DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

FEB 04 2014

TO: Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

/S/

FROM: Stuart Wright
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431

This memorandum report describes selected covered entities' contract pharmacy arrangements and their oversight of those arrangements to prevent (1) diversion of drugs purchased through the 340B Drug Pricing Program to ineligible patients and (2) duplicate discounts through Medicaid.

SUMMARY

Covered entities participating in the 340B Drug Pricing Program (hereinafter referred to as the 340B Program) may contract with pharmacies to dispense drugs purchased through the program (hereinafter referred to as 340B-purchased drugs) on their behalf. Such pharmacies are referred to as contract pharmacies.

According to Health Resources and Services Administration (HRSA) guidance, covered entities that establish contract pharmacy arrangements must oversee these arrangements to prevent diversion of 340B-purchased drugs to ineligible patients and duplicate discounts through Medicaid. Diversion and duplicate discounts are statutorily prohibited. HRSA guidance recommends that covered entities' oversight activities include periodic comparisons of covered entity records and contract pharmacy records, as well as annual independent audits.

We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. The covered entities that we reviewed in our study use different methods to identify 340B-eligible prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility across covered entities. That is, two covered entities may categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract

pharmacy arrangements. As a result, there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.

We also found that contract pharmacy arrangements create complications in preventing duplicate discounts. Most covered entities in our study prevent duplicate discounts by not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies, though difficulties exist with identifying beneficiaries covered by Medicaid managed care organizations (hereinafter referred to as MCO Medicaid). However, some covered entities that *do* dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

Additionally, we found that some covered entities in our study do not offer the discounted 340B price to uninsured patients at their contract pharmacies. Neither the 340B statute nor HRSA guidance addresses whether covered entities must do so; however, if covered entities do not, uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies.

Finally, we found that most covered entities in our study do not conduct all of the oversight activities recommended by HRSA. Although almost all covered entities reported monitoring their contract pharmacy arrangements, the extent of such monitoring varies. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.

BACKGROUND

Although the majority of covered entities do not use contract pharmacies, the use of contract pharmacies has increased rapidly over the past few years. Since 2010, the percentage of all covered entities that use contract pharmacies has risen from 10 percent to 22 percent. Moreover, the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent.[1]

Additionally, recent HRSA audits of covered entities have found instances of diversion and duplicate discounts related to contract pharmacies. Of the 32 covered entities for which finalized HRSA audits resulted in adverse findings, 10 were cited for diversion and/or duplicate discounts through contract pharmacies.[2]

The 340B Drug Pricing Program

[1] Office of Inspector General (OIG) analysis of HRSA's covered entity database, June 2013. These growth figures reflect calculations between March 5, 2010, and May 31, 2013. Covered entities may have multiple health care delivery sites (represented by "parent" and "child" records in the database) as well as multiple contract pharmacies. To account for this complexity and avoid duplicate counting, we have defined a contract pharmacy arrangement as a unique association between a pharmacy and a covered entity "parent" record, and have attributed all contract pharmacies associated with "child" records to their "parent" records. Throughout this report, counts of covered entities represent unique "parent" records.

[2] Results of HRSA's 340B Program audits as of January 8, 2014. Accessed at http://www.hrsa.gov/opa/programintegrity/auditresults/results.html on January 13, 2014.

The Veterans Health Care Act of 1992 established the 340B Program in section 340B of the Public Health Service Act (PHS Act).[3] The 340B Program requires drug manufacturers participating in Medicaid to provide discounted covered outpatient drugs to certain eligible health care entities, known as covered entities. Congress intended for the savings from 340B-purchased drugs "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] However, the 340B statute speaks only to covered entities' eligibility and compliance; it does not specify how savings from the 340B Program should be used.

Covered entities include community health centers and disproportionate share hospitals (DSHs), among other provider types.[5] As of May 31, 2013, 10,510 covered entities were participating in the 340B Program, including 1,103 community health centers and 1,039 DSHs.[6, 7]

To participate in the 340B Program, covered entities must register with HRSA, the agency responsible for administering the program. HRSA adds covered entities to its database after receiving and approving their registration forms. Covered entities must annually sign an agreement certifying that they meet 340B Program requirements and that their information in the database is correct.[8]

Once approved, covered entities may purchase covered outpatient drugs under the 340B Program at or below the 340B ceiling price.[9] 340B ceiling prices are calculated using a statutorily defined formula. Drug manufacturers that participate in Medicaid must sell covered outpatient drugs to covered entities at or below the 340B ceiling price.[10]

Prohibition of diversion. Covered entities may dispense 340B-purchased drugs only to eligible patients. According to HRSA's patient definition, an individual is an eligible patient "only if:

(1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
(2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for a consultation) such that responsibility for the care provided remains with the covered entity; and

