Medicaid and 340B: What Health Centers Should be Doing and Watching

September 2016

A growing number of States are seeking to implement policies that will dramatically reduce -- and in some cases eliminate -- Health Centers’ ability to retain 340B savings on drugs dispensed to Medicaid managed care patients. Also, a new Federal policy will eliminate 340B savings for all Medicaid fee-for-service patients.

1. Ensure that your health center senior leadership (CEO/CFO/Compliance Officer) have sound knowledge and understanding of the basic framework of the program. Knowledge of the program and compliance requirements is essential to provide context and a framework for informed discussion of the reimbursement policies. The NACHC 340B Manual is an excellent starting place.

2. Develop a detailed understanding of how Medicaid and 340B interact in your State. This understanding is critical to ensuring compliance, and to protecting Health Centers’ ability to retain savings on drugs provided to Medicaid managed care patients. The following are some questions you should be able to answer:

   - Are the costs of drugs included in Health Centers’ PPS rates? The costs of clinic administered drugs are included in Michigan Health Centers’ PPS rate. Is there a distinction between drugs that are dispensed versus those that are administered at the clinic? Dispensed drugs are not included in the Health Centers’ PPS rates.
   - Does Michigan require carve-in or carve-out, either at contract pharmacies, or more generally? The majority of Michigan Health Centers carve out FFS and carve in MCO. The few Health Centers that carve in FFS are only dispensing 340B drugs.
   - For what types of drugs does the state request a Medicaid rebate from manufacturers? Michigan requests a Medicaid rebate from manufacturers on FFS member medications.
   - What is Michigan’s current process for avoiding duplicate discounts (for ensuring that they don’t request a Medicaid rebate on a drug that was purchased under 340B)? Currently Health Centers are sending a quarterly report to MDHHS indicating if they are carve in or out for FFS and MCO and include all the NDC (National Drug Codes) for drugs dispensed as 340B to avoid duplicate discounts. One way this process could be strengthened is by indicating whether the medications are 340B on the claims. This process would increase efficiency and replace the need to track the quarterly reports.
• Are Health Centers fully aware of, and compliant with, all State policies and expectations re: 340B drugs and Medicaid? Make sure your Health Center has a specified staff dedicated to 340B compliance, policies, and expectations.

3. For drugs provided to fee-for-service patients:
  • Understand the new national reimbursement policy. In February 2016, CMS issued a final regulation that made many changes to the Medicaid drug rebate program. This rule states that for drugs provided to fee-for-service patients:
    o Reimbursement will equal the sum of two factors: the “ingredient cost” (the cost for the drug itself) and an “appropriate professional dispensing fee.”
    o The ingredient cost is limited to “actual acquisition cost” (AAC).
      ▪ For providers who participate in 340B, the AAC may be no higher than the 340B ceiling price. This means that the full savings associated with the 340B ceiling price will be passed on to the state.
      ▪ If a 340B provider negotiates a sub-ceiling price (i.e., a price less than the 340B ceiling price) the state may reimburse them at the sub-ceiling price. However, the state has the option to reimburse at the ceiling price, and let the 340B provider keep the difference.
    o The regulation does not establish specific dispensing fees, but indicates that these fees should reflect “the cost of the pharmacist’s professional services and cost to dispense the drug product to a Medicaid beneficiary.”

  • Know the timeline for the new reimbursement policy. States are required to implement these new rules effective April 1, 2017 (even though the deadline to submit their State Plan Amendments (SPA) outlining how they will implement is June 30, 2017). However, most states are already planning how they will implement them – so now is the time to work with the state, and other 340B providers, to influence these policies.

  • Work with your state Medicaid agency to:
    o Establish an appropriate professional dispensing fee. Like PPS rates, the fees that are established at the start will likely be in place for a long time. MDHHS collected information to inform an appropriate professional dispensing fee from all Medicaid pharmacy providers through a Michigan Medicaid Cost of Dispensing Survey in August 2016.
    o Enable FQHCs (& other 340B providers) to keep any difference between ceiling and sub-ceiling prices. Note that if Medicaid reimburses only the sub-ceiling price, there is no longer an incentive for Health Centers to negotiate sub-ceiling prices -- so the savings to Medicaid will be short-lived. In contrast, if Health Centers are allowed to keep these savings, they will continue to negotiate for them and invest them in valuable services to the community.

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1 “Medicaid Program: Covered Outpatient Drugs,” available at https://www.federalregister.gov/articles/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs

4. For drugs provided to managed care patients:

- **Understand recent changes around 340B and Medicaid managed care.** Prior to the Affordable Care Act (ACA), states could seek Medicaid rebates only on drugs dispensed under fee-for-service. However, the ACA expanded the Medicaid drug rebate program to managed care. As a result, both states and FQHCs are currently entitled to seek discounts on drugs dispensed to managed care patients - but only one discount is permitted. **There is no official policy on who gets the discount – the state or the 340B provider** – so this has created a tension which is playing out differently in every state.

  *In other states, we are seeing the state Medicaid agency take steps that ensure that they receive the full benefit of the savings associated with drug discounts for managed care patients.* This is occurring in many ways, such as:

  - The state requires all 340B providers to carve-out Medicaid, so there are no 340B savings. This can be done just for contract pharmacies, or across-the-board.
  - The state permits carve-in, but reimburses the 340B provider only its actual acquisition cost, so the benefits of the 340B price are passed directly to the state.

  In addition, some managed care plans are taking steps that effectively direct the 340B savings to their plan. For example, the managed care plan may refuse to contract with providers who carve in, or reimburse providers only at actual acquisition cost.

- **Make it easy for your state to avoid duplicate discounts.** Beyond the financial incentive, there is an important administrative reason why states are interested in requiring 340B providers to carve-out managed care – it reduces their workload by eliminating the need to avoid duplicate discounts.

  Duplicate discounts (seeking a Medicaid rebate for a drug purchased under 340B) are clearly prohibited by the statute, and the official responsibility for compliance rests with States and MCOs. To meet this responsibility, the state must determine which drugs were purchased under 340B, and remove them from the list of drugs for which they request rebates from manufacturers. States can avoid this administrative work– and enhance compliance with the statute – by requiring 340B providers to carve-out Medicaid. The more complicated it is for them to avoid duplicate discounts, the greater the administrative incentive to require carve-out.

  Thus, it is in Health Centers’ best interests to work directly with MDHHS to make it as easy as possible for them to avoid duplicate discounts, as this will decrease their incentive to require carve-out. MPCA is working with NACHC to prepare information on approaches that will decrease the administrative burden on the state while ensuring compliance.

- **Be prepared to respond quickly to proposed changes.** Our first meeting with MDHHS is on October 5, at which time we will learn more of the process in Michigan and timeline for complying with the new regulations. If changes are proposed, you may have a very small window to respond. That is why it is important to fully understand how 340B and Medicaid managed care interact for your Health Centers. (See #1 and #2 above.)