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Client Alert

FDA & Life Sciences Practice Group

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HRSA Publishes Proposed 340B Drug Pricing Program Omnibus Guidance

Comments Due to HRSA on or before Tuesday, October 27, 2015

On Friday, August 28, 2015, the Health Resources and Services Administration ("HRSA" or "the Agency") published in the Federal Register Notice of its proposed "omnibus" or "mega" guidance ("Proposed Guidance") regarding pharmaceutical manufacturer and covered entity participation in the 340B Drug Discount Program ("340B Program"). A copy of the Proposed Guidance is available **here**. While not a formal rulemaking, HRSA has requested input from stakeholders before the Proposed Guidance is finalized. Comments on the Proposed Guidance are due to HRSA on or before ***Tuesday, October 27, 2015.***

The Proposed Guidance aims to "provide increased clarity in the marketplace for all 340B Program stakeholders and strengthen HHS's ability to administer the 340B Program." 80 Fed. Reg. 52,300 (August 28, 2015). It remains unclear, however, whether and to what extent HRSA can require compliance with the views articulated in the Proposed Guidance once the document is finalized. The forthcoming court decision in PhRMA's pending legal challenge to HRSA's orphan drug "interpretive rule" may provide direction regarding the degree to which such guidance is binding on 340B Program participants.

With several important exceptions, the Proposed Guidance essentially reiterates policy pronouncements previously issued by HRSA. Nonetheless, in its current form, the Proposed Guidance is useful as it consolidates HRSA's thinking on how the Agency believes the 340B Program should operate. We highlight below key takeaways from the Proposed Guidance, as well as issues that merit close scrutiny and comment by industry.

Background

Historically, HRSA has not issued 340B Program regulations, but rather has issued program guidance through a series of Federal Register Notices and other forms of sub-regulatory guidance, such as FAQs posted on the Agency's website.

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In January 2014, HRSA announced that it would be "working to formalize existing program guidance through regulation," and that a "Mega Rule" issued by the Agency would address various aspects of 340B Program operations. *See* **HRSA, 340B Drug Pricing Program: Important Benefit, Significant Responsibility (January 9, 2014)**. Specifically, HRSA indicated that this Mega Rule would cover four topics, all of which had been subjects of HRSA's past Notices: (1) the definition of an eligible patient, (2) compliance requirements for contract pharmacy arrangements, (3) hospital eligibility criteria and (4) eligibility of off-site facilities. *Id.*

The proposed Mega Rule was to be published and available for public comment no later than June 2014. Consistent with that timeline, HRSA forwarded a draft of the proposed Mega Rule to the Office of Management and Budget ("OMB") for review in early April 2014. On November 13, 2014, however, the Agency withdrew the proposed Mega Rule from consideration by OMB, citing the lack of explicit Congressional authority to issue rulemakings in areas covered by the proposed Mega Rule. On June 17, 2015, HRSA published a proposed rule on subjects for which it believes it has Congressional authority to promulgate a formal rule: calculation of 340B ceiling prices and manufacturer civil monetary penalties. See our June 17 **Client Alert** on this subject. On May 6, 2015, HRSA submitted the Proposed Guidance to OMB for review. The Proposed Guidance was published in the Federal Register on August 28, 2015, and presumably includes topics that would have been addressed in HRSA's proposed Mega Rule.

HRSA's change of course with respect to its proposed Mega Rule came on the heels of the U.S. District Court for the District of Columbia's decision in May 2014 to vacate HRSA's regulation interpreting the orphan drug exception added to the 340B statute in 2010. The court invalidated this regulation on the grounds that HRSA lacked authority from Congress to issue such a rulemaking. *See Pharmaceutical Research and Manufacturers v. Department of Health and Human Services,* 1:13-cv-01501 (D.D.C., May 23, 2014); HRSA, Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, Final Rule, 78 Fed. Reg. 44,016 (July 23, 2013).

Following the court's decision, HRSA reissued the orphan drug rule as an interpretive rule, which instructs the public on the agency's interpretation of its own statute, but lacks the force and effect of law. *See* HRSA, "**Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program**" (July 2014). A renewed PhRMA challenge to HRSA's interpretive rule is pending. As such, the legal authority of HRSA's guidance documents is currently in a state of flux.

