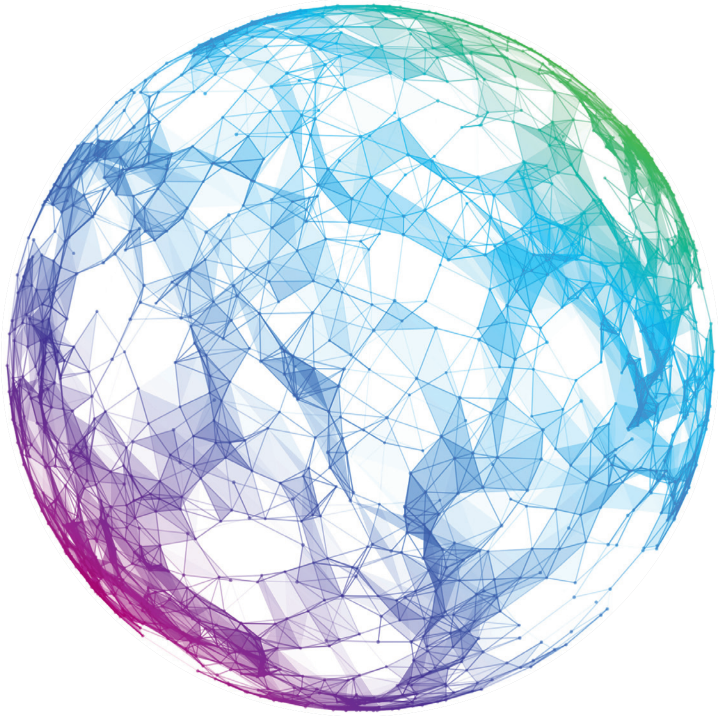


Fair market value for bona fide service fee agreements

Qualifications to