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GAO Recommends Improvements to 340B Contract Pharmacy Oversight

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The Government Accountability Office (GAO) issued a report on June 28, 2018 regarding federal oversight of compliance at 340B program contract pharmacies. The 340B drug pricing program requires drug manufacturers to sell outpatient drugs at discounted rates to certain public and non-profit hospitals that treat high volumes of low-income patients or are located in rural areas and other safety net providers that receive federal grant funding.

Under guidance issued by the Health Resources and Services Administration (HRSA), 340B providers can contract with community pharmacies to dispense 340B-discounted drugs to patients of a 340B provider on the provider's behalf.

The report, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," was issued in response to a request by the House Energy and Commerce (E&C) Committee Republicans.

The request follows the Committee's investigation into the 340B program last year that included two oversight hearings and the release of a report earlier this year recommending legislative and administrative changes to the program. Media reports have indicated the Committee plans to hold another 340B hearing this summer to review proposed 340B legislation.

The Senate Health, Education, Labor, and Pensions (HELP) Committee also held three hearings on 340B this year and is considering whether to pursue legislative changes to the program.

Key Findings

GAO collected written responses from 55 covered entities, including 28 hospitals and 27 grantees, and interviewed ten of the 55 entities for additional information. GAO also reviewed 30 contracts (15 hospitals and 15 grantees). GAO found:

- About one-third of covered entities had one or more contract pharmacies to dispense 340B drugs on their behalf;
- 30 of the 55 covered entities reviewed provided discounts on 340B drugs to low-income, uninsured patients at some or all of their contract pharmacies. Of these, 23 passed on the full 340B discount to patients. Federal grantees were much more likely than hospitals to provide discounts. A number of covered entities that reported not providing discounts through their contract pharmacies nevertheless reported providing discounts through other means, such as in-house pharmacies; and
- Of the 30 contracts reviewed by GAO, all but one included a flat fee per prescription, ranging from $6 – 15. In addition, 13 contracts also agreed to pay pharmacies a percentage of revenue generated by each prescription. Flat fees varied widely across contracts and among different products. For example, two contracts contained substantially higher flat fees for specialty medications: in one, the flat fees were $125 per prescription for brand and generic HIV drugs and $1,750 for brand HCV drugs.

GAO also made a series of findings related to HRSA's oversight of contract pharmacies and identified the following weaknesses that, according to GAO, prevent HRSA from ensuring compliance at 340B contract pharmacies:

- HRSA does not have sufficient data to conduct oversight of contract pharmacies;
- HRSA's audit process does not evaluate Medicaid managed care duplicate discounts;
- HRSA does not direct covered entities how far back in time they must look for related noncompliance in order to close an audit;
- HRSA allows covered entities to self-attest that they have addressed all audit findings in order to close an audit; and
- HRSA's guidance on oversight that covered entities must conduct of their contract pharmacies "lacks specificity."

GAO found that, "Given these weaknesses, HRSA does not have a reasonable assurance that covered entities have adequately identified and addressed noncompliance with 340B Program requirements."

Recommendations

The GAO made seven recommendations to HRSA to improve oversight of 340B contract pharmacies:

1. The Administrator of HRSA should require covered entities to register contract pharmacies for each site of the entity for which a contract exists;
2. The Administrator of HRSA should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with Centers for Medicare and Medicaid Services as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs;
3. The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities;
4. The Administrator of HRSA should issue guidance on the length of time covered entities must look back following an audit to identify the full scope of noncompliance identified during the audit;
5. The Administrator of HRSA should require all covered entities to specify their methodology for identifying the full scope of noncompliance identified during the audit as part of their corrective action plans, and incorporate reviews of the methodology into their audit process to ensure that entities are adequately assessing the full scope of noncompliance;
6. The Administrator of HRSA should require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits, including documentation of the results of the entities' assessments of the full scope of noncompliance identified during each audit; and
7. The Administrator of HRSA should provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight.

Implications for Stakeholders

GAO's recommendation that HRSA improve oversight of 340B contract pharmacies is consistent with other recent recommendations related to the 340B program. E&C Committee Chairman Greg Walden (R-OR) and Health Subcommittee Chairman Michael Burgess (R-TX) issued a press release touting the GAO report's release, highlighting the Committee's January 2018 report finding insufficient program oversight. The chairmen stated, "It is clear that we must continue to examine how this program is working with the goal of ensuring the program properly enables safety net providers to truly help patients in need."

Changes to the 340B program enacted by Congress or the Administration in response to these recommendations could significantly impact hospitals' use of the 340B program and access to savings. For example, requirements that providers must pass the 340B discount to low-income, uninsured patients could limit how providers are able to use their program savings. Implementation of mechanisms to prevent Medicaid managed care duplicate discounts could affect hospitals' ability to use 340B for Medicaid managed care patients. Changes to the HRSA audit process could affect repayments required to manufacturers as a result of audit findings.

Baker Donelson will continue to monitor Congressional and administrative activity related to the 340B program. The Administration is currently soliciting feedback from the public on whether growth in the 340B program has caused higher drug prices. Comments are due July 16, 2018. See Baker Donelson's alert, HHS Solicits Comments on Possible 340B Program Changes to Reduce Drug Prices. Baker Donelson policy advisors and attorneys are available to assist clients with the drafting of comments.

If you have questions regarding the content of this alert, please contact Nicole D. Carelli or any member of Baker Donelson's Government Relations and Public Policy Group.