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Recent Developments in the Federal Prescription Drug Pricing Programs

by **Constance A. Wilkinson, Benjamin S. Martin, Wendy C. Goldstein, and Kathleen A. Peterson**

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The U.S. Department of Health and Human Services ("HHS") recently issued several program guidances and announcements related to two federal prescription drug pricing programs: (1) the Section 340B Discount Drug Program ("340B Program"), administered by the Health Resources and Services Administration ("HRSA"); and (2) the Medicaid Drug Rebate Program ("MDRP"), administered by the Centers for Medicare & Medicaid Services ("CMS"). We have set forth below an overview of these recent developments.

I. 340B Program: Two Advance Notices of Proposed Rulemaking: Public Comments Sought

On September 20, 2010, HRSA issued two Advance Notices of Proposed Rulemaking ("Notices") to implement certain of its obligations under Section 7102 of the Patient Protection and Affordable Care Act,[1] as amended by Section 2302 of the Health Care and Education Reconciliation Act of 2010[2] (collectively "the Affordable Care Act").[3] Importantly, these Notices are not proposed rules. Rather, as a preliminary step, HRSA is soliciting comments from the public that it will then use in developing proposed regulations that it will publish as "proposed rules" in the future. Interested parties will have an opportunity to comment on those proposed regulations. HRSA will take those comments into account when finalizing the regulations subsequently published in the "final rules."

1 Pub. L. No. 111-148 (2010).
2 Pub. L. No. 111-152 (2010).
3 *See* "340B Drug Pricing Program, Manufacturer Civil Monetary Penalties," 75 Fed Reg. 57230-32 (Sept. 20, 2010); "340B Drug Pricing Program, Administrative Dispute Resolution Process," 75 Fed Reg. 57233-35 (Sept. 20, 2010).

These regulations, once promulgated, will be the first regulations issued for the 340B Program, because the legislation that created the 340B Program did not grant HRSA rulemaking authority. HRSA has issued previous program guidances in the form of "Notices" in the Federal Register. However, prior to the enactment of the Affordable Care Act, HRSA did not have the authority to promulgate regulations with the force and effect of law.

The deadline for submitting comments to each Notice is November 19, 2010.

A. Notice Regarding Civil Monetary Penalties for Pharmaceutical Manufacturers

The Affordable Care Act directs HRSA to promulgate regulations that establish standards for assessing civil monetary penalties ("CMPs") against pharmaceutical manufacturers that "knowingly and intentionally" sell drugs to 340B Program Covered Entities[4] at prices that exceed those drugs' calculated ceiling prices.[5] Under the statute, CMPs shall not exceed $5,000 for "each instance" of overcharging that occurs.[6]

In the Notice regarding CMPs, HRSA states that it had no authority to impose CMPs prior to the enactment of the Affordable Care Act. HRSA seeks comments regarding aspects of existing CMP models from a number of federal agencies that could be adapted to the 340B Program, with a particular emphasis on the authorities of the HHS Office of Inspector General ("OIG") to impose CMPs under the MDRP (as recommended by OIG in an October 2005 report entitled "Deficiencies in the Oversight of the 340B Drug Pricing Program" (OEI-05-02-00072)) and the procedures codified at 42 C.F.R. pt. 1003, which describe the process OIG uses for assessing CMPs for violations of requirements under the Medicare and Medicaid programs. HRSA identifies nine specific issues for which it is seeking comments from the public (described below). HRSA also expressly solicits comments from the public about any other issues that stakeholders believe are key to implementing an effective process for CMPs.

HRSA specifically seeks comments regarding the threshold determination of when it would be appropriate for HRSA to impose CMPs on manufacturers, rather than utilizing "other available compliance mechanisms." HRSA states that it may take into account the following factors (among others) in evaluating whether CMPs would be appropriate: the amount of the overcharge, the frequency of the overcharge, the number of Covered Entities affected, and the compliance history of the pharmaceutical manufacturer in question.