Key Takeaways – Covered Entities

- **Individuals Eligible to Receive 340B Drugs ("Patient" Definition)**. The Proposed Guidance's most significant change to current practice relates to the definition of a patient eligible to receive drugs at the 340B price. Pursuant to the 340B statute, covered entities may dispense drugs purchased at the 340B price only to the covered entity's own "patients," a term that is not defined by the statute. The Proposed Guidance would narrow and clarify the three-part test first articulated by HRSA in 1996 and subsequently reconsidered by the Agency in 2007. As proposed, an eligible patient would be one who meets the following *six* criteria:

    1. Receives a health care service at a registered covered entity;
    2. Receives that service from a provider who is either employed by the covered entity or is an independent contractor for the covered entity, such that the covered entity may bill for the service;
    3. Is prescribed a drug as a result of the service provided by the covered entity;
    4. Receives a health care service that is consistent with the scope of the covered entity's grant, project, designation or contract (or the child site's scope), excluding hospital covered entity types;

5. Is prescribed a drug pursuant to an *outpatient* health care service, as determined by the way the service is billed to the patient's insurance (or, if cash-pay, pursuant to the covered entity's policies and procedures); and
6. The patient records for whom are accessible to the covered entity and demonstrate that the covered entity is responsible for care. 80 Fed. Reg. at 52,306-52,308.

The dispensing or infusion of a drug alone, without a "patient-to-provider encounter," does not make the individual a patient of the covered entity. Merely infusing a drug the prescription for which was written by a physician outside the infusion center covered entity, for example, would not qualify for 340B discounts. 80 Fed. Reg. at 52,307. HRSA notes that, where permitted under state law, telemedicine visits are sufficient to establish 340B patient eligibility. 80 Fed. Reg. at 52,306.

Further, the Proposed Guidance states that, if finalized, the proposed patient definition would be applied "on a prescription-by-prescription or order-by-order basis." 80 Fed. Reg. at 52,306. As such, a patient would not be able to qualify for drugs at the 340B prices for all of patient's medical needs based on being treated by a covered entity for a particular medical condition, but not all.

Employees of covered entities are not 340B-eligible patients unless all the other specific criteria are met; a covered entity's financial responsibility for an employee's health care alone does not establish the employee as a patient of the covered entity. 80 Fed. Reg. at 52,307. In times of public health emergency, the Secretary of HHS may loosen the patient eligibility requirements. 80 Fed. Reg. at 52,307-52,308. Exception to the patient eligibility requirements is also made for AIDS Drug Assistance Programs ("ADAPs"). 80 Fed. Reg. at 52,307.

Covered entities may employ replenishment models (a process by which a covered entity reorders drug inventory based on actual prior drug usage), but auditable records demonstrating receipt of drugs by 340B-eligible patients must be maintained, and purchasing errors are expected to be identified and cured through credit/rebill within 30 days of the initial purchase. 80 Fed. Reg. at 52,308. HRSA states in the Proposed Guidance that a covered entity's improper accumulation or tally of its 340B drug inventory, even prior to the placement of an order, equals diversion and constitutes a violation. *Id*. Importantly, HRSA notes that "covered entities are responsible for requesting 340B pricing at the time of the original purchase," and appears to criticize covered entities that attempt to retroactively re-characterize purchases (à la the AIDS Healthcare Foundation's attempts to do so over the last several years). *Id.*

Significantly, Condition 5, above, may be the most impactful change in the patient definition in that it appears to prevent pre-admit and discharge prescriptions written pursuant to *inpatient* care from qualifying for 340B pricing.

In sum, the patient definition articulated in the Proposed Guidance is a narrower, tighter definition than the one that has been in place since 1996. Manufacturers should support HRSA's attempt to focus the availability of 340B-priced drugs on those individuals who are truly patients receiving outpatient care from 340B covered entities.

