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The Fifth Element? A New Look At The CMS 'Four-Part Test'

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GIVEN THE US GOVERNMENT'S CONTINUED INTEREST in service fees paid to PBMs, sponsors would be wise to ensure that such fees are not contingent upon the volume or value of referrals or other business.

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Twenty years ago, the earliest Corporate Integrity Agreements (CIAs) into which pharmaceutical manufacturers entered with the Office of Inspector General at the U.S. Department of Health and Human Services (OIG) focused on alleged kickbacks "disguised" as service fees paid to Pharmacy Benefit Managers, wholesalers, and others in the drug supply chain.

The enforcement theory went something like this: because the manufacturers could not produce a bona fide business rationale for those service fees in question, the government alleged that the fees constituted kickbacks aimed at influencing formulary placement decisions. And the government went a step further, asserting that – beyond the kickback implications – the payments should have been included as discounts in the manufacturers' government price reporting calculations.

Had these discounts been included, the price that the government paid for the treatments under Federal healthcare programs like Medicaid would have been lower – so the government further alleged that the companies were guilty of submitting artificially inflated reimbursement claims, in violation of the False Claims Act.

Judging by the language in the OIG's draft PBM Service Fee Safe Harbor Final Rule – originally proposed by the OIG in January 2019, and now delayed until 2023 (the "draft Final Rule") – what's old is new again in terms of the focus of enforcement bodies.

Where We've Been: The CMS Four-Part Test

Pharmaceutical manufacturers have long been aware of the Centers for Medicare & Medicaid Services "Four-Part Test" established in 2007's Average Manufacturer Price (AMP) Final Rule (see box), which guides manufacturers as they determine whether fees paid to third parties should be considered discounts for the purposes of government price reporting calculations.

If a service fee satisfies all four criteria, it can be considered "bona fide" and therefore need not be considered a discount when calculating the various reported prices (e.g., the aforementioned AMP) for reimbursement under Federal health care programs.

THE CMS FOUR-PART TEST

Fees paid to third party entities like PBMs may be excluded as discounts from government price reporting calculations if they satisfy all four of the following criteria:

- The fee for services must represent Fair Market Value (FMV);
- The services must be itemized;
- The services must actually be performed on behalf of the manufacturer and must be activities that the manufacturer would otherwise perform (or for which they would contract) in the absence of a service agreement;
- The fee may not be passed on (in whole or in part) to a client or customer of an entity, whether or not the entity takes title to the drug.

Source: 42 C.F.R.§ 414.802 (2011)

Where We're Headed: A 'Fifth Element?'

The 19 November 2015 addendum to Novartis AG's 2010 CIA began to reveal the OIG's view on potential shortcomings in the Four-Part Test, hinting at an evolution in the OIG's thinking around what constitutes a bona fide payment to a third party. The government's suit alleged, among other things, that Novartis offered improper discounts and rebates related to the company's immunosuppressive, Myofortic.

Specifically, the suit alleged that the company granted rebates to pharmacies as an inducement to switch patients to Myofortic from other therapies and to prevent patients' switching from Myofortic to another treatment.

The OIG took particular issue with the fact that these rebates were based on a percentage of the drug's price, alleging that – as structured – these discounts and rebates constituted disguised kickbacks that promoted the Myofortic sales. This was the first time that the government took such a public and strong stance against rebates structured in such a way, and alleged that they constituted illegal kickbacks – but it would not be the last.

Just over four years later, the draft Final Rule revealed yet another significant step in this direction, within a proposed safe harbor to protect fees paid to PBMs by manufacturers for services rendered. The draft Final Rule states that the safe harbor would apply under the following circumstances:

- The fees are consistent with FMV;
- The services and fees are set forth in a written agreement;
- The fees are paid in the form of a fixed payment (i.e., not based on percentage of sales); and
- The PBM makes annual written disclosures to each health plan with which it contracts regarding the services rendered to each manufacturer.

Even though the Final Rule has been delayed until at least 2023 – and it's still possible that the safe harbor described above is never formalized – the trend in the OIG's scrutiny of fees paid by manufacturers to PBMs is clear: the focus on fees paid to the "middlemen" – and the OIG's questioning of what manufacturers may be receiving in exchange for those fees – is not going away.