HRSA also identifies two key terms as needing "clearly established definition[s]." The first such term is "instance." HRSA states that it believes "instance" could be defined either as each unit of drug sold or as each commercial transaction, as well as instances of refusing to sell a covered drug at its 340B Program ceiling price. Pharmaceutical

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4 Covered Entities are delineated in the law and are further identified in prior guidances. *See* 42 U.S.C. § 256b(a)(4) (listing categories of Covered Entities).

5 *See* Pub. L. No. 111-148 § 7102(a) (codified at 42 U.S.C. § 256b(d)(1)(B)(vi)).

6 *See id*.

manufacturers and Covered Entities will want to consider whether the term "instance" should be defined in reference to the sale (*e.g.,* each purchased unit or each transaction, as HRSA is considering), or the price report (*e.g.,* to include each price that exceeds a covered outpatient drug's calculated ceiling price, such that there could be only one penalty assessed per product per quarter). Any definition may have a significant impact on the amount of potential CMPs assessed against pharmaceutical manufacturers but would have no effect on the amount of any refunds resulting from price adjustments to which Covered Entities might be entitled.

The second such term is "knowing and intentional." HRSA is contemplating a standard under which the requisite intent for assessing a CMP could be inferred even when no single individual had knowledge of all the elements of a claim – *i.e.*, different individuals knew the ceiling price, the status of the purchaser as a Covered Entity, and that the price charged was in excess of the 340B Program ceiling price – or where the pharmaceutical manufacturer has established a system where overcharges are "a highly probable consequence."

In addition, HRSA expressly identified for public comment several other issues, including the elements of the administrative process, the hearing structure, the appeals process, and the processes for calculating and paying penalties. Therefore, the public has the opportunity to attempt to shape the penalty calculations and the due process afforded pharmaceutical manufactures under the circumstances.

B. Notice Regarding Administrative Dispute Resolution

The Affordable Care Act also directs HRSA to promulgate regulations "to establish and implement an administrative process for the resolution of":

- Claims by Covered Entities that a pharmaceutical manufacturer has overcharged them for drugs purchases under the 340B Program; and

- Based on information obtained during an audit, claims by pharmaceutical manufacturers that a Covered Entity has violated the statutory prohibitions against selling drugs purchased under the 340B Program to anyone other than patients of the Covered Entity or causing a state Medicaid program to request a rebate from a manufacturer for drug units that the Covered Entity already purchased at the 340B Program ceiling price pursuant to the 340B Program.[7]

In its second Notice arising from this new legal authority, HRSA identifies 13 issues for public comment, but also expressly solicits comments on any other issues that stakeholders believe are key to implementing an effective alternative dispute resolution process for the 340B Program.

HRSA expressly seeks comments regarding what aspects of other existing models for administrative dispute resolution could be adapted to the 340B Program, although it considers most useful the current dispute resolution process for the 340B Program,

[7] *See id.* (codified at 42 U.S.C. § 256b(d)(3)).

which it notes has been underutilized because it is voluntary. As previously noted, a pharmaceutical manufacturer must first audit a Covered Entity before submitting a claim for dispute resolution. HRSA seeks public comments regarding the sufficiency of the current guidelines for initiating such audits. A number of issues identified relate to process, such as the structure of hearings; the decision-making official or body that would make preliminary and/or final determinations regarding the sufficiency of claims; appropriate procedures for appealing determinations; discovery; and whether there should be a deadline for filing after which claims would be barred. Another issue relates to the standard of evidence required to initiate a claim and the Covered Entity's ability to base a claim on indirect evidence of a violation, such as a pharmaceutical manufacturer's refusal to sell at the 340B Program price that caused the Covered Entity to purchase the drug at a higher commercial price.