- **Repayment**. In cases of both diversion and double-dipping, covered entities may determine that they owe manufacturers refunds for drugs improperly dispensed or billed. HRSA (somewhat disingenuously) notes in the Proposed Guidance that manufacturers may elect not to request repayment, "bear[ing] in mind the potential impact of such decisions on CMS price reporting requirements." 80 Fed. Reg. at 52,308. It is worth noting here that the Medicaid Drug Rebate Program statute specifically excludes "any prices charged" to a covered entity from Best Price (and, by extension, Average Sales Price), and the proposed Medicaid Drug

Rebate Program regulations exclude any prices to a covered entity from Average Manufacturer Price. *See* 42 U.S.C. §1396r-8(c)(1)(C)(i)(I); 42 C.F.R. §447.504(c)(1).

- **Covered Entity Termination**. The Proposed Guidance makes clear that any covered entity that loses its program eligibility must (a) immediately notify HRSA, (b) stop purchasing drugs at the 340B price and (c) refund manufacturers for discounted purchases made after the entity termination date (as listed by HRSA on the 340B database). 80 Fed. Reg. at 52,302-52,303. If a parent entity loses eligibility, so do all of its child sites. HRSA promises to provide communications and website notices to manufacturers to alert them to covered entity deletions that occur mid-quarter. Once terminated from the program, an entity may not re-enroll until it has demonstrated that it will comply with all program requirements *and has completed or is in the process of offering repayment to affected manufacturers*, a welcome development. Short of draconian exclusion from the 340B Program, however, there appear to be no measures HRSA can take to punish covered entities for violating program requirements. Re-enrollment seems to be guaranteed – even for the most egregious violations – for any covered entity that simply promises not to do it again.

- **GPO Prohibition**. HRSA proposes an exception to the GPO prohibition for hospitals that cannot access drugs at the 340B ceiling price *or* at WAC. 80 Fed. Reg. at 52,305. One wonders when product might be available for purchase at a GPO price, but not at WAC. Nevertheless, this seems to be a sound and limited exception to the GPO rule. Hospitals subject to the GPO prohibition may not purchase drugs using a GPO for 340B-eligible or 340B-ineligible outpatients, and hospitals that order drugs based on 'actual prior usage' may not tally 340B-ineligible outpatient use for drug orders on a GPO account. Finally, HRSA proposes to provide a thirty-day window for credit/rebill to cure GPO violations.

- **Medicaid Managed Care Organizations ("MCOs") and Duplicate Discounting**. The Proposed Guidance would expand the Medicaid exclusion file currently in use to address Medicaid Managed Care Organization ("MCO") patients. 80 Fed. Reg. at 52,309. HRSA contends that use of a 340B Medicaid Exclusion File would identify the covered entity billing practices used for MCO patients; however, beyond "encouraging" covered entities, states and Medicaid MCO's to cooperate to identify 340B claims and eliminate duplicate discounting when 340B drugs are dispensed to patients covered by Managed Medicaid, the Proposed Guidance offers very little in terms of practical solutions to this pernicious problem. In our experience, none of those three stakeholders take very seriously their obligation to ensure that manufacturers are not double-dipped. Stronger enforcement, oversight and accountability measures must be part of any final guidance if the epidemic of duplicate discounting in the Medicaid MCO context is to be ended, consistent with the statute.

- **Contract Pharmacies**. As noted in recent **GAO** and **OIG** reports, contract pharmacy arrangements present troubling opportunities for diversion and double dipping. The Proposed Guidance does not directly address those concerns beyond calling for strengthened covered entity oversight of the pharmacies with which they contract. In the Proposed Guidance, HRSA reiterates its longstanding position that a covered entity "retain complete responsibility" for contract pharmacy compliance with program requirements. Further, it notes that it expects covered entities "to conduct quarterly review and annual independent audits of each contract pharmacy location." 80 Fed. Reg. at 52,321. HRSA proposes to require record retention of these reviews such that HRSA and manufacturers can audit against them. The quarterly and annual reviews, as proposed, are steps in the right direction, but one wonders if their practical implications will be sufficient to allay fears of diversion and duplicate discounting. Moreover, whether HRSA's comment that contract pharmacy arrangements should be implemented "…in accordance with all… applicable Federal, State, and local laws, including the Federal anti-kickback statute" signals an enforcement focus in this area remains to be seen.