THE PROBLEM WITH PERCENTAGE-BASED SERVICE FEES

The government has indicated that a service fee arrangement based upon a percentage of annual sales or product price could satisfy the Four-Part Test and yet might still constitute an inducement to prescribe (i.e., a kickback). For specialty drugs that generally are expensive and therefore highly rebated, a fee dependent upon a percentage of sales or price could imply that a large portion of the final drug price flows to the PBM – and raise the question of why a manufacturer would allow such a condition to persist.

In the eyes of government enforcement agencies, the answer to that question tends to come in the form of an allegation that the manufacturer does so as a tacit means of influencing the PBMs' decisions on formulary placement of the manufacturer's products – which could thereby constitute an illegal kickback.

Rather, regulators are taking a long, hard look at whether fees paid by manufacturers to PBMs take into account the volume or value of referrals or business otherwise generated – and therefore could constitute an illegal kickback.

Given this scrutiny, manufacturers would be wise to consider adding a fifth element to the CMS Four-Part Test when reviewing arrangements with PBMs and other entities in the drug supply chain:

5. THE FEE IS NOT CONTINGENT UPON THE VOLUME OR VALUE OF REFERRALS OR OTHER BUSINESS OTHERWISE GENERATED

While regulators have focused on the relationships between manufacturers and PBMs to date, the regulators' questioning what the manufacturers are "really" paying for with such fees is not new nor unique to relationships with PBMs.

One need look no further than expanding theories of what constitutes a kickback in other life sciences interactions with third parties – the ongoing enforcement actions around manufacturer donations to independent charity patient assistance programs, for instance, or the current focus on other types of external funding activities – to see that is the case.

That the regulators' kickback focus is coming home to roost in the government price reporting arena (where it was born with the earliest CIAs) means that we can expect this fifth element to grow in importance in the months and years ahead – and that companies would do well to incorporate it into their service fee evaluations sooner rather than later, lest they leave themselves open not only to anti-kickback enforcement, but the types of enforcement experienced by those earliest recipients of CIAs in the life sciences space.

What Should We Do?

As with most things in the life sciences compliance space, there tends to be a strong mix of art and science when it comes to defining what "good" looks like. This is in part because manufacturers of varying size, geographic scope, and therapeutic focus may have vastly different risk postures, and in part because the rules are not spelled out with great precision and seem to evolve constantly.

For example – while CMS has clearly defined the Four-Part Test and requires that it be applied to service fees – the agency has not codified key requirements like what constitutes "fair market value."

This places the burden squarely upon the manufacturer to document what CMS refers to as "reasonable assumptions" – so what "good" looks like may mean both performing an appropriate level of due diligence as part of an independent and objective review of the arrangement, and then documenting the "reasonable assumptions" that the company has made as part of that review.

Because the fees paid to third parties can have a dramatic effect on government price reporting calculations – and depending how they're treated, may drive some calculated prices higher while driving others lower – the OIG has placed increased focus upon them and their treatment.

A lack of due diligence and documentation of the treatment of fees paid may therefore place a company at risk of allegations related to both the False Claims Act (i.e., overcharging the government) and the Anti-Kickback Statute (i.e., payments to third parties to promote prescribing).

Compliance and Legal practitioners should recognize the compliance risks related to the payment of service fees to third parties, and ensure that they have adequate internal controls and safeguards in place – including:

- Robust policies and procedures covering interactions with third parties and any fee-for-service arrangements with those third parties – including guidelines around the application of the Four-Part Test and the Fifth Element.
- Adequate knowledge and know-how, either internally or in partnership with external advisors, to perform the due diligence necessary to conduct the procedures required to assess compliance with Four-Part Test and the Fifth Element.
- Independent, objective monitoring and continuous improvement mechanisms for relevant policies and procedures, to help ensure that fees are paid and services are provided in a compliant manner.
- Close partnership between Compliance, Legal, and the relevant business functions to help ensure that any new guidance (e.g., the upcoming Final Rule) is incorporated into ways of working in a timely, effective manner.
- Regular training of relevant business functions on the importance of compliance with regulatory guidance related to government price reporting, FMV, the Four-Part Test, and the Fifth Element.

There is no "shortcut" for performing a thorough Bona Fide Service Fee review.

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