One of the more interesting issues raised by the Notice is the extent to which a third party (for example, a trade association) could bring claims on behalf of member Covered Entities and whether a signed representation agreement to authorize the action should be required. Other issues include whether to permit the consolidation of claims by multiple pharmaceutical manufacturers or multiple Covered Entities against one or more pharmaceutical manufacturers (akin to class action suits).

This Notice does not address the circumstances under which pharmaceutical manufacturers and Covered Entities could litigate claims related to the 340B Program in court, in light of the administrative dispute resolution process that the Affordable Care Act requires HRSA to establish. Under the process contemplated both by the Affordable Care Act and the Notice, the resolution of the dispute reached at the conclusion of HRSA's administrative process would be a "final agency decision . . . binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." One open question is whether this statutory language means that, for example, a Covered Entity that believes it was overcharged by a pharmaceutical manufacturer must exhaust the administrative remedy available through this new dispute resolution process before seeking relief in court.[8] Other open questions are: (1) whether the party seeking judicial relief would bring suit against HRSA, *i.e.*, the agency that rendered the "final agency decision," or the other party to the dispute; and (2) the scope of the court's review, in light of the administrative proceedings before HRSA. Pharmaceutical manufacturers and Covered Entities should consider whether to request that HRSA address these open questions.

If the effect of this statutory language is to require Covered Entities to exhaust the administrative dispute resolution process prior to seeking relief in court, this statutory language could represent a change in law. In a case involving alleged overcharges to Covered Entities that occurred prior to the enactment of the Affordable Care Act, the U.S. Court of Appeals for the Ninth Circuit held that Covered Entities are third-party beneficiaries to the 340B Program Pharmaceutical Pricing Agreements ("PPAs") between manufacturers and HRSA and, therefore, could sue pharmaceutical

[8] Indeed, this language echoes language in the Administrative Procedure Act that permits judicial review of a "final agency action." *See* 5 U.S.C. § 704.

manufactures for alleged overcharges *without first having to request administrative resolution*.[9] The U.S. Supreme Court has agreed to hear the pharmaceutical manufacturers' appeal of that decision during its 2010-2011 term.[10]

II. MDRP: CMS Letter to State Medicaid Directors

In a letter dated September 28, 2010, to State Medicaid Directors (the "CMS Letter"),[11] CMS provided additional guidance regarding implementation of changes to the MDRP made by the Affordable Care Act. Of interest to pharmaceutical manufacturers are: (1) additional guidance about the manner in which manufacturers' MDRP rebate obligations are extended to prescription drug utilization by beneficiaries of Medicaid managed care organizations ("MCOs"); and (2) the date on which CMS expects to resume calculating Unit Rebate Amounts ("URAs") and providing those URAs to the States, rather than relying on manufacturers to calculate those URAs.[12] The CMS Letter also revised the formula by which CMS will "claw back" a portion of the MDRP rebate under the Affordable Care Act (in a way that is likely more beneficial to the States, in contrast to the formula previously established by CMS prior guidance).

A. MDRP Rebates for Medicaid MCO Utilization

Regarding the extension of MDRP rebates to Medicaid MCO prescription drug utilization, the Affordable Care Act left some ambiguity as to the flexibility Medicaid MCOs would continue to have to utilize their own formularies and other utilization management tools independent of the requirements imposed by the States with respect to their fee-for-service Medicaid programs. In other words, given that Section 2501(c) of the Affordable Care Act appears to have subjected Medicaid MCO utilization to the entirety of the MDRP statute, with rebates on that utilization then paid to the States rather than to the MCOs, it was not clear whether a Medicaid MCO would have to adopt the formulary, preferred drug list, prior authorization, step therapy, or other requirements of the State's fee-for-service Medicaid program with which it contracts.

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9 *See Astra USA, Inc. v. County of Santa Clara*, 588 F.3d 1237 (9th Cir. 2009), *cert. granted* (Sept. 28, 2010) (No. 09-1273).