- **Record Retention Requirement**. HRSA proposes to require covered entities to maintain auditable records demonstrating compliance with all 340B Program requirements for at least five years. This standard would apply to records for all child sites and contract pharmacies. Failure to produce such records could lead to a presumption the covered entity was out of compliance with those requirements, which could result in penalties, including removal from the 340B Program. 80 Fed. Reg. at 52,309.

Key Takeaways – Manufacturers

- **Must Offer**. The ACA amended the 340B statute to provide that the 340B Pharmaceutical Pricing Agreement ("PPA") require that manufacturers participating in the 340B Program "must offer" covered outpatient drugs to covered entities at or below the 340B ceiling price if such drugs are "made available to any other purchaser at any price." 42 U.S.C. 256b(a)(1). Although HRSA has yet to revise the PPA to reflect the "must offer" requirement, the Proposed Guidance signals that HRSA believes the "must offer" provision is currently binding.

  Manufacturers may, however, institute limited distribution plans, restricted distribution networks and distribution limitations due to shortage. The Proposed Guidance would require manufacturers to notify HRSA in writing prior to the implementation of such a plan, which HRSA may publish on its website. 80 Fed. Reg. at 52,321. Components of a restrictive plan would include (a) the rationale for the plan, (b) an assurance that the restrictions will be imposed equally on covered entities and commercial purchasers, (c) a mechanism that would allocate sales to covered entities and non-340B purchasers with no previous purchase history of the drug, (d) effective dates of the plan and (e) a plan for notification of wholesalers and covered entities of the restrictive plan. *Id.* HRSA encourages covered entities to contact HRSA and other federal agencies, including the Department of Justice and the HHS Office of Inspector General, if issues regarding such plans cannot be resolved.

  The Proposed Guidance does not specifically define when an arrangement qualifies as "limited," but suggests that any specialty pharmacy, restricted or limited supply distribution arrangement would trigger HRSA's expectation of disclosure. Manufacturers of specialty pharmaceutical products or products subject to restricted or limited supply distribution arrangements should consider submitting comments on this issue.

- **Refunds to Covered Entities**. The ACA amended the 340B statute to require HHS to "establish[] procedures for manufacturers to issue refunds to covered entities in the event there is an overcharge by the manufacturers." 42 U.S.C. §256b(d)(1)(B)(ii). The Proposed Guidance falls far short of this requirement. Essentially, all the Proposed Guidance does is announce expectations on manufacturers of what and when they must refund. *See* 80 Fed. Reg. at 52,321. Specifically, manufacturers must refund overcharges within ninety days of discovery; they may not net undercharges and overcharges, they may not aggregate across NDCs, they may not ignore *de minimus* amounts and they must provide written reports to HRSA describing in detail the process of repayment. These requirements are unfair, unrealistic and objectionable on many levels, and manufacturers should consider submitting comments opposing them.

  Equally, if not more importantly, HRSA has completely failed to articulate a process or a mechanism by which repayments can be made efficiently, accurately and with the minimum disruption to the operations of manufacturers and covered entities alike. We believe drug manufacturers deserve a robust and easily administrable mechanism for making refund payments to covered entities when required, one that recognizes that often tiny repayment amounts must be made to thousands of entities across multiple NDCs merely, in many cases, due to a routine restatement of Best Price. HRSA is statutorily required to "establish procedures"

for refunds, not merely announce rules around the edges of this critical – and critically burdensome – requirement.

HRSA proposes one element of the process of restatement with which we agree, however: a covered entity that fails to act to accept a direct repayment (*e.g.*, cash a check) within ninety days of a manufacturer's refund, or affirmatively dispute the calculated repayment amount, waives its right to repayment. 80 Fed. Reg. at 52,312.

