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Department of Health and Human Services (HHS) Office of Inspector General (OIG) Reports Findings on 340B Contract Pharmacy Program

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Program often fails to pass through savings to uninsured patients and creates risk of diversion and duplicate discounts.

As a condition of payment for covered outpatient drugs by Medicaid, manufacturers must enter into a contract with the Department of Health and Human Services (HHS) to sell their drugs to eligible safety net hospitals and clinics, called “covered entities,” at a deeply discounted statutory price, referred to as the 340B price after the section of the Public Health Service Act that created this program.[1] In order to make it easier for patients of covered entities to receive 340B drugs, the Health Resources and Services Administration (HRSA) permits covered entities to contract with outside pharmacies to dispense prescriptions on behalf of the covered entities.[2] On February 4, 2014, the HHS Office of Inspector General (OIG) issued a report of its review of the 340B contract pharmacy program.[3]

The OIG Report includes four key findings:

- The contract pharmacy program has increased the volume of drugs purchased by covered entities at 340B prices, but has frequently failed to provide discounted drugs to uninsured patients.
- The complicated arrangements between covered entities and outside pharmacies make it more difficult for covered entities to comply with the statutory prohibition against diversion of 340B drugs, i.e., providing 340B drugs only on an outpatient basis to persons who are eligible patients.
- The arrangements also create risk of noncompliance with the statutory requirement that covered entities prevent duplication of discounts when the drugs are paid for by the Medicaid program and subject to manufacturer rebates.
- Most covered entities do not conduct all the oversight activities recommended by HRSA.

Since HRSA dramatically expanded the contract pharmacy program in 2007, the pharmaceutical industry has expressed concerns about the program's lack of controls intended to prevent diversion and duplicate discounts; the OIG Report echoes those concerns.

Report Findings

Uninsured Patients

The 340B discounts were intended to help covered entities reduce costs and use the savings to provide more care to indigent and uninsured patients. Covered entities are also allowed to generate profits from the sale of 340B drugs to insured patients in order to help uninsured patients access needed medication. However, that fundamental program goal is not always being achieved under the contract pharmacy program. According to the OIG Report, a majority of contract pharmacies dispense prescriptions from their own stock and adjudicate managed-care claims at the point of sale, and then determine after the pharmacy has been paid by the customer and third-party payer whether the dispensed drugs need to be replenished with 340B drugs.[4] In this claim adjudication model, the OIG Report notes, unless a patient has a pharmacy benefit card from the covered entity, which would necessitate adoption of cumbersome and costly procedures, an uninsured cash-paying customer will not be identified as a patient of that covered entity until after the transaction is complete and the patient has paid the contract pharmacy's undiscounted rate.[5] Additionally, pharmacies must be willing to charge a discounted price for drugs dispensed to uninsured patients.[6] To date, many retail pharmacies have been unwilling or unable to adapt their operations to recognize and honor covered entities' patient assistance programs.

The irony of the contract pharmacy program is that it is supposed to make it more convenient for patients of covered entities to access 340B drugs, but that does not mean that pharmacies provide such patients with discounts on drugs purchased under the 340B program. Insured patients of covered entities do not benefit from 340B prices when their prescriptions are filled by contract pharmacies—health plans pay pharmacies the rate established by agreement between the plan or its pharmacy benefit manager and the pharmacy. And though uninsured patients often receive free or discounted drugs from covered entities' in-house pharmacies, retail pharmacies typically charge cash payers a higher rate than their insured customers. Consequently, the most vulnerable patients of covered entities may pay more when they take their prescriptions to their neighborhood pharmacies.