[3] Veterans Health Care Act of 1992, P.L. 102-585 § 602; PHS Act § 340B; 42 U.S.C. § 256b.
[4] H.R. Rep. No. 102-384 (Part 2), at 12 (1992)(Conf. Rep.).
[5] 42 U.S.C. § 256b(a)(4) enumerates the complete list of the types of entities eligible to become covered entities.
[6] OIG analysis of HRSA's covered entity database, June 2013.
[7] References to community health centers include all covered entities in HRSA's covered entity database of the entity type Consolidated Health Center Program, which covers some additional providers. See http://opanet.hrsa.gov/OPA/CoveredEntityAcronyms.aspx.
[8] 42 U.S.C. § 256b(d)(2)(B)(i).
[9] 42 U.S.C. § 256b(a)(1).
[10] 42 U.S.C. §§ 1396r-8(a)(1) and 256b(a)(1).

(3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. DSHs are exempt from this requirement."[11]

Dispensing 340B-purchased drugs to ineligible patients, a practice known as diversion, is prohibited by law.[12]

Prohibition of duplicate discounts. Subjecting drug manufacturers to duplicate discounts on 340B-purchased drugs is prohibited by law.[13] Duplicate discounts occur when a drug manufacturer pays a State Medicaid agency a rebate under the Medicaid drug rebate program on a drug sold at the already-discounted 340B price.[14] The risk of duplicate discounts applies to MCO Medicaid as well as traditional fee-for-service Medicaid (hereinafter referred to as FFS Medicaid) in States where drug manufacturers are paying rebates on drugs dispensed through MCO Medicaid.[15, 16]

Covered entities choose whether to dispense 340B-purchased drugs to Medicaid beneficiaries. Covered entities indicate their choice in HRSA's covered entity database. State Medicaid agencies use this information to identify Medicaid payments for 340B-purchased drugs and exclude those drugs from rebate requests to drug manufacturers.[17]

340B Contract Pharmacies

Covered entities may contract with one or more pharmacies to dispense 340B-purchased drugs on their behalf.[18] A pharmacy dispensing 340B-purchased drugs on behalf of a covered entity is referred to as a contract pharmacy.[19]

---

[11] 61 Fed. Reg. 55156, 55157–55178 (October 24, 1996).
[12] 42 U.S.C. § 256b(a)(5)(B).
[13] 42 U.S.C. § 256b(a)(5)(A)(i).
[14] Under the Medicaid drug rebate program, drug manufacturers are required to pay rebates to State Medicaid agencies, which are calculated using a statutorily defined formula, for most covered outpatient drugs. 42 U.S.C. § 1396r-8.
[15] In general, MCO Medicaid differs from FFS Medicaid in that State Medicaid agencies prospectively pay managed care organizations a fixed monthly amount to provide care to beneficiaries, rather than paying providers directly for care provided to beneficiaries. See 42 U.S.C. § 1396b(m).
[16] Beginning in March 2010, drug manufacturers that participate in the Medicaid drug rebate program were required to pay rebates for covered outpatient drugs dispensed to individuals enrolled in MCO Medicaid if the managed care organization is responsible for coverage of such drugs. 42 U.S.C. § 1396r-8(b)(1)(A). Covered outpatient drugs dispensed through MCO Medicaid and subject to discounts under the 340B Program are not subject to rebates under the Medicaid drug rebate program. 42 U.S.C. § 1396r-8(j)(1). However, a previous OIG report found that not all States are collecting rebates on drugs dispensed through MCO Medicaid. OIG, *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations*, OEI-03-11-00480, September 2012.
[17] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.
[18] 75 Fed. Reg. 10272, 10277 (March 5, 2010).
[19] Covered entities may dispense 340B-purchased drugs through in-house pharmacies instead of or in addition to contract pharmacies.

Contract pharmacy inventory models. Contract pharmacy arrangements generally use one of two distinct inventory models: the pre-purchased inventory model or the replenishment inventory model.[20]

In the pre-purchased inventory model, the covered entity's 340B-purchased drugs are kept in stock at the contract pharmacy. When filling prescriptions on behalf of the covered entity, the contract pharmacy uses the covered entity's 340B-purchased drugs. When filling other prescriptions, the contract pharmacy uses its own non-340B-purchased drugs.

In the replenishment inventory model, no 340B-purchased drugs are kept in stock at the contract pharmacy. When filling prescriptions on behalf of the covered entity, the contract pharmacy uses its own non-340B-purchased drugs. When a sufficient quantity of a given drug has been dispensed on behalf of the covered entity, the covered entity purchases that quantity of the drug at the discounted 340B price and has it delivered to the contract pharmacy. This order of 340B-purchased drugs thus replaces or "replenishes" the non-340B-purchased drugs originally dispensed on behalf of the covered entity.

