340B Program – Manufacturer Inquiries and Audits

Health systems around the country are reporting increases in manufacturer 340B inquiries and audits in the past six months. The program continues to receive a lot attention both from the media and Congress, plus the anti-hospital billionaire groups (Arnold Ventures, Patient Rights Advocate, West Health) are making it part of their messaging as well.

The 340B Health System Coalition conducted an informal poll and learned that about half of our members have experienced an increase in manufacturer inquiries. Of those inquiries, three have escalated to an audit. From what we have been told, the inquiries themselves seem as intense as a manufacturer audit.

Administrative Dispute Resolution Process
This increase in inquiries and audits is apparently the result of the administrative dispute resolution (ADR) process recently fully implemented by HRSA. Not only do covered entities have more ways to ensure that drug makers adhere to 340B rules, but manufacturers also have more leverage against covered entities and can seek evidence up to a year of an event. The manufacturer inquiries seem to be targeting covered entities with large contract pharmacy networks, according to the information from our informal poll.

Manufacturers are emboldened by this new power afforded by the ADR process. Timelines for covered entities to provide data during inquiries and audits are short with no extensions allowed. Additionally, the new inquiries are more intense and seem worse than an HRSA audit. During an actual ADR process, they get up to a year to decide so they can continually collect information from the covered entity.

Alternative Distribution Models
Other changes leading to increased intensity by the manufacturers are the new and creative ways 340B entities purchase drugs as a 'work around' to the manufacturers' increasing restrictions on contract pharmacies. Many covered entities are turning to an Alternative Distribution Model. This is when the 340B replenishment drug is initially delivered directly to a covered entity pharmacy, then subsequently transferred to the contract pharmacy for dispensing. These arrangements carry varying levels of risk based on where the provider and pharmacy are located, and the type of license held by the covered entity.

This model has resulted in health systems increasing their savings – some reporting as much as doubling their savings over just a few months. However, manufacturers are now scrutinizing covered entities that have launched this new model. From the informal information we have gathered so far, most of the manufacturer inquiries have led to audits for those hospitals that have started an alternative distribution model.

Next Steps
We continue to welcome information on this topic and encourage Coalition members to contact me to discuss what is happening with your programs. We now plan to discuss the issue with both HRSA and interested Congressional staff. We are seeking clarification on a few key issues:

- What can happen if a covered entity misses the short deadlines set by the manufacturers?
    - What kind of authority do the manufacturers have under these audits and/or the ADR process?
- What is HRSA's authority to intervene into an ongoing audit?
    - Can the agency act as an intermediary during the inquiry or audit process?

Again, please email me if you have any questions or would like to discuss further. Thank you!

Devon