340B prices, so 340B pricing does not apply.