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OIG Dusts off the Old Rule Book to Say No to Free Expensive Drugs to Hospitals

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Summary

The Office of Inspector General, Department of Health and Human Services posted an unusual negative Advisory Opinion (AO 18-14) on a drug company's proposal to provide free drugs to hospitals for use with pediatric patients suffering from a form of epilepsy. Of particular interest is OIG's reliance on a longstanding, but rarely used, authority to justify finding and relying on public information about the drug at issue, including pricing information, to support its unfavorable conclusion. This advisory opinion might counsel future opinion requestors to withdraw their opinion request once OIG indicates the opinion will be unfavorable.

In Depth

On November 16, 2018, the Office of Inspector General (OIG), Department of Health and Human Services posted an unusual negative Advisory Opinion (AO 18-14) on a drug company's (the Requestor's) proposal to provide free drugs to hospitals for use with pediatric patients suffering from a form of epilepsy (the Syndrome). AO 18-14 is notable, not because negative opinions are themselves unusual, but for the manner in which OIG reached it. Citing a longstanding, but rarely used, rule, OIG found and relied on public information about the drug at issue, including pricing information, to support its unfavorable conclusion. This advisory opinion might counsel future opinion requestors to withdraw their opinion request once OIG indicates the opinion will be unfavorable.

The Proposed Arrangement:

The Requestor markets a drug that is used to treat a number of rare conditions, including the Syndrome. Patients with the Syndrome are frequently diagnosed in an inpatient setting, where the drug is not separately reimbursable. Studies and medical literature referenced by the Requestor support better outcomes when treatment—and there is at least one other FDA approved treatment on the market—starts closer to symptom onset. Treatment with Requestor's drug typically requires two doses per day for two weeks, followed by two more weeks of tapered dosing. Premature treatment termination can have serious health consequences for patients. According to the Requestor,

hospitals frequently do not stock the drug for a variety of reasons (including inventory risk related to unused stock for long time periods), which results in a delay in initiating treatment. Further, according to the Requestor, many hospitals do not want to administer the drug in an inpatient setting because of insufficient payor reimbursement. While the Requestor considered reducing the price for the drug when sold to hospitals for treating the Syndrome, it chose not to do so because of the impact on pricing in other contexts that would result from the best price provisions of the Medicaid Drug Rebate Program.

Under its proposal (the Proposed Arrangement), the Requestor would stock the drug on consignment at hospitals at no cost. It would also provide the drug for free to the hospitals to use with inpatients who were diagnosed with the Syndrome and for whom the drug had been prescribed. In the event that the patient was unable to obtain insurance coverage for the drug during the post-discharge treatment period, the Requestor would also provide the drug for free to the patient for the balance of the course of treatment.

The Analysis (And Then Some):

Historically, OIG has based its advisory opinions on the facts that are provided and certified by a requestor. But OIG deviated from this historical approach for AO 18-14. Citing its longstanding regulatory authority at 42 C.F.R. § 1008.39(d), OIG referenced and may have based its analysis to some extent on additional, publicly available information about the Requestor and the drug. That cited regulatory provision states that "in connection with any request for an advisory opinion, the OIG or DOJ may conduct whatever independent investigation they believe appropriate." It appears that this may be the first time that OIG has expressly relied on this authority to pull in, and rely on, additional information that OIG found on its own initiative and was not provided by and certified by a requestor to establish the factual basis upon which it would opine. In this instance, OIG noted the following additional, publicly available information:

1. The drug's list price has significantly increased over the last 15 years and is the second highest cost drug for the Medicaid program in the "total spending per prescription fill" category.

2. The drug has been around for a long time (originally approved by the FDA in 1952) and historically used to treat the Syndrome.

3. As a result of a recent settlement with the Federal Trade Commission (FTC), Requestor is required to grant a license to another company to develop, for use in the US, a competing synthetic substance used to treat the Syndrome outside of the US. This settlement related to allegations that a predecessor owner of the drug, which Requestor acquired in 2014, acquired the competing synthetic substance to stifle competition, thereby enabling it to maintain high prices on the drug. OIG acknowledged that the Requestor did not concede the allegations and OIG stated it expressed no opinion about the allegations. Rather, OIG stated that it included this information to highlight that there is another treatment possibility for the Syndrome that is now able to be developed in the US.

