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Life Sciences Health Industry

HRSA Publishes 340B Drug Pricing Program Omnibus Guidance Notice: Significant Policy Ramifications Should Trigger Public Comment

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On August 28, 2015, the Health Services Resources Administration ("HRSA") published its 340B Drug Pricing Program Omnibus Guidance Notice in the *Federal Register*.[1] Although many aspects of the Notice reiterate previous HRSA guidance, several elements will generate significant debate among program stakeholders regarding the scope of the 340B program. In addition, the Notice presages a more robust – if still somewhat ill-defined – oversight and enforcement environment for both covered entities and manufacturers participating in the program.

In this Client Alert, we provide an overview of the Notice, highlight significant policy issues that it raises, and identify potential areas that 340B program stakeholders may wish to comment on. HRSA will be accepting public comments through **October 27, 2015**.

I. 340B PROGRAM BACKGROUND AND IMPORTANT CONTEXTUAL CONSIDERATIONS

Congress enacted section 340B of the Public Health Service Act ("PHSA")[2] as part of the Veterans Health Care Act of 1992. The statute requires manufacturers of covered outpatient drugs, as a condition to federal Medicaid matching funds being available for their products, to enter into a Pharmaceutical Pricing Agreement ("PPA") with the Secretary of the Department of Health and Human Services. Under the PPA, the manufacturer must extend discounts on sales of its covered outpatient drugs to "covered entities." Covered entities include specified classes of Public Health Service grantees providing primary care

services, as well as various other hospitals and clinics that furnish services to medically underserved populations.[3] The amount of the discount that must be offered is determined based on pricing data submitted by manufacturers under the Medicaid rebate statute.[4] The minimum discounts are generally 13 percent for generic drugs and 23.1 percent for brand drugs.

Historically, HRSA's oversight of the 340B program has been relatively *laissez-faire* because of limited resources, with most program guidance taking the form of program notices of agency positions that have been published in the *Federal Register* for comment, or "frequently asked questions" published by HRSA or the 340B program prime vendor. In recent years, however, the 340B program has been subjected to significant scrutiny from stakeholders, policymakers, and enforcement authorities. For their part, covered entities argue that manufacturers have not always extended 340B pricing where required, and that there has been little validation regarding whether 340B prices are accurate or transparent. At the same time, manufacturers question whether 340B drugs have been used inappropriately by covered entities, have created an undue profit opportunity with respect to public (e.g., Medicare Part D and Medicaid managed care) and private (e.g., commercial insurance) dispensing that has not inured to the benefit of needy patients, and whether covered entities are appropriately administering the proliferation of contract pharmacy relationships in the market. Moreover, the expansion of patient access to insurance coverage under the Affordable Care Act ("ACA") has led others to question the continuing need for the program. As part of the ACA, Congress enacted significant amendments to section 340B designed to enhance HRSA's oversight of the program, improve transparency, and provide remedies for noncompliance by the various program stakeholders.

On balance, the Notice imposes greater limits and compliance burdens on covered entities than it does on manufacturers. It is important to note, however, that HRSA's initial regulatory efforts have met with stiff resistance in some cases, notably including ongoing litigation by the Pharmaceutical Research and Manufacturers of America regarding HRSA's "orphan drug" regulation.[5] That litigation provides important context for the Notice. In an earlier decision in that litigation, the district court ruled that HRSA's authority to promulgate regulations was limited to discrete subjects identified in the ACA.[6] For that reason, the Omnibus Guidance takes the form of a notice rather than a proposed rule.

The Notice therefore reflects the agency's current proposed interpretation of the statute and may be subject to deference, but it would not have the force and effect of law that would apply in the case of a regulation. Thus, when reviewing the Notice, stakeholders should not only evaluate the substantive policy interpretations the agency is now articulating, but should also consider the degree to which they will implement its provisions before the Notice is finalized.

II. KEY PROVISIONS OF THE NOTICE

The Notice covers eight general areas: (i) 340B program eligibility and registration; (ii) drugs eligible for purchase under section 340B; (iii) individuals eligible to receive 340B drugs; (iv) covered entity requirements (including the prevention of duplicate discounts); (v) contract pharmacy arrangements; (vi) manufacturer responsibilities; (vii) the AIDS drug assistance program ("ADAP") rebate option; and (viii) program integrity.