Contract pharmacy arrangements using the replenishment inventory model generally use computerized tracking systems because the prescribed quantity of a drug rarely matches the quantity by which the drug is ordered. For example, a drug may be prescribed in quantities of 30 pills but ordered in quantities of 100 pills. Thus, a replenishment order of 340B-purchased drugs can be placed only after the contract pharmacy has filled four prescriptions for the drug (i.e., dispensed a total of 120 pills) on behalf of the covered entity. This order replaces 100 of the 120 pills dispensed on behalf of the covered entity, leaving 20 pills awaiting replenishment. Covered entities often hire companies known as 340B administrators (hereinafter referred to as administrators) to manage these tracking systems.

Contract pharmacy billing process for insured patients. When contract pharmacies dispense 340B-purchased drugs to patients with health insurance, they bill health insurers for the 340B-purchased drugs dispensed. Pharmacies send insurance claims for dispensed drugs to electronic transaction routing companies, which forward the claims to the correct insurers. The routing companies use a combination of two codes from the insurance claims—the Bank Identification Number and Processor Control Number (hereinafter referred to as BIN/PCN)—to identify a patient's health insurer and benefits.[21]

[20] OIG analysis of interviews with covered entities and administrators, 2013.
[21] National Council for Prescription Drug Programs. *Explanation of BIN/PCN*. Accessed at http://www.ncpdp.org/pdf/ExplanationofBIN.PCN.pdf on October 25, 2013.

Covered Entity Oversight of Contract Pharmacy Arrangements

Covered entities must ensure that their contract pharmacy arrangements comply with the 340B statute and relevant HRSA guidance.[22, 23] In guidance, HRSA generally directs covered entities to:[24]

(1) ensure that contract pharmacy arrangements prevent diversion of 340B-purchased drugs to ineligible patients;
(2) ensure that contract pharmacy arrangements do not result in duplicate discounts; and
(3) conduct oversight of contract pharmacies to detect and remedy any instances of diversion, duplicate discounts, or other program violations.

HRSA has announced plans to issue formal regulations that will address program elements, including its patient definition and contract pharmacy arrangements.[25]

Preventing diversion in contract pharmacy arrangements. To prevent diversion, covered entities identify which prescriptions filled at their contract pharmacies will be categorized as 340B-eligible (hereinafter referred to as 340B-eligible prescriptions). Covered entities and their contract pharmacies may dispense 340B-purchased drugs only to individuals who meet all applicable components of HRSA's patient definition. Such individuals can, however, fill any of their prescriptions at a covered entity's contract pharmacy—not just those that originate from the covered entity. As a result, if a covered entity does not consider *all* prescriptions for an individual to be 340B-eligible, then in practice the covered entity will have to determine 340B eligibility at the prescription level. Administrators often assist covered entities in identifying 340B-eligible prescriptions.

Preventing duplicate discounts in contract pharmacy arrangements. To avoid duplicate discounts in contract pharmacy arrangements, HRSA presents covered entities with two options:

(1) not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies; or
(2) dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies, and making an arrangement with the State Medicaid agency to prevent duplicate discounts. HRSA guidance notes that covered entities should inform HRSA of any such arrangement.[26]

[22] 75 Fed. Reg. 10272, 10274–10278 (March 5, 2010).
[23] Since the inception of the 340B Program, HRSA has generally used interpretive guidance and statements of policy, rather than formal rulemaking, to administer it. See 75 Fed. Reg. 10272, 10273 (March 5, 2010). However, HRSA recently issued a final rule addressing limited program elements. See 78 Fed. Reg. 44016, 44027–44028 (July 23, 2013).
[24] 75 Fed. Reg. 10272, 10277–10278 (March 5, 2010).
[25] HRSA. *340B Drug Pricing Program: Important Benefit, Significant Responsibility*. Accessed at http://www.hrsa.gov/opa/update.html on January 22, 2014.
[26] 75 Fed. Reg. 10272, 10278 (March 5, 2010).

Although covered entities indicate in HRSA's covered entity database whether they dispense 340B-purchased drugs to Medicaid beneficiaries, that indication does not necessarily apply to their contract pharmacy arrangements.

HRSA's recommended oversight activities. HRSA guidance recommends that covered entities conduct oversight activities for their contract pharmacy arrangements, including the following:[27]

(1) monitoring their contract pharmacy arrangements by periodically comparing the covered entity's prescribing records with the contract pharmacies' dispensing records to detect irregularities (e.g., potential diversion or duplicate discounts); and
(2) retaining independent auditors to perform annual audits.