10 If the Supreme Court were to uphold the Ninth Circuit's decision, an interpretation of the statutory language in the Affordable Care Act to require exhaustion of the administrative dispute resolution process would appear to overturn that holding, meaning that the Supreme Court's holding in this case would relate only to Covered Entities' rights prior to the enactment of the Affordable Care Act. On the other hand, if the Supreme Court were to reverse the Ninth Circuit's decision, *e.g.*, by holding that Covered Entities' have no private right of action under the PPAs, the statutory language in the Affordable Care Act would appear to create a private right of action for Covered Entities, albeit perhaps after exhausting the administrative dispute resolution process.

11 Available at: http://www.cms.gov/smdl/downloads/SMD10019.pdf.

12 For a complete summary of the changes to the MDRP made by the Affordable Care Act and subsequent legislation, please see our previous Client Alerts of March 31, 2010, "Medicaid Drug Rebate Program 'Reform': Key Considerations and Implementation Tips for Pharmaceutical and Biotech Manufacturers," and September 10, 2010, "CMS Proposes to Withdraw Regulations on Average Manufacturer Price Determination, Multiple Source Drug Definition, and Medicaid Federal Upper Limits."

In the CMS Letter, CMS says that it does not plan to require Medicaid MCOs to modify their formularies, although it acknowledges that the States have the authority to impose such requirements. CMS explains that this means that Medicaid MCOs may continue to cover drugs of manufacturers that do not currently participate in the MDRP. Conversely, this also appears to mean that Medicaid MCOs could exclude from coverage the drugs of manufacturers that do participate in the MDRP, although presumably any such exclusion would be required to meet the MDRP statute's requirements for Medicaid MCO formularies.

In the CMS Letter, CMS also confirms that Medicaid MCOs are obligated to report to the States utilization of physician-administered drugs by their enrolled Medicaid patients so that the States may collect MDRP rebates on that utilization. This appears to require Medicaid MCOs to utilize similar procedures that the MDRP statute[13] requires States to adopt so that they may "crosswalk" J-codes typically used in reimbursement claims for physician-administered drugs to the National Drug Codes of the actual drugs administered and, in turn, used to obtain MDRP rebates from pharmaceutical manufacturers. This clarification may affect manufacturers' financial projections regarding the potential impact of MDRP rebates for Medicaid MCO utilization.

B. Resumption of URA Calculation by CMS

CMS was not immediately prepared to calculate URAs to reflect changes made by the Affordable Care Act, including, for example, increases to minimum basic rebate percentages and a change to the methodology used to calculate additional rebate amounts for line extensions of solid oral dosage forms retroactive to January 1, 2010. Instead, in the CMS Letter, CMS stated that it currently is relying on manufacturers to calculate URAs for their covered outpatient drugs and to use those URAs to calculate the MDRP rebate amounts owed to the States, based on the Medicaid patient's utilization that the States report on their quarterly invoices sent to pharmaceutical manufacturers.

In the "Timeline" in the enclosure to the CMS Letter, CMS states that it expects that its systems will be able to calculate URAs in accordance with the revised methodology by May 3, 2011. In other words, CMS will begin calculating URAs and providing them to the States for the first quarter of 2011 and forward. Therefore, pharmaceutical manufacturers should be prepared to continue to calculate the URAs used to calculate MDRP rebates at least until that date. Pharmaceutical manufacturers may still want to calculate URAs for their products in order to confirm that the URAs calculated by CMS and included on the States' MDRP rebate invoices are accurate.

III. Recent OIG Activities Related to the MDRP and 340B Program

In September 2010, OIG issued a report entitled "Drug Manufacturers' Noncompliance with Average Manufacturer Price Reporting Requirements," and a corresponding Special Advisory Bulletin entitled "Average Manufacturer Price and Average Sales Price

[13] *See* 42 U.S.C. § 1396r-8 (a)(7).

Reporting Requirements." On October 1, 2010, OIG also released its Work Plan for 2011 that describes various activities related to the MDRP and 340B Program.