A. 340B Program Eligibility and Registration

The initial section of the Notice incorporates statutory standards and many existing agency processes relating to the eligibility and registration of covered entities. As a general matter, the key theme these provisions underscore is that an entity or part thereof is only eligible to the extent that it continues to meet participation standards, and when it does not, the entity has a duty to notify HRSA and discontinue 340B purchases. Further, covered entity eligibility is limited to the qualifying entity itself. For example, a hospital covered entity's association with a health system or Accountable Care Organization ("ACO") does not authorize the system or ACO to purchase drugs at 340B discounts.

1. Covered Entity Eligibility Standards and Registration

The Notice generally differentiates between non-hospital and hospital covered entities. A non-hospital covered entity ("parent site") may register associated health care delivery sites that are located at a different address ("child sites") if it demonstrates that each child site furnishes services pursuant to the parent site's main 340B qualifying grant or contract.

For hospital covered entities, the Notice primarily focuses on three issues. First, with respect to the disproportionate share hospital standard for private hospitals operating under a grant of governmental authority, the Notice clarifies that the authority must be governmental in nature, and not just a provider license. Second, the Notice clarifies that the disproportionate share adjustment percentage to be used for eligibility is the one in the latest filed cost report, and that if that percentage changes so as to render the hospital ineligible, the entity must promptly notify HRSA of its ineligibility. Third, the Notice addresses the eligibility of off-site child site clinics. The agency proposes to continue the existing practice of requiring that the child site be listed on the hospital's Medicare cost report, and that the services provided at each child site have associated outpatient Medicare costs and charges. However, HRSA specifically seeks comments on alternatives to demonstrating the eligibility of an off-site outpatient facility or clinic.

Covered entities may register for the 340B program during one of four annual open registration periods. The entity must annually recertify its

compliance with eligibility standards, and that it maintains appropriate processes and controls (including self-audits) to ensure compliance with program standards.

2. Loss of Eligibility

As noted, a significant focus of the Notice is that a covered entity must immediately notify HRSA in the event of a change in circumstances that renders it ineligible to participate in the program, and must repay manufacturers for any discounts obtained during a period of ineligibility. In the case of a hospital covered entity with associated off-site "child" sites, the eligibility of the off-site outpatient facility or clinic is tied to the parent hospital's 340B program eligibility. However, a child site may lose eligibility separately from the parent covered entity (e.g., by violating the statutory group purchasing organization ("GPO") prohibition).

3. Group Purchasing Organization Prohibition for Certain Covered Entities

To be eligible for the 340B program, the statute provides that disproportionate share hospitals, children's hospitals and freestanding cancer hospitals are prohibited from obtaining covered outpatient drugs through a GPO or under group purchasing arrangements. The guidance defines "group purchasing arrangements" to include arrangements "created to leverage the purchasing power of multiple entities to obtain discounts from manufacturers, distributors, and other vendors based on collective buying power." The prime vendor program established pursuant to the PHSA is *not* a GPO for purposes of the statutory GPO prohibition, however. This definition may create ambiguities with respect to generic drugs, where substantial discounts are commonly offered through wholesaler distribution channels.

HRSA interprets the GPO prohibition to mean that these covered entities may only use a GPO to purchase drugs that are either dispensed to inpatients or that do not satisfy the definition of a covered outpatient drug. The Notice identifies three exceptions to the statutory GPO prohibition. First, a GPO account may be used at an off-site outpatient facility of a covered entity that is *not* participating in the 340B program and maintains a separate purchasing account. Second, GPO drugs may be provided to an inpatient whose status is subsequently changed to outpatient by a third party (e.g., an insurer or a Medicare Recovery Audit Contractor) or a hospital review, provided sufficient documentation of the patient's change of status exists. Finally, a hospital subject to the statutory GPO prohibition may purchase GPO drugs to prevent disruptions in patient care where that hospital demonstrates that it cannot access the drug at the 340B price or at wholesale acquisition cost ("WAC"), and that hospital notifies HRSA of

the drug at issue, its manufacturer, and a description of the attempts to purchase the drug at the 340B price and the WAC price prior to purchasing the drug through a GPO.

For covered entities using replenishment models, the Notice specifies that hospitals may not tally 340B-ineligible outpatient use for drug orders on a GPO account. On the other hand, a newly participating entity need not exhaust its supply of GPO-purchased covered outpatient drugs on or after the entity's start date for the 340B program, but may not purchase through GPOs as of the first day of participation.

HRSA also emphasizes that the GPO prohibition is a condition of eligibility for many covered entities. At the same time, HRSA recognizes and encourages covered entities and manufacturers, as standard business practice, to monitor and correct errors in GPO purchasing within 30 days of the initial purchase through a credit and rebill process. Covered entities should monitor internally to identify errors within 30 days of an erroneous purchase.