Although HRSA guidance states that covered entities are expected to conduct oversight activities, it also states that "[t]he precise methodology utilized to ensure compliance and obtain the necessary information is up to the covered entity given its particular circumstances."[28] Covered entities must notify HRSA if they find that diversion or duplicate discounts have occurred in their contract pharmacy arrangements.[29]

Related Office of Inspector General Work

In June 2011, OIG published a review of States' reimbursement policies and oversight related to 340B-purchased drugs. OIG found that States lacked pricing information needed for oversight and that nearly half of States did not have written 340B policies.[30]

In September 2012, OIG published a review of States' collection of rebates for covered outpatient drugs dispensed through MCO Medicaid. OIG found that most States that pay for covered outpatient drugs through MCO Medicaid had obtained the utilization data needed to collect rebates, but that some had not yet collected rebates. OIG also found that most States had processes in place to verify that MCO Medicaid payments for 340B-purchased drugs were excluded from rebate requests to drug manufacturers.[31] The review did not specifically address issues related to contract pharmacy arrangements.

METHODOLOGY

Scope

We interviewed 30 covered entities—15 community health centers and 15 DSHs—to learn about how they operate and oversee their contract pharmacy arrangements. We did

[27] Ibid.
[28] Ibid.
[29] Ibid.
[30] OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.
[31] OIG, *States' Collection of Rebates for Drugs Paid Through Medicaid Managed Care Organizations*, OEI-03-11-00480, September 2012.

not include other types of covered entities (hemophilia treatment centers, family planning clinics, etc.) in this study.

Data Collection and Analysis
To describe how covered entities operate and oversee their contract pharmacy arrangements, we interviewed 30 covered entities and 8 administrators.

We selected a purposive sample of 15 community health centers and 15 DSHs from HRSA's covered entity database. We selected our sample to represent a diverse group of covered entities, on the basis of the following considerations:

- number of covered entity sites (i.e., unique "parent" and "child" records);
- dispensing of 340B-purchased drugs to Medicaid beneficiaries;
- number of contract pharmacy arrangements; and
- location (i.e., rural versus urban, State).

The 30 covered entities in our final sample represent contract pharmacy arrangements with 199 unique contract pharmacies. See Appendix A for a detailed description of the selection process for our sample of covered entities.

We conducted structured interviews with staff from the selected covered entities regarding their contract pharmacy arrangements. Our interviews focused on the covered entities' methods to prevent diversion and duplicate discounts, as well as their oversight activities.

We also interviewed eight administrators to learn about how they assist covered entities in preventing diversion and duplicate discounts in contract pharmacy arrangements. We selected these administrators based on availability and prevalence in the industry. These administrators worked with 20 of the 30 covered entities in our final sample. The remaining 10 covered entities either worked with an administrator that we were unable to interview or did not work with an administrator.

Limitations
The results of this memorandum report are limited to the 30 covered entities selected in our purposive sample, and are not representative of or generalizable to other covered entities. We did not verify the accuracy of covered entities' or administrators' interview responses for this memorandum report, nor did we review the records of covered entities or contract pharmacies to identify instances of diversion or duplicate discounts.

Standards
This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

To prevent diversion in their contract pharmacy arrangements, covered entities in our study use different methods to identify 340B-eligible prescriptions; in some cases, this leads to differing determinations of 340B eligibility across covered entities

Covered entities in our sample reported different methods of identifying 340B-eligible prescriptions to prevent diversion in their contract pharmacy arrangements. To prevent diversion, covered entities must accurately identify 340B-eligible prescriptions filled at their contract pharmacies. Some covered entities reported that they identify 340B-eligible prescriptions when the prescriptions are written, whereas others reported that their administrators do so after the prescriptions are written.

Nine covered entities reported that they identify 340B-eligible prescriptions when the prescriptions are written. These covered entities reported that they determine whether a given prescription is 340B-eligible and indicate that determination on the prescription for the contract pharmacy. Covered entities reported using a variety of tools to distinguish 340B-eligible prescriptions for their contract pharmacies, including printed barcodes for paper prescriptions and designated values in notes fields for electronic prescriptions.

The remaining 21 covered entities reported that in at least one of their respective contract pharmacy arrangements, their administrators identify 340B-eligible prescriptions after the prescriptions are written. In such arrangements, these covered entities provide data to an administrator, which identifies 340B-eligible prescriptions by comparing the data to prescriptions filled at contract pharmacies. Covered entities reported that this method prevents diversion.

Covered entities whose administrators identify 340B-eligible prescriptions after the prescriptions are written provide their administrators with a variety of data types. For covered entities in our sample, these data types most commonly include patient lists (e.g., names, dates of birth) and/or prescriber lists (e.g., National Provider Identifiers (NPI), Drug Enforcement Administration numbers). Some covered entities reported providing clinical information (e.g., diagnosis codes, procedure codes), lists of eligible sites, and/or detailed patient encounter data. Some administrators reported that covered entities may also provide them with electronic prescribing data. Additionally, covered entities reported that they sometimes filter data before providing it to their respective administrators (e.g., by limiting the prescriber list to only those who work exclusively at the covered entity).