OIG cites to various internet-based sources for this information, such as the Requestor's website and 10-K filings, the Centers for Medicare and Medicaid Services' 2015 Medicaid Drug Spending Dashboard, an FTC press release and Action Memo from FTC's website, and medical journal articles available online.

At the outset of its substantive analysis, OIG concluded that the Proposed Arrangement would implicate the federal Anti-Kickback Statute because the free drugs would constitute remuneration to the hospitals, which would be in a position to make direct referrals (through employed physicians) or arrange for or recommend the purchase of the drug (through formulary placement). After acknowledging that it has approved other free drug arrangements with certain safeguards in the past, that in the US the drug is a first-line treatment for the Syndrome, and that research supported receiving treatment for the Syndrome quickly after diagnosis, OIG stated that it "[could not] analyze the Proposed Arrangement in a vacuum . . . ." Relying on a combination of the additional information and the facts certified by the Requestor, OIG identified the following reasons for concluding that the Proposed Arrangement would present more than a minimal risk of fraud and abuse:

1. The Proposed Arrangement would relieve hospitals of significant financial obligations associated with acquiring the drug.

2. Federal health care programs would not share in any of the savings that resulted from the hospitals receiving the free drugs.

3. The Proposed Arrangement could be a seeding program and allow the Requestor to effectively reduce the price of the drug for use with patients suffering from the Syndrome without having to reduce the price for all patients and payors.

4. Steering and unfair competition could result from the Proposed Arrangement because it could cause hospitals to influence prescribers to choose the drug over other available treatment options.

5. Providing the drug for free would not be necessary to address the concerns about treatment delay, as the two main causes cited by the Requestor—lack of immediate access to the drug and hospital unwillingness to bear the inventory risk—would be addressed by providing the drug on a consignment basis.

6. Notwithstanding the Requestor's certification to the contrary, because of the health risks posed by discontinuing treatment early, the free drugs would, in effect, be conditioned on future purchases for insured patients with coverage of the drug.

Interestingly, OIG signaled that it might have reached a favorable conclusion had the Requestor proposed to provide the drug for free (for both patients and payors) for the entire course of treatment.

The Potential Broader Impact of OIG's Approach to AO 18-14:

As mentioned, OIG appears to have diverged from the approach it had taken to advisory opinions for over 20 years by relying on its authority at 42 C.F.R. 1008.39(d) to bring in information and facts beyond those presented and certified by the Requestor. The interesting question is why OIG believed it needed to both obtain additional information and then cite to that additional information to support the unfavorable opinion. Although the Proposed Arrangement had certain safeguards built in, such as steps to ensure hospitals did not bill Medicaid for the free drug, and limited patient marketing, it is unclear whether the additional information OIG found, which largely focused on the drug's price, tipped the scales on the opinion. The negative factors identified by OIG (listed above) reflect the structure of the proposal and not the additional information identified by OIG. While AO 18-14 could represent a one-off situation, it may mark a more general shift in tactics such that other requestors

can expect a similar approach by OIG.

A second interesting question is whether the Requestor knew that OIG would be relying on and discussing the additional information before it received its issued opinion. Typically, requestors are not surprised by a negative opinion; OIG usually informs a requestor that OIG's analysis is leading to an unfavorable conclusion and they have the opportunity to withdraw their request before they receive an official opinion. If a requestor does not withdraw, the requestor then receives the opinion a few days before it is published, but the opinion is final at that point. Some requestors may want the negative opinion so that they can point to OIG as the reason for not entering into an arrangement that they otherwise find undesirable, but for which they are experiencing external pressure to undertake, or because the requestor wants to chill conduct in which it believes its competitors are engaged.

One can speculate a few reasons why the Requestor did not withdraw its request once it learned OIG's conclusion was unfavorable. What we do know is that, going forward, others who may wish to receive a negative opinion should be mindful of the fact that OIG may rely on and highlight information about a requestor or arrangement that the requestor has not certified to, and may not want broadly publicized, to buttress OIG's unfavorable analysis. This additional information also had the practical effect of revealing the identity of the Requestor. Here, with only two drugs on the market, the Requestor's identity would not have been very difficult to guess even without the additional information. In a more crowded field, requestors may need to consider the risks of obtaining an unfavorable opinion if their identity could be known to their competitors, customers, and the public.

Like diamonds, advisory opinions are forever (of course, unless OIG terminates them on its own accord). Requestors may not want a permanent record of this nature if there is the possibility that its content will be unpredictable.

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