Passing through 340B savings to uninsured patients can create operational challenges for contract pharmacies; these pharmacies are also commercial ventures and may have little business reason to adjust their operations to identify 340B prescriptions before the drugs are dispensed. Pharmacies often participate in this program only to the extent that the administrative fee or share of the resale price for 340B drugs (deducted from the amount remitted to the covered entity) is more profitable than the sale of their own stock. For example, contract pharmacy arrangements sometimes omit prescriptions of generic drugs because the retail margin over cost is greater than brand drugs. As a result, the parties to contract pharmacy arrangements may profit more on the resale of 340B drugs to an uninsured patient than they would on the resale to a patient covered by insurance, which pays the pharmacy a lower negotiated rate.

Diversion

A covered entity may provide 340B drugs only to its patients. Although this statutory provision seems simple, the point at which a person is considered a patient is not clearly understood. The OIG Report

found significant discrepancies regarding prescriptions written by medical professionals not on the covered entity's staff or under contract, prescriptions written for medication unrelated to a patient's treatment, and the length of time after a patient encounter that a covered entity will consider a prescription eligible to be filled with 340B drugs.[7] Some covered entities consider prescription refills eligible for a year after the initial encounter. Unless the definition of a patient is tightened up, covered entities can effectively become dispensers of chronic care drugs through contract pharmacies, earning significant revenue from their patients' medications for long periods of time and taking business from traditional pharmacies.

Duplicate Discounts

Both Medicaid fee-for-service and managed-care plans pay pharmacies for drugs dispensed to their beneficiaries on an outpatient basis; the states also collect rebates from manufacturers on those prescriptions. The 340B statute requires covered entities to ensure that rebates are not paid on the discounted drugs they purchase under the program.[8]Otherwise, manufacturers can pay triple discounts: a discounted purchase price to the covered entity, a base rebate to Medicaid, and an additional rebate to the Medicaid managed-care organization or a supplemental rebate to the state Medicaid program. This combination of discounts and rebates could easily create a below-cost sale for the manufacturer. According to the OIG Report, however, many contract pharmacies cannot determine when a managed-care plan is covering a Medicaid patient of a covered entity, and thus replenish such prescriptions with 340B drugs without notifying the state.[9] Others notify the state when they dispense 340B drugs to Medicaid beneficiaries but lack a method to prevent duplicate discounts. As a result, a significant percentage of Medicaid prescriptions are being subjected to double and triple discounts.

The OIG Report notes that some covered entities instruct their contract pharmacies to use the covered entity's unique number when adjudicating Medicaid prescriptions to enable the states to locate the covered entity in HRSA's database and identify 340B utilization to be excluded from rebate claims.[10] Requiring the use of these identifiers in connection with all 340B patient prescriptions would help prevent duplicate discounts and enable manufacturers to verify claims. As discussed below, it would also prevent improper inclusion of 340B utilization in rebate claims submitted to the Department of Defense (DoD) under the Tricare program and could facilitate enforcement of duplicate discounts provisions in Medicare Part D agreements. However, covered entities and contract pharmacies do not like to use identifiers because pharmacy benefit managers that can identify 340B prescriptions may want to use their leverage to reduce their health care plans' costs and insist on paying less for the discounted drugs.

Concerns Not Addressed in the Report

Orphan Drug Rule

The Affordable Care Act expanded the number of covered entities eligible to purchase 340B drugs by adding several new categories of hospitals to the list of covered entities in section 340B, and at the same time, for those newly eligible entities, excluded drugs designated as orphan drugs under section 526 of the Federal Food, Drug, and Cosmetic Act from the program.[11] In 2013, HRSA promulgated a final rule that significantly limited the application of this statutory provision by interpreting it as limited to purchases of drugs designated as orphan drugs only when the hospitals use them for orphan indications.[12]Hospitals subject to the rule have to develop system controls to ensure that they can identify and segregate purchases of 340B drugs by treatment in order for the

exclusion to apply. Industry comments on the rule raised issues presented by contract pharmacy arrangements because prescription data needed to identify 340B patients typically does not include diagnosis or procedure codes indicating an orphan or non-orphan indication. The OIG apparently did not review whether newly eligible hospitals' contract pharmacies could determine whether drugs they dispense are used to treat an orphan disease or condition, which would make the drugs ineligible for 340B prices.