Administrators interviewed for this study use a variety of data-comparison methods to identify 340B-eligible prescriptions after the prescriptions are written. Some administrators reported that they customize their comparison methods to accommodate covered entities' preferences and/or data availability. For example, some covered entities and administrators reported using time limits that govern how long a patient's prescription is identified as 340B-eligible following the patient's most recent visit to the covered entity. Additionally, one covered entity and one administrator reported that 340B eligibility is not always determined solely on the basis of automatic data

comparison; in some cases, prescriptions may be "queued" for the covered entity to manually review and identify those it deems 340B-eligible.

The variety of data types and comparison methods used to identify 340B-eligible prescriptions can result in differing determinations of 340B eligibility across covered entities. In some cases, covered entities using different data types and/or comparison methods categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements. Although our sample cannot account for all possible combinations of data types and comparison methods, covered entities and administrators did note several instances in which they would categorize similar types of prescriptions differently. The four scenarios below illustrate the different determinations of 340B eligibility that covered entities told us they would make for specific types of prescriptions.

Scenario 1: Nonexclusive physician

A physician practices part time at a covered entity, but also has a private practice. The physician first sees an individual at the covered entity. On a separate occasion, the physician sees the same individual at his private practice and writes a prescription for the individual. The individual fills the prescription at the covered entity's contract pharmacy.

One covered entity in our sample noted that it would automatically categorize the prescription in Scenario 1 as 340B-eligible. This covered entity uses a list of all prescribers to identify 340B-eligible prescriptions. Because the physician in Scenario 1 would be on the prescriber list, the prescription would be categorized as 340B-eligible, even though it was written at the physician's private practice (i.e., originated outside of the covered entity).

Another covered entity in our sample noted that it would not categorize the prescription in Scenario 1 as 340B-eligible. This covered entity also uses a prescriber list to identify 340B-eligible prescriptions, but the covered entity limits the prescriber list to only those prescribers who work exclusively at the covered entity. Because the physician in Scenario 1 would not be on the prescriber list (as he does not work exclusively at the covered entity), the prescription would not be categorized as 340B-eligible.

A third covered entity in our sample noted that it may or may not categorize the prescription in Scenario 1 as 340B-eligible, on the basis of a manual review. This covered entity provides its administrator with a list of all prescribers who work at the covered entity, but flags those prescribers who do not work exclusively at the covered entity. Its administrator automatically categorizes prescriptions from exclusive prescribers as 340B-eligible, but queues prescriptions from nonexclusive prescribers for covered entity staff to review and categorize as 340B-eligible or not 340B-eligible.

Scenario 2: Time limit after patient's visit

A physician sees an individual at a covered entity and writes a prescription for the individual. Four months after filling the original prescription, the individual refills the prescription at the covered entity's contract pharmacy. The individual is not seen at the covered entity during those 4 months.

One covered entity in our sample noted that it would not categorize the refilled prescription in Scenario 2 as 340B-eligible. This covered entity categorizes prescriptions filled at its contract pharmacies as 340B-eligible only if they are filled within 60 days of the patient's most recent visit to the covered entity.

Several other covered entities in our sample noted that they would categorize the refilled prescription in Scenario 2 as 340B-eligible. Some of these covered entities have longer time limits regarding patient visits (e.g., 12 months) that would include the prescription in Scenario 2. Alternatively, one of these covered entities has no limit as to how long after the patient's visit a prescription can be filled and still be categorized as 340B-eligible.

Scenario 3: Prescription from a referred physician

A physician sees an individual at a covered entity and refers the individual to a specialist who is not affiliated with the covered entity. The specialist writes a prescription for the individual, and the individual fills the prescription at the covered entity's contract pharmacy.

Two covered entities in our sample noted that they would not categorize the prescription in Scenario 3 as 340B-eligible. These covered entities use prescriber lists to identify 340B-eligible prescriptions. Because the specialist in Scenario 3 would not be on the prescriber list (as he does not work at the covered entity), the prescription would not be categorized as 340B-eligible.

One covered entity in our sample noted that it would categorize the prescription in Scenario 3 as 340B-eligible. This covered entity also uses a prescriber list to identify 340B-eligible prescriptions. However, the covered entity's administrator queues prescriptions written by prescribers who are not on the prescriber list for the covered entity to manually review and identify those it deems 340B-eligible. The covered entity noted that during this manual review, it categorizes prescriptions as 340B-eligible if its records indicate that the patient was referred to the prescriber. Because the covered entity's physician in Scenario 3 referred the individual to the specialist, the prescription would be categorized as 340B-eligible, even though it originated outside of the covered entity.