Under the Notice, HRSA proposes to extend a notice and hearing process to covered entities found in violation of the GPO prohibition. A covered entity that demonstrates that it committed an isolated violation of the GPO prohibition would be permitted to remain in the 340B program upon submitting a corrective action plan. If, after notice and hearing, the GPO violation is determined not to be isolated, then the covered entity would be removed from the 340B program, effective as of the date of the violation.

B. Drugs Eligible for Purchase Under the 340B Program

Section 340B generally defines covered outpatient drugs by reference to the Medicaid rebate statute's use of that term, which has two parts. First, it is generally defined to include all FDA-approved drugs, biologics, and insulin. Second, the statute contains a "limiting definition" that applies when a product is used as part of another health care service, and payment for the product is bundled into payment for the service.[7] Historically, there has been some ambiguity regarding whether and how the limiting definition may apply when determining whether a drug may be purchased at a 340B discount by a covered entity.

In the Notice, HRSA clarifies past guidance and states that if a drug satisfies *both* limiting definition conditions above – that it is furnished and paid for as part of a bundled service – then it will not qualify as a covered outpatient drug in the 340B program. For those drugs, covered entities would be permitted to use GPOs for outpatient purchases. HRSA also clarifies that the limiting definition only applies when payment for the drug is included in the bundled

payment for the service in the settings described under section 1927(k)(3). Therefore, a drug provided as part of an outpatient service but billed to a third party or directly billed to Medicaid would still be eligible for 340B discounts.

However, significant ambiguity remains regarding how this provision should actually be implemented. For example, it is unclear whether the application of the limiting definition may be determined for a drug generally, or whether it must be evaluated on a prescription-by-prescription basis in light of an individual patient's insurance coverage. Further, the Notice suggests that the bundled payment analysis should be based on Title XIX (i.e., the Medicaid statute), yet Medicaid payment provisions may vary by state, and moreover, they may differ substantially from Medicare or commercial insurance payment methods.

C. Eligible Patients Under the 340B Drug Program

HRSA has historically emphasized that a covered entity may only dispense covered outpatient drugs purchased at 340B prices to persons who are "patients" of the covered entity. The agency has issued several previous guidance notices concerning the term "patients," which generally have required that drugs may only be used in outpatient contexts and for persons for whom the entity is otherwise providing health care. In the Notice, HRSA repeatedly emphasizes that dispensing drugs purchased at 340B discounts to persons who are not "patients" constitutes diversion, for which the covered entity will be liable to the manufacturer for the amount of the discount. Covered entities therefore must maintain auditable records, including under replenishment models, to establish that "every prescription or order" for 340B dispensing occurs only for eligible patients. This language could be interpreted to impose a more rigorous auditability standard under replenishment models.

1. Revised and Updated Patient Eligibility Criteria

HRSA is proposing a new, six-part definition of "patient" with several significant elements, and emphasizes that covered entities must maintain auditable documentation to establish that drugs are being dispensed appropriately.

Further, HRSA proposes that a "patient's" eligibility must be determined on a "prescription-by-prescription or order-by-order basis." That phrase in itself is ambiguous, and raises the obvious question of the extent to which refills on an original qualifying prescription for a "patient" may be filled with 340B products. Under the Notice, a person will be considered a "patient" if they meet each of six elements:

- **First, the individual must receive health care at a facility or clinic that is registered for the 340B program and listed on**

the public database: Ultimately, the covered entity must be responsible for the patient's underlying health care. Services delivered via telemedicine qualify if they are authorized under applicable state and federal law. However, care provided off-site by a private practice physician or specialist does not qualify, even if pursuant to a referral from a covered entity site.

- **Second, the individual must receive care from a provider either employed by or an independent contractor of the covered entity, such that the covered entity is able to bill for services on behalf of the provider:** Qualifying providers may include those under faculty practice arrangements and established residency and volunteer health care programs but physicians or other practitioners who have clinical privileges but are not otherwise employed or under contract to a covered entity, alone, do not qualify. The impact of this provision on the scope of 340B covered entities' purchasing of 340B drugs may depend on the size of the facility.

- **Third, the drug must be ordered "as a result of" the underlying health care service:** The Notice reiterates HRSA's position that the covered entity must provide more than pharmacy services. Instead, there must be a practitioner patient service encounter involved in prescribing the drug. In particular, HRSA emphasizes that the mere infusion of a drug without the prior encounter is not sufficient. This clarification may warrant evaluation of affiliation care models in light of the significant migration of oncology care to outpatient settings.

- **Fourth, the individual's care must be consistent with the scope of the covered entity's federal grant, project, contract, or designation:** Consistent with prior guidance for non-hospital covered entities, the care cannot exceed the scope of the services designated in the qualifying contract or other agreement.

- **Fifth, the individual's drug must be prescribed or ordered pursuant to an outpatient service:** Perhaps most significantly, HRSA has called into question whether "discharge prescriptions" issued to an inpatient upon discharge can be dispensed with 340B drugs. Instead, the Notice provides that the underlying service must be billed as outpatient to the patient's third-party payor or insurance. The logic of that rationale may also call into question whether drugs dispensed in emergency room settings to patients who are subsequently admitted as inpatients may be purchased at 340B prices.

- **Sixth, the covered entity must maintain the individual's patient**

records that demonstrate that it is responsible for the patient's health care: The covered entity must maintain "auditable health care records" tracking the 340B drugs ordered and dispensed, and that demonstrate the provider-to-patient relationship.

2. Eligibility for covered entity employees

The Notice reiterates HRSA's longstanding position that covered entity employees are not eligible for 340B drugs solely because they are employees of a covered entity, unlike the concept of "own use" under the nonprofit institution exception to the Robinson-Patman Act.[8] An employee must otherwise meet the new patient definition criteria discussed above.

3. Drug inventory/replenishment models

The Notice confirms that covered entities may use replenishment models to manage drug inventory and associated software to track drug use for different patient types. HRSA emphasizes, however, that the covered entity is ultimately responsible for maintaining auditable records to demonstrate prior receipt of the drug by a 340B-eligible patient to support replenishment, and to demonstrate that any drug inventory discrepancies – taking into account returns and destroyed product – have not resulted in diversion.

HRSA encourages manufacturers and covered entities to continue working together to identify and correct errors in purchasing in the ordinary course of their relationships through the review of wholesaler chargeback data and credit-rebill arrangements. Where errors are identified, HRSA expects covered entities to repay manufacturers for undercharges within 90 days of identifying a diversion violation. Moreover, the Notice provides that covered entities should notify HHS of corrective actions regarding diversion and manufacturer repayment agreements. This notice requirement, however, does not contain any materiality or similar requirement, and could prove burdensome if applied to small errors that are corrected in the ordinary course. Such notices could also serve as a potential predicate for compliance proceedings, but the "trigger" for such proceedings is not clearly specified. HRSA allows manufacturers to waive repayment, but cautions that they should consider such actions in light of anti-kickback and government price reporting rules.[9]

Finally, HRSA's guidance with respect to "banking" practices, whereby an entity seeks to retroactively recharacterize prior dispensing as 340B eligible, is ambiguous. On the one hand, the agency reiterates that covered entities are responsible for requesting 340B prices at the time of original purchase (i.e., the 340B program is not a rebate program). On the other hand,

HRSA notes that covered entities may notify manufacturers if they wish to recharacterize prior purchases if there is an audit trail establishing the facts and timing of the original transaction.

D. Covered Entity Requirements

1. Duplicate Discount Prohibition

Section 340B(a)(5)(A)(i) requires covered entities to comply with mechanisms to prevent manufacturers from paying duplicate discounts, which may occur if a covered entity bills a state Medicaid program for covered outpatient drugs that are subject to rebates under the Medicaid Drug Rebate Program.

In the context of Medicaid fee-for-service patients ("FFS"), HHS has established the 340B Medicaid Exclusion File, and the Notice provides that covered entities must continue to use this mechanism. Specifically, covered entities must notify HHS at the time of 340B registration that they will purchase and provide 340B drugs to Medicaid FFS patients and then bill the state at the 340B price ("carve-in" status). Thereafter, the covered entity's Medicaid number, National Provider Identifier ("NPI"), or both, are listed in the 340B Medicaid Exclusion File. Alternatively, they may register for "carve out" status, which means they may not use 340B drugs for Medicaid patients, but may bill Medicaid programs based on their standard rates and Medicaid payment amounts. The Notice provides that covered entities may change their elections on a quarterly basis. HRSA does seek comments on alternative mechanisms to implement the duplicate discount prohibition.

The Notice also seeks to extend this approach in the context of Medicaid managed care, since Medicaid managed care utilization is now subject to Medicaid rebates, but its proposals in this regard are ambiguous, incomplete, and could create significant implementation challenges. In the context of Medicaid managed care patients who receive services and covered outpatient drugs on-site at the covered entity, the Notice provides that covered entities may make a different carve-in or carve-out designation than it has elected for FFS patients, and also that these decisions may even vary "by covered entity site and by [Managed Care Organization]" if notice is provided to HRSA for inclusion in the Medicaid Exclusion File. HRSA specifically seeks comments on the "utility of this billing information for other stakeholders" and the format for presenting it to the public. Setting aside the potentially extraordinary difficulty of monitoring and maintaining auditable data to identify 340B and non-340B purchases on a site and MCO basis (even assuming that an entity is not changing its designations over time), this guidance, from our perspective, ultimately provides only

half of a solution. What makes the duplicate discount mechanism work in the FFS context is the mandate that covered entities bill for 340B carve-in claims in an identifiable manner at their 340B prices. HRSA (rightfully) notes that it lacks the authority to establish provider Medicaid billing mandates, however, and encourages other stakeholders (covered entities, states, and Medicaid MCOs) to work together to establish a method to identify, bill, and reimburse 340B claims appropriately.

The Notice also draws a harder line on duplicate discounts where, as is often the case, the covered entity has entered into contract pharmacy arrangements. HRSA commented that such situations raise greater compliance risks, and accordingly, proposes that a contract pharmacy listed on the public 340B database will be presumed to not dispense 340B drugs to Medicaid FFS or MCO patients. If any covered entity wishes to purchase and dispense 340B drugs through a contract pharmacy for Medicaid or MCO patients, then it must provide HHS with a written agreement entered into with its contract pharmacy and the state Medicaid agency or MCO that describes a devised system to prevent duplicate discounts. This presumption may significantly impact 340B opportunities for contract pharmacies that dispense primarily to Medicaid patients.

A covered entity may be audited for its compliance with the duplicate discount prohibition. If a covered entity is found in violation of the prohibition, it may be required to repay manufacturers.

2. Maintenance of auditable records

Under section 340B(a)(5)(C) of the PHSA, the Secretary and certain manufacturers have the right to audit a covered entity's records for compliance with the 340B program, including records pertaining to arrangements with contract pharmacies to dispense 340B drugs. In response to stakeholders' requests for a standard for record retention, HRSA generally proposes a five-year, record-retention standard from the time of product purchase. The failure to maintain auditable records is a basis for termination of a covered entity's eligibility under the program after notice and the opportunity for a hearing. In other words, the recordkeeping requirement can effectively be invoked to threaten termination for any form of covered entity noncompliance (e.g., loss of eligibility, diversion, duplicate discounts).

What is less clear is whether and when informal notifications of noncompliance that have been remedied, or occasional audit findings of noncompliance that are otherwise immaterial, will lead to potential termination proceedings. HRSA indicates, however, that it will exercise some leniency in invoking termination for entities whose failure to retain

records is "non-systematic" (i.e., the records are generally available but it cannot produce a specific record). In this case, the entity may be liable for repayment to the manufacturer but would not lose eligibility. But it is not clear whether that discretionary remedy will be provided before or after a termination notice has been issued. If terminated, a covered entity may re-enroll during the next regular registration period, but only after showing its ability to comply with program requirements.

E. Contract Pharmacy Arrangements

HRSA cautions covered entities that all 340B drug distribution arrangements with third parties, including those with contract pharmacies, must meet program requirements and all local, state, and federal laws, including health care fraud and abuse laws. The Notice permits covered entities to contract, directly or on behalf of a child site, with one or more licensed pharmacies to dispense 340B drugs, along with or as a substitute for an in-house pharmacy. The Notice does not restrict the number or location of contract pharmacies relative to a covered entity. Consistent with current practices, contract pharmacies must be registered on the HRSA website by covered entities based on appropriate contract documentation and attestations.

Once registered, a covered entity is responsible for the contract pharmacy's compliance with 340B program requirements. A contract pharmacy may be removed from the 340B program if HHS finds instances of non-compliance with the program requirements. A covered entity is liable for any cases of diversion or duplicate discounts by the contract pharmacy, including any repayments to manufacturers. HRSA proposes that covered entities complete an annual, independent audit of contracting pharmacies, and perform a quarterly review of the contracting pharmacy's prescribing and dispensing records. Covered entities must report any instances of diversion or duplicate discounts found during these reviews or audits to HHS.

F. Manufacturer Responsibilities

1. General

Once a manufacturer signs a PPA, it is subject to all 340B program statutory requirements and changes, including updating its 340B database record, maintaining auditable records for five years, and allowing HRSA to audit for compliance. HRSA also proposes to require manufacturers to update their database information on an annual basis.

The core manufacturer obligation, of course, is to offer 340B discounts to covered entities where appropriate. In determining whether it must offer 340B prices, manufacturers must rely on the information in the public 340B database, rather than a covered entity's assurance of compliance with

program requirements. Manufacturers may also offer discounts greater than those mandated by the statute.

2. Limited Distribution Networks

HRSA recognizes that there are circumstances where manufacturers may distribute products through limited distribution networks, and the Notice provides that manufacturers may use those networks as long as there are mechanisms to facilitate 340B pricing to covered entities. However, the Notice contains a significant ambiguity and also requires manufacturers to notify HRSA of their limited distribution networks, which is certain to generate manufacturer comments.

Specifically, the Notice does not appear to distinguish between limited distribution networks and mechanisms that may be "necessary" (e.g., because of an FDA-mandated Risk Evaluation and Management Strategy or a drug shortage necessitating an allocation plan), and those that the manufacturer has implemented based on its own business considerations (e.g., because the product is a specialty drug, because the patient population is limited). This leads to at least two significant issues.

First, it is not clear whether HRSA is intending to suggest that a manufacturer may only distribute drugs through a limited distribution network when it is "necessary" as suggested above. If so, the agency's authority to do so is unclear at best. Second, the Notice provides that a manufacturer must notify HRSA of any limited distribution network, and must provide the following information that may be published by HRSA:

- Explanation of the product's short supply or special requirements and the rationale for restricted distribution;
- Assurance that manufacturers will impose the restrictions in an equitable fashion;
- Details of the drug allocation plan, including a method "to allocate sales to both covered entities and non-340B purchasers with no previous purchase history of the restricted drug";
- Beginning and end dates for restricted distribution; and
- A plan to notify wholesalers and 340B covered entities about the limited distribution plan

Again, it is unclear whether this Notice would be required in all cases, and in any event, it has the potential to result in the disclosure of proprietary business information. These provisions also strike us as arguably outside the scope of "interpretive rulemaking" and considerably closer to the

substantive rulemaking precluded by the *PhRMA* case, since there is no such obligation in the statute itself.

3. Procedures for Refunds or Credits for Manufacturer Overcharges

HHS proposes procedures for the oversight of refunds or credits in cases of manufacturer overcharges, including overcharges resulting from Medicaid pricing statements by the manufacturer. First, the Notice provides no flexibility with respect to the scope or timing of the duty to make refunds (i.e., there is no *de minimis* exception or deferral process contemplated, nor may a manufacturer net undercharges against overcharges or rebill covered entities for undercharges). Second, the manufacturer must notify HRSA of the overcharge, the reason for it, and the remedy provided. Again, there is no qualification to this standard, which could yield burdensome reporting obligations even where modest overcharges result from or are corrected in the ordinary course of dealings. Third, HRSA allows a covered entity to choose to receive a credit on its account rather than a refund.

Manufacturers are expected to refund or credit the required amount within 90 days of the determination that an overcharge occurred. If the repayment is not accepted within 90 days of the refund, then the covered entity has waived its right to the amount, unless the amount is disputed by the covered entity.

G. Rebate Option for ADAPs

Consistent with the status quo, ADAPs will remain eligible to participate in the 340B program through a rebate model. ADAPs can access 340B prices either through a direct purchase option, a rebate option, or a combination of both methods. In the rebate context, the amount of the rebate due will be the full Medicaid drug rebate amount.

Those ADAPs seeking the rebate mechanism are expected to take three actions: (i) inform HHS during the registration process as to whether they will participate through direct purchase, a rebate option, or both; (ii) make a "qualified payment" for the drug as described below; and (iii) submit claims-level data to a manufacturer to support each qualified payment in order to receive a rebate. HRSA is specifically seeking public comments regarding the supporting data to be provided with rebate requests, but it may include, among other things, ADAP name and state, medication name/label name, medication National Drug Code, the ADAP payment for the medication, and a declaration that the claim is not for a drug subject to a Medicaid rebate.

The Notice defines two circumstances where ADAPs will make a qualified payment of a covered outpatient drug: (i) direct purchase of a drug at a price greater than the 340B price; or (ii) purchase of the ADAP client's insurance

in addition to the payment of the cost-sharing amount. The payment of the cost-sharing amount, alone, is not sufficient to constitute a qualifying payment. However, HHS provides the opportunity for comment on this policy. Additionally, HHS recognizes the possibly disruptive nature of the proposed changes through which ADAPs may be required to alter program policies and implement certain payment processes in response to the proposed rule. As a result, it proposes to delay the effective date of this provision until 12 months after the publication of the final guidance.

The Notice also seeks to limit the proposal for duplicate discounts in an ADAP rebate context, since a patient may receive a product from a covered entity pharmacy but have that claim covered by an ADAP participating through the rebate option. The Notice does not provide guidance on how duplicate discounts may be prevented, however.

H. Program Integrity

1. HHS audits of covered entities

Under section 340B(a)(5)(C), HRSA has the authority to audit covered entities for compliance with prohibitions on diversion and duplicate discounting. However, the Notice provides that only one audit of a covered entity will be performed at any one time.

The Notice sets forth a notice and hearing process where a covered entity may respond to adverse audit findings, alleged noncompliance, or a proposed termination of eligibility. The notice will include an explanation of the findings of noncompliance and, thereafter, the covered entity has 30 days to respond, unless an extension is granted. Any non-response to an issue of noncompliance is deemed as the covered entity's agreement with the issue. In the event that HRSA issues a final determination of noncompliance, the covered entity must submit a corrective action plan ("CAP") (which may include repayment of overpayments), or, if the agency elects a termination remedy, the covered entity will be removed from the program. Covered entities may reenroll in the first open enrollment period following correction of the underlying basis for the prior termination.

2. Manufacturer audits of covered entities

The statute also authorizes manufacturers to audit covered entities' compliance. HRSA requires manufacturers to resolve disputes informally with covered entities, but if those efforts do not succeed, manufacturers must obtain HRSA approval to audit the entity. Specifically, the Notice proposes that the manufacturer must provide documentation of "reasonable cause" to believe that diversion or duplicate discounting has occurred, such as significant changes in purchasing quantities, deviations from

national averages, and evidence of duplicate discounts received from states. The manufacturers must also submit a defined work plan for HRSA approval, and the plan must be designed to limit disruption to the entity. Further, audits must be conducted through an independent certified public accountant in accordance with government auditing standards and patient privacy protections, with a total duration not to exceed one year. The audit report must be submitted to HRSA upon completion.

3. HHS audit of manufacturer

Finally, HRSA may audit manufacturers and wholesalers to ensure 340B program compliance, through on-site procedures, off-site procedures, or both. After the conclusion of an audit, manufacturers will be afforded an opportunity for notice and a hearing. After the agency's evaluation of the manufacturer's response, it will make a final determination and may request corrective action, including both retrospective remedies and prospective control procedures.

III. DISCUSSION AND POTENTIAL ISSUES FOR COMMENT

The Notice potentially represents a significant milestone for the 340B program not only because it suggests a much heavier oversight hand, but also because of its potential to narrow the scope of permissible 340B purchasing and dispensing. The Notice raises significant issues for all stakeholders and should spark a vigorous debate on certain issues. Companies that participate in or support the 340B program may wish to consider commenting on key aspects of the Notice, including:

Agency disclosures and enforcement processes. The proposal suggests a much more robust enforcement environment in several ways. The Notice contemplates that both manufacturers and covered entities may have unbounded obligations to notify HRSA of program noncompliance (e.g., overcharges, diversion, GPO prohibition violations, and duplicate discounts), even where those noncompliance situations are *de minimis* or have otherwise been addressed by the parties in the ordinary course of their monitoring. Aside from the fact that this notification could become extraordinarily burdensome, the Notice does not specify whether all or some of those agency disclosures will lead to the notice-and-hearing processes described in the Notice, or what criteria will guide those decisions. Finally, the Notice does not describe any of the procedures or standards that will apply to the notice and hearing process.

Entity eligibility. In the area of entity eligibility, four areas strike us as potentially significant. First, the Notice emphasizes the "immediacy" of ineligibility when an entity violates a program requirement. While technically true, that concept is in tension with HRSA's recommendation that entities and manufacturers seek to

work issues out informally, particularly if they are *de minimis*. Second, the ability to have offsite child sites participate on different eligibility bases or in different manners (e.g., with respect to carve-in and carve-out of Medicaid patients) may complicate purchasing administration. Third, HRSA has specifically invited comments on the alternative approaches to identifying appropriate child sites, in lieu of the traditional Medicare cost report test. Finally, with respect to the GPO limitation, HRSA's definition of group purchasing arrangements may increase costs for non-340B generic drugs if interpreted to include wholesaler sourcing programs for such products.

Eligible drugs. The Notice is ambiguous with respect to how the Medicaid "limiting definition" will be administered. Further, HRSA's guidance that the patient's service reimbursement determines his or her eligibility may suggest that certain emergency room drugs are no longer 340B eligible if patients using those drugs are admitted from the emergency room as an inpatient, since the emergency room costs would typically be bundled with the inpatient rate.

Eligible 340B patients and prescriptions. The patient eligibility standards raise a number of significant issues. First, it is unclear what it means to determine eligibility "prescription by prescription or order by order," and this language raises the unaddressed question of the scope of refill prescription eligibility. Second, the ineligibility of prescriptions written in an outpatient department by non-employed/non-contracted providers with privileges may limit smaller hospitals' use of the program simply by virtue of smaller staffs. Third, the guidance may have significant implications for infusion drugs, since the infusion administration itself would not qualify as the outpatient service to which the 340B drug purchase could be tied. Fourth, the potential elimination of inpatient "discharge prescriptions" could significantly cut the scope of 340B program use. Fifth, HRSA's reiteration of its position that 340B drugs may not be used for covered entity employees has not been fully implemented by all covered entities.

Replenishment model administration. The Notice is not clear about the appropriateness of "banking" models. Moreover, the Notice suggests a "letter perfect" standard of auditability and recordkeeping that may pose challenges in virtual inventory settings if accumulation software is not appropriately tied to entity medical records.

Duplicate discount prohibitions. The Notice specifically seeks comments on alternative methods of preventing duplicate discounts in the ordinary course. Further, its mechanisms for Medicaid managed care seem incomplete and may warrant specific further steps with respect to billing. Moreover, the presumption of Medicaid managed care carve-outs in the contract pharmacy setting may limit 340B program use in geographic or therapeutic areas with significant Medicaid populations.

Contract pharmacies. With respect to contract pharmacies, the Notice is notable for its omission of any limits on contract pharmacy networks, as some third-party commentators had expected. Covered entities may also wish to consider the administrative burdens associated with quarterly reviews and independent third-party audits of multi-pharmacy contract pharmacy networks.

Manufacturer overcharges. Manufacturers may also wish to consider commenting on the requirement for continual affirmative reporting of all covered entity overcharges, as well as the duty to immediately repay even *de minimis* amounts. As an alternative to waiver, other mechanisms such as deferred payment of such amounts, may achieve program objectives without raising the same administrative burdens. Further, the proposed notice may provide the first opportunity to comment on the "one-way door" aspect of 340B pricing, i.e., HRSA's historic position that covered entity undercharges cannot be recouped.

Limited distribution networks. Manufacturers – particularly those of specialty products – should consider seeking clarity around HRSA's proposal that such networks must be disclosed to HRSA along with assurances regarding distribution, even where they are established in the ordinary course because of manufacturers' business considerations.

ADAP rebate option. HRSA has specifically sought comments on the revised definition of ADAP qualifying payments and appropriate claims data for ADAPs seeking rebates. Further, the Notice does not provide clear guidance concerning the mechanisms for preventing duplicate discounts.

Finally, as noted in the introduction, aside from considering the submission of public comments, 340B stakeholders should consider the effect of the Notice, and the degree to which they will implement its guidance immediately or wait until the Notice is finalized.

If you have questions concerning the HRSA Notice, the 340B program, or other government pricing programs affecting pharmaceutical manufacturers and industry stakeholders, please contact Joseph Metro, Julia Krebs-Markrich, Salvatore Rotella, Jacquelyn Godin, Zachary Portin, or any other Reed Smith attorney with whom you work.

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1. 80 Fed. Reg. 52300 (Aug. 28, 2015).
2. 42 U.S.C. § 256b.
3. Hospital covered entities include certain disproportionate share hospitals, children's hospitals, cancer hospitals, critical access hospitals, and rural referral centers. 42 U.S.C. § 256b(a)(4).
4. 42 U.S.C. § 1396r-8.
5. *See Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services,* Civil Action No. 1:14-cv-01685 (D.D.C.).
6. *Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services,* Civil Action No. 13-1501 (D.D.C. May 23, 2014).
7. 42 U.S.C. § 1396r-8(k)(2)-(3).
8. *See* 13 U.S.C. § 13(c).
9. The anti-kickback statute prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce the purchasing, ordering, or recommending or arranging for purchasing items or services under federal health care programs. 42 U.S.C. § 1320a-7b. The waiver of repayment amounts might constitute prohibited remuneration if the facts and circumstances indicated that it was intended to induce future purchases of the manufacturer's products. With respect to government price reporting issues, such as Medicaid best price and Medicare average sales price, the waiver of *de minimis* or uncollectable amounts under standard collection practices does not necessarily imply a reduction in the price of a future sale, any more than the inability to collect on an invoice outside of the 340B context. Again, the facts and circumstances should be analyzed in these cases.