



# Taking the right path

## Bona fide service fee determination

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### Frame the issue

Pharmaceutical manufacturers face increased scrutiny over the delineation between a bona fide service fee (BFSF) and a discount. Manufacturers should exclude bona fide service fees from the AMP calculations but include and subtract discounts from AMP. Especially highlighted in the recent Streck case,<sup>1</sup> manufacturers are expected to know what constitutes a BFSF. In the Streck case, manufacturers allegedly reduced AMP and Medicaid rebate payments by improperly including BFSF as discounts.

### Resolution to the issue

Manufacturers have developed policies and procedures to assess current service fees. Manufacturers who have not performed this assessment are outliers and at risk. Additionally, to guard against improper classification, manufacturers have developed ongoing operational procedures for new service fees. Departments which may be involved include legal, contract and pricing, sales operations, government pricing, and compliance. The assembled departments should focus their efforts on classifying new service fees to meet CMS and the VA definition of which fees can be excluded:

#### CMS four-part test<sup>2</sup>

Bona fide service fees means fees paid by a manufacturer to an entity wholesaler or retail community pharmacy that:

1	<b>FMV</b>	Represents fair market value (FMV)
2	<b>Service</b>	Is an itemized service performed on behalf of the manufacturer
3	<b>Service</b>	Would otherwise be performed by a manufacturer in the absence of a service agreement
4	<b>Pass-through</b>	Is not 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

#### VA guidance

Wholesaler fees are generally excludable from non-FAMP if they are:

1 Associated with inventory management agreements (i.e., fees charged by general wholesalers to manufacturers that have chargeback agreements with them)

2 Defined service charges imposed on manufacturers generally.

Product discounts granted in order to make their drugs more attractive in the marketplace cannot be excludable fees. Additionally, percent-of-sales incentive fees offered to wholesalers, in order to achieve business goals of the manufacturer, are not excludable from non-FAMP.<sup>3</sup>

Trying to implement definitions that meet the CMS four-part test and VA's definitions may be challenging without a disciplined and experienced approach. Efforts to coordinate such a wide range of stakeholders can be daunting, and there are frequent struggles to finding answers to nebulous questions.

<sup>1</sup> In the Streck case, manufacturers allegedly reduced AMP and Medicaid rebate payments by improperly including BFSF as discounts. See U.S. ex rel. Ronald Streck v. AstraZeneca, LP, et al., C.A., No. 08-5135.

<sup>2</sup> ASP Rule: 42 C.F.R. § 414.802; ACA Proposed Rule: 42 C.F.R. § 447.502

<sup>3</sup> See October 26, 2007 Dear Manufacturer letter

### Why KPMG

KPMG LLP (KPMG) brings tested methodologies, approaches, and toolkits to guiding manufacturers through these confusing issues. KPMG has developed the following approach to energize and lead an organization through the relevant BFSF issues:

#### KPMG knows what questions to ask

KPMG brings an experienced cross-functional team that has a wealth of experience working with complex organizations and developing wide-ranging assistance from historical look-backs, methodology development, data assessment, and operational process assistance. KPMG cuts through the myriad of questions to identify core issues. The team has developed questions such as the following to assist manufacturers develop a criteria that can be used to determine if a service fee is bona fide:

## 1 FMV

- To what extent should other FMV processes be leveraged?
- What are implications of payment methods such as % of price, fixed fee, \$/unit, etc.?
- Which valuation method(s) in which circumstances? Perform blind to actual amount?
- What is GP implication of actual fee > FMV?
- When is it acceptable to perform internally and who decides?
- What are the criteria and point of determination for refresh?
- Is the process auditable/repeatable?

## 2 | 3 Service

- What assumptions are made in the absence of knowledge?
- What constitutes knowledge of a fee being passed through?
- What questions and/or procedure are necessary? Any prohibited?
- What documentation, if any, will be required from the vendors?
- What is the implication of vendor being owned by its customers?
- What is the implication of it being passed through in part?

## 4 Pass-through

- What is a service? Core business function? Customer requirements?
- What if service benefits manufacturer and vendor? What if vendor does more due to payment?
- What if manufacturer cannot perform the service currently? What if manufacturer would do it but to lesser extent?
- How are prior questions impacted by vendor's participation in distribution chain?
- What circumstances drive sufficiency of itemization?
- Is up-front business need and meaningful plan-to-use documentation necessary?
- Is back-end determination that business value be met required? Monitoring and auditing sufficiency?
- What services are relevant to government pricing?

### FMV

#### Valuation specialists

KPMG differentiates its BFSF services by teaming with valuation accredited professionals. The valuation specialists have developed a proprietary cloud-based tool that KPMG and manufacturers may leverage. KPMG's valuation specialists produce a repeatable and auditable process for determining FMV, and the valuation specialists are a rare team of professionals who will offer an opinion on valuation.

## Bona fide service fees assessment process (sample activities)

### Project planning

- Identify and interview key stakeholders
- Define criteria for success
- Define project scope, milestones, output, and budget and timing

### Current-state assessment

- Service agreements
- Policies and processes
- Systems
- Operating groups
- Identify gaps

### Methodology development

- Responses to prior slide and standard terminology
- Document effectively
- Update dependent methodologies (e.g., GP)

### Design future-state process

- Identify key activities and controls including contract changes
- Determine order of operations
- Determine task owners and consider full RACI

### Implement

- Catch up all FMV assessments
- Modify contracts, if applicable
- Modify systems and build new if relevant

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