Scenario 4: Matching prescription to clinical information

A physician sees an individual at a covered entity for chest pain and writes the individual a prescription for a blood pressure medication (related to the chest pain). During that visit, the physician also writes the individual a prescription for a sleep medication (related to a previously diagnosed condition).

One covered entity in our sample noted that only the prescription for blood pressure medication in Scenario 4 would be categorized as 340B-eligible. This covered entity's administrator uses clinical information from patients' visits (i.e., diagnosis and procedure codes) to identify 340B-eligible prescriptions. Specifically, the administrator identifies a prescription as 340B-eligible only when it relates to one of the diagnosis or procedure codes from the patient's most recent visit. Because the prescription for blood pressure medication in Scenario 4 relates to the individual's diagnosis from his most recent visit (i.e., chest pain), it would be categorized as 340B-eligible. Because the prescription for sleep medication does not relate to that diagnosis, however, it would not be categorized as 340B-eligible.

Many covered entities in our sample do not use clinical information from patients' visits to identify 340B-eligible prescriptions, and thus would likely categorize both prescriptions in Scenario 4 as 340B-eligible. Because both prescriptions are written at the covered entity by a prescriber who works for the covered entity, there would be no basis on which to categorize the prescriptions differently without comparing them to clinical information from the patient's visit.

Twenty-two of thirty covered entities reported that to prevent duplicate discounts, their contract pharmacies do not dispense 340B-purchased drugs to Medicaid beneficiaries

Twenty-two of thirty covered entities reported preventing duplicate discounts by not dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies.[32] Twenty of these covered entities reported that their contract pharmacies do not dispense 340B-purchased drugs to either FFS Medicaid beneficiaries or MCO Medicaid beneficiaries. The remaining two reported that their contract pharmacies do not dispense 340B-purchased drugs to FFS Medicaid beneficiaries, but that they did not know whether their contract pharmacies do so for MCO Medicaid beneficiaries.

To avoid dispensing 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies, covered entities or their administrators identify prescriptions for Medicaid beneficiaries and do not categorize them as 340B-eligible. Covered entities

[32] These covered entities may still dispense 340B-purchased drugs to Medicaid beneficiaries at their in-house outpatient pharmacies and/or have physicians administer 340B-purchased drugs to Medicaid beneficiaries at their eligible sites.

and administrators reported that they identify these prescriptions by comparing the insurer's BIN/PCN to the list of Medicaid BINs/PCNs for the State. While Medicaid beneficiaries may still use contract pharmacies to fill prescriptions originating from the covered entity, those prescriptions will be filled using the contract pharmacies' own non-340B-purchased drugs.

Administrators reported difficulties in identifying prescriptions for MCO Medicaid beneficiaries. Administrators reported that it can be difficult to identify prescriptions for MCO Medicaid beneficiaries in contract pharmacy arrangements. Specifically, they reported that accurately identifying such prescriptions is difficult for two reasons: insufficient information from State Medicaid agencies and BINs/PCNs that are not exclusive to Medicaid.

First, administrators reported that BINs/PCNs for MCO Medicaid plans are not readily available. Administrators reported that as a result, they must research which BINs/PCNs represent MCO Medicaid plans, which is inefficient and may still result in incomplete information. Without a complete list of MCO Medicaid BINs/PCNs, covered entities and their administrators cannot be sure they are accurately identifying all Medicaid prescriptions to avoid duplicate discounts.

Second, administrators reported that many insurers that operate both MCO Medicaid plans and private insurance plans use the same BIN/PCN for both types of plans. One administrator reported that in an attempt to avoid the risk of duplicate discounts, it categorizes all prescriptions with BINs/PCNs used for MCO Medicaid plans as not 340B-eligible, even though some of those prescriptions may be for privately insured patients and thus do not pose a risk of duplicate discounts. As a result, covered entities may forgo potential savings from prescriptions for privately insured patients that could be categorized as 340B-eligible without risking duplicate discounts.

Although 8 of 30 covered entities reported that their contract pharmacies dispense 340B-purchased drugs to Medicaid beneficiaries, 6 did not report a method to prevent duplicate discounts. Eight of thirty covered entities reported that their contract pharmacies dispense 340B-purchased drugs to FFS Medicaid and/or MCO Medicaid beneficiaries. Only five of these covered entities reported notifying their State Medicaid agency that they do so, and none reported notifying HRSA.

Six of the eight covered entities did not report a method to avoid duplicate discounts. According to HRSA guidance, covered entities should not dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies unless they have made an arrangement with their State Medicaid agency to prevent duplicate discounts. Two of the six covered entities dispense 340B-purchased drugs to both FFS and MCO Medicaid patients through contract pharmacies, whereas four dispense 340B-purchased drugs to MCO Medicaid beneficiaries but not to FFS Medicaid beneficiaries.