A. OIG's Report and Special Advisory Bulletin

In the September 2010 report, OIG noted the following three primary findings, based on its review of the Average Manufacturer Price ("AMP") submissions for each month and quarter in 2008 of all pharmaceutical manufacturers that participate in the MDRP:

1. Fifty-three percent (53%) of the manufacturers did not submit at least one quarterly AMP value by its statutory due date, *i.e.*, within 30 days of the end of the quarter.

2. Seventy-eight percent (78%) of the manufacturers did not submit at least one monthly AMP value by its statutory due date, *i.e.*, within 30 days of the end of the month.

3. Although CMS took some action against 78 manufacturers for failure to comply with quarterly AMP-reporting requirements, CMS took no action against any manufacturer for failure to comply with monthly AMP-reporting requirements.

Based on these findings, OIG recommended that CMS be more proactive in monitoring manufacturers' compliance with the timely filing requirements for quarterly and monthly AMP submissions and in pursuing available enforcement actions, as appropriate. CMS concurred with these recommendations. Although quarterly AMP values are currently utilized to calculate MDRP rebates, monthly AMPs currently are not utilized for any purpose, due to the injunction that was issued by a court in connection with litigation brought by two pharmacy trade associations.[14] Once that litigation is resolved, CMS may then provide monthly AMPs to the States for all covered outpatient drugs and will use monthly AMPs to calculate weighted average AMPs for multiple source drugs that will be published on a public website and that will be used, in turn, to calculate Federal Upper Limit ("FUL") payments, in accordance with statutory revisions to the FUL calculation methodology made by the Affordable Care Act.

Contemporaneously with the release of the September 2010 report, OIG issued a Special Advisory Bulletin announcing an enforcement initiative to promote manufacturers' compliance with their price-reporting requirements under not only the MDRP, but also under Medicare Part B regarding the reporting of Average Sales Price used to calculate reimbursement amounts for drugs covered under that benefit. In OIG's words, OIG will begin imposing CMPs on noncompliant manufacturers, under the provision in the MDRP statute that authorizes a penalty of $10,000 for each day that a price report is late because "HHS's past approach of promoting voluntary compliance has not been fully effective." OIG did not also announce the criteria that it will use to evaluate whether to seek CMPs, *e.g.*, the number of days that a price report is past due,

[14] Changes made by the Affordable Care Act to the AMP calculation methodology may affect the pending litigation.

the number of price reports that are past due, and/or the manufacturer's history of noncompliance.

B. OIG's 2011 Work Plan

Included within the OIG's Work Plan for 2011 are a number of activities related to the MDRP and 340B Program that OIG will review, including, but not limited to, the following:

- Pharmaceutical manufacturers' compliance with AMP calculation methodological requirements. [Based on the description of the activity, OIG's review will likely focus on the AMP calculation methodology prior to enactment of the Affordable Care Act.]

- Pharmaceutical manufacturers' recalculations of the "base date" AMPs used to calculate the additional rebate portions of URAs, such that those base date AMPs would reflect changes to the AMP calculation methodology created by the Deficit Reduction Act of 2005 and CMS's implementing regulations. [Our understanding is that manufacturers are seeking permission from CMS to recalculate their base date AMPs again to reflect changes made by the Affordable Care Act, and this report might provide insight into OIG's view of the data that are necessary to perform these recalculations.]

- States' efforts to identify drug units purchased by Covered Entities under the 340B Program and submitted for Medicaid fee-for-service reimbursement in order to prevent requests by the States for MDRP rebates on those same drug units. [This report might enable manufacturers to enhance their ability to police whether they are providing "duplicate discounts" under the two programs.]

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This Client Alert was authored by ***Constance A. Wilkinson***, ***Benjamin S. Martin***, ***Wendy C. Goldstein***, and ***Kathleen A. Peterson****. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the EpsteinBeckerGreen attorney who regularly handles your legal matters.*

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Lynn Shapiro Snyder, Esq.
EDITOR

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