Tricare Retail Pharmacy Regulation

Pursuant to 32 C.F.R. § 199.21(q), DoD is entitled to mandatory rebates on prescriptions of innovator drugs dispensed by retail pharmacies within the Tricare network, except for prescriptions filled with 340B drugs. This prohibition against duplicate discounts is thus established by DoD regulation, rather than the 340B statute. Nevertheless, transactions with covered entities are by law excluded from Tricare rebate claims. Unlike the 340B statute, the Tricare regulation imposes no obligation on covered entities to ensure that they are notifying DoD when 340B drugs are dispensed to Tricare beneficiaries. As a result, Tricare cannot identify when a prescription adjudicated by a retail pharmacy is dispensed on behalf of a covered entity, and manufacturers usually lack data to dispute the Tricare claim. Use of an identifying number on prescriptions, as some pharmacies are doing with Medicaid managed-care organizations, would resolve this issue.

Conclusion

The OIG Report exposes multiple problems with the contract pharmacy program, which has expanded the 340B program beyond the borders of participating institutions and grown exponentially over the last three years.[13] Although HRSA created this program to make it more convenient for patients of covered entities to get their medications at neighborhood pharmacies, there has never been a restriction on which pharmacies can dispense prescriptions generated by these hospitals and clinics. Moreover, the only patient benefit to receiving drugs that were purchased under the 340B program is if the contract pharmacy arrangement provides the drugs to the patients at a discount. However, insured patients pay the same rate to a pharmacy regardless of whether the pharmacy is dispensing 340B drugs, and, unfortunately, as the OIG Report found, uninsured patients often receive no discount on drugs purchased under the 340B program when dispensed by contract pharmacies. The OIG Report also revealed compliance problems that have been the subject of pharmaceutical industry concerns for many years. Some of these issues could be resolved if unique covered entity identifiers were required to be included in the prescription data when 340B drugs are dispensed, and if this data were available to the contract pharmacy administrator, Medicaid, Tricare, and manufacturers that need to validate rebate claims.

In the meantime, covered entities remain responsible for contract pharmacy compliance with the 340B program. Accordingly, those participating in contract pharmacy arrangements should consider the adequacy of their oversight and ensure that they have robust policies and procedures in place. In addition, covered entities may wish to consider how they can work with contract pharmacies to implement the covered entity's pharmacy assistance program for indigent and uninsured patients and to enlist HRSA's help by including a requirement to provide such assistance to these patients as an element of the contract pharmacy program.

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[1]. 42 U.S.C. § 1396r-8(a)(5); 42 U.S.C. § 256b.

[2]. 75 Fed. Reg. 10,272 (Mar. 5, 2010)

[3]. *Contract Pharmacy Arrangements in the 340B Program* (OIG Report), OEI-05-13-00431

[4]. *Id*. at 5.

[5]. *Id.* at 14. If covered entities identify 340B prescriptions as written, contract pharmacies can charge a discounted price if they are willing to do so.

[6]. *Id.* The OIG Report found that about half of the covered entities in the OIG's survey offered discounted 340B prices to uninsured patients in at least one of their contract pharmacy arrangements, suggesting that only certain pharmacies are willing to do offer a discounted rate. Some of these charge uninsured patients on a sliding-scale basis.

[7]. *Id.* at 9–12.

[8]. 42 U.S.C. § 256b(a)(1)(5).

[9]. *Id.* at 13.

[10]. *Id*. at 13–14.

[11]. 42 U.S.C. § 256b(e).

[12]. 78 Fed. Reg. 44,016 (July 23, 2013).

[13]. From March 5, 2010 to May 31, 2013, the number of unique pharmacies participating in the program has increased by 770% and the total number of contract pharmacy arrangements has increased by 1,245%. OIG Report at 2.

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