Two of the eight covered entities reported methods for avoiding duplicate discounts. For example, one covered entity instructs its contract pharmacies to include the covered

entity's NPI on Medicaid claims for 340B-purchased drugs, per the State Medicaid agency's policy. The State Medicaid agency is thus able to identify those claims and exclude the 340B-purchased drugs from its rebate requests to drug manufacturers.[33]

Eight covered entities do not offer the discounted 340B price to uninsured patients in any of their contract pharmacy arrangements

Eight of thirty covered entities reported that they do not offer the 340B price to uninsured patients in any of their contract pharmacy arrangements. Neither the 340B statute nor HRSA guidance addresses whether covered entities must do so, but if covered entities do not, their uninsured patients pay the full non-340B price for prescriptions filled at contract pharmacies. Seven of these eight covered entities use administrators that determine 340B eligibility after drugs are *dispensed*, which means that their contract pharmacies do not know at the time they dispense the drugs whether patients' prescriptions are 340B-eligible. As a result, the contract pharmacies do not know to charge the discounted 340B price. Administrators may later identify uninsured patients' prescriptions as 340B-eligible, but those patients will have already paid the full non-340B price. All but one administrator reported being able to allow covered entities to offer the discounted 340B price to uninsured patients at contract pharmacies; however, some covered entities choose not to do so. Seven of the eight covered entities are DSHs.

Eighteen of thirty covered entities reported offering the discounted 340B price to uninsured patients in at least one of their contract pharmacy arrangements.[34] In a commonly reported process, covered entities work with their administrators to provide uninsured patients with a 340B discount card, which the patients present at contract pharmacies so the pharmacies know to charge the discounted 340B price. Alternately, if the covered entity identifies 340B-eligible prescriptions when the prescriptions are written, the contract pharmacy knows for all patients which prescriptions are 340B-eligible, and can therefore charge the discounted 340B price to uninsured patients. Of the 18 covered entities, 13 are community health centers.

For the remaining four covered entities in our sample, it is unclear whether their contract pharmacies offer the discounted 340B price to uninsured patients.

Almost all covered entities in our study monitor their contract pharmacy arrangements, but few have retained independent auditors as recommended in HRSA guidance

Twenty-five of thirty covered entities reported that they monitor their contract pharmacy arrangements internally to detect potential diversion or duplicate discounts. Covered entities reported monitoring their contract pharmacy arrangements in a variety of ways, including:

[33] The State Medicaid agency uses the NPI on contract pharmacies' Medicaid claims to locate the covered entity's record in HRSA's covered entity database. Because the covered entity has indicated in HRSA's covered entity database that it dispenses 340B-purchased drugs to Medicaid beneficiaries, the State Medicaid agency excludes the drugs for those claims from its rebate requests to drug manufacturers.

[34] Some of these covered entities charge uninsured patients a fee based on a sliding scale in at least one of their contract pharmacy arrangements; this sliding-scale fee may be lower than the 340B price.

- comparing drug dispensing records from their contract pharmacies to their internal records of prescriptions, patients, prescribers, and/or clinical information; and
- reviewing reports provided by administrators to look for Medicaid beneficiaries whose prescriptions were incorrectly identified as 340B-eligible.

Monitoring may be conducted on a regular schedule, or may be performed on an ad hoc basis. Of the 25 covered entities that reported monitoring their contract pharmacy arrangements internally, 17 reported doing so on a regular schedule and 8 reported doing so on an ad hoc basis.

Only 7 of 30 covered entities reported that they have retained independent auditors for their contract pharmacy arrangements, as recommended in HRSA guidance. Six of these covered entities retain auditors in addition to doing their own monitoring as described above, while one of these covered entities relies only on its auditor for oversight. HRSA guidance states that while specific compliance methods are left up to the covered entity, annual independent audits are expected.

Four covered entities reported that they neither monitor their contract pharmacy arrangements nor retain independent auditors.

Some covered entities have detected problems through their oversight activities. Ten covered entities reported that they have discovered instances that could be considered diversion or that could have resulted in duplicate discounts in their contract pharmacy arrangements.

These 10 covered entities reported that they did not notify HRSA of the instances because their administrators or contract pharmacies had corrected the problems. Eight of the ten covered entities reported that their administrators corrected the problems by changing the status of filled prescriptions from 340B-eligible to not 340B-eligible. The other two covered entities reported that their contract pharmacies were able to correct the problems. Specifically, one of the two covered entities reported that its contract pharmacy purchased non-340B drugs to replace the 340B-purchased drugs that were incorrectly dispensed. The other covered entity reported that it did not know how its contract pharmacy corrected the problem.

CONCLUSION

Contract pharmacy arrangements create complications in preventing diversion in the 340B Program, and the covered entities in our study reported addressing those complications in different ways. Covered entities in our study reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA's patient definition should be applied in contract pharmacy arrangements. Covered entities appear to have differing interpretations of what HRSA guidance requires; some may also have chosen to apply more stringent criteria in the absence of a clear directive. Regardless, there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.

Contract pharmacy arrangements also create complications in preventing duplicate discounts. Most covered entities in our study reported that, to prevent duplicate discounts, they do not dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies. However, administrators reported difficulties in identifying beneficiaries covered by MCO Medicaid, and some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

Furthermore, some covered entities in our study have implemented additional processes to offer the discounted 340B price to uninsured patients at contract pharmacies, but others have not. Neither the 340B statute nor HRSA guidance addresses whether covered entities must offer the discounted 340B price to uninsured patients; however, if covered entities do not, uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies.

Moreover, most covered entities in our study do not conduct all of the oversight activities recommended by HRSA. Although almost all covered entities reported monitoring their contract pharmacy arrangements, the extent of such monitoring varies. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance. Without adequate oversight, the complications created by contract pharmacy arrangements may introduce vulnerabilities to the 340B Program.

This memorandum report is being issued directly in final form because it contains no recommendations. We are continuing to review contract pharmacy arrangements in the 340B Program and may include recommendations in an upcoming report if appropriate. If you have comments or questions about this report, please provide them within 60 days. Please refer to report number OEI-05-13-00431 in all correspondence.

APPENDIX A

Detailed Description of Process for Selecting Sample of Covered Entities

We selected a purposive sample of 30 covered entities—15 community health centers and 15 DSHs—from HRSA's covered entity database. We chose to focus on a limited sample so we could conduct in-depth interviews that captured the many details and complexities of covered entities' contract pharmacy arrangements.

We selected only covered entities with at least one contract pharmacy arrangement that had been active for a year or more (i.e., since July 1, 2012, or before). We did so because, according to initial conversations with stakeholders, it can take upwards of 6 months for contract pharmacy arrangements to become fully operational after being established. HRSA's covered entity database listed a total of 1,658 covered entities with at least 1 contract pharmacy arrangement that had been active for a year or more. The 30 covered entities in our final sample represent contract pharmacy arrangements with 199 unique contract pharmacies.

To ensure a final sample of sufficient size, we selected an initial sample of 40 covered entities. Our final sample included the first 30 covered entities that met our criteria and with which we were able to schedule interviews.

We selected our sample to represent a diverse group of covered entities, on the basis of the following considerations:

- Number of covered entity sites (i.e., unique "parent" and "child" records)

  We classified covered entities by 3 categories: those with only 1 site, those with 2–9 sites, and those with 10 or more sites. We selected at least one covered entity from each category.

- Dispensing of 340B-purchased drugs to Medicaid beneficiaries

  We classified covered entities by 3 categories: those for which all sites dispense 340B-purchased drugs to Medicaid beneficiaries, those for which some sites do so, and those for which no sites do so. We used the covered entity's indication in HRSA's covered entity database to make this classification. We selected only covered entities from the "all" or "some" categories, to increase the likelihood of including at least some covered entities that dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies.

- Number of contract pharmacy arrangements (only those active for a year or more)

  We classified covered entities by 3 categories: those with only 1 contract

pharmacy arrangement, those with 2–9 contract pharmacy arrangements, and those with 10 or more contract pharmacy arrangements. We selected at least one covered entity from each category.

- Location

  We classified covered entities by three categories: rural; both rural and nonrural (i.e., some sites were marked rural and some sites were marked nonrural); and nonrural or no indication. We used the rural indicator in HRSA's covered entity database to make this classification.[35] We selected at least one covered entity from each category. We also attempted to select covered entities from a variety of different States.

Table 1 shows the breakdown of the 1,658 covered entities with at least 1 contract pharmacy arrangement active for a year or more, as well as the 30 covered entities in our final sample, by the categories described above.

Table 1: All Covered Entities and Final Sample, By Category

Category	Number of All Covered Entities	Number of Covered Entities in Final Sample
Number of Covered Entity Sites		
1	816	6
2–9	661	16
10+	181	8
Dispensing of 340B-Purchased Drugs to Medicaid Beneficiaries		
All sites	530	23
Some sites	133	7
No sites	995	0
Number of Contract Pharmacy Arrangements		
1	851	8
2–9	629	17
10+	178	5
Location		
Rural (DSH only)	73	5
Both Rural and Nonrural (DSH only)	4	2
Nonrural or No Indication	1,581	23
Total	**1,658**	**30**

Source: OIG analysis of HRSA's covered entity database, 2013.

[35] The rural indicator in HRSA's covered entity database applies only to DSHs. As such, only DSHs are represented in the "rural" and "both rural and nonrural" classifications.