- **Certification**. HRSA proposes to require manufacturers to annually certify the accuracy of their information in the 340B database. 80 Fed. Reg. at 52,312. The scope of the certification is not articulated in the Proposed Guidance. Presumably it would apply to basic contact and program participation information. If the proposed certification were broader – covering, for example, 340B prices, information about the manufacturer's covered outpatient drugs, restricted distribution plans and the like – such certification could be onerous and potentially far beyond what covered entities are expected to certify to.

- **ADAP Rebates**. AIDS Drug Assistance Programs ("ADAPs") may obtain their 340B discounts either at the point of purchase (like all other covered entities) or via a rebate (equal to the Medicaid URA). Additionally, ADAPs, unique among covered entities, may pay their patients' insurance amounts rather than use their money to purchase drugs directly. This has led to situations in which ADAPs could pay a small fraction of the purchase price of a drug (a copayment, say), and seek a full rebate from manufacturers (also known as 'partial pay for full rebate'). In this way, the ADAP is not receiving a discount for covered outpatient drugs, but is making a profit on every unit of ADAP utilization. The Proposed Guidance takes steps to limit this practice.[1] ADAPs would be permitted to seek rebates only when the ADAP makes a "qualified payment" for a drug product: first, where the ADAP pays more than the 340B ceiling price for the drug, or second, where the ADAP pays both the patient's insurance premium *and* copayment, coinsurance or deductible (payment of solely the latter, HRSA concluded, is too attenuated to constitute a purchase of the drug). 80 Fed. Reg. at 52,313. Moreover, HRSA proposes to require ADAPs to submit claims-level data to a manufacturer in support of each qualified payment to receive a rebate from that manufacturer. These proposed restrictions, while imperfect and arguably difficult to monitor, would go a long way to reducing partial pay for full rebate. When effective (a year after the issuance of the final guidance), ADAPs would no longer be able to use the 340B program as a pure profit center.

- **Audits**. The Proposed Guidance does not alter in any meaningful way the historic process under which manufacturers may audit covered entities, though it does clarify that manufacturers may audit the child sites and contract pharmacies of covered entities, and provides examples of what would be considered "reasonable cause" for a manufacturer audit (*e.g.*, a covered entity's refusal to respond to manufacturer questions). *See* 80 Fed. Reg. at 52,314-52,316. Manufacturers should consider commenting on the limited bases upon which they can base an audit, however. Currently, and under the Proposed Guidance, manufacturers may only pursue a covered entity audit to address suspicions of diversion or double-dipping. Manufacturers should be permitted to pursue audits to ensure compliance with the ADAP "qualified payment" rule and the GPO prohibition.

  HRSA proposes procedures for HRSA auditing of manufacturers and wholesalers for compliance with 340B requirements. The Proposed Guidance discusses notification of intent to audit, an opportunity for notice and hearing (before whom is not specified) and information regarding corrective action plans. *Id.*

[1] HRSA considered and rejected a percentage rebate contingent on the percentage of the total cost of the drug borne by the ADAP as so operationally burdensome as to be inoperable.

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Agency guidance is not binding law like a statute or formal final ("legislative") regulation. Rather, it is the agency's opinion about how a statute should be interpreted or how the agency's program is to operate. That opinion, like those of other stakeholders, will be considered by a court of competent jurisdiction in the event of a dispute. The opinion will not be given the same degree of legal deference as would a formal agency rulemaking. Manufacturers should keep this in mind as HRSA moves ahead with guidance rather than rulemaking in important areas of 340B compliance and administration.

Many manufacturers would prefer the certainty of final regulations – particularly in highly sensitive areas such as patient definition – to less predictable and less enforceable standards set out in guidance. Additionally, one would hate to see the 340B program administered through a series of idiosyncratic HRSA dispute resolution precedents or expensive and time-consuming litigation in federal court.

The K&S Government Pricing Team is ready to assist you in the preparation of comments to this Proposed Guidance at every stage—evaluation, consideration and articulation. Please keep us in mind if there is any way we can help. We have extensive experience interpreting proposed guidance documents and in drafting agency comments. We would be very happy to help you create effective, thoughtful, coherent and persuasive comments on any and all government pricing issues, including those presented in this Proposed Guidance. For more information, please see our **Practice at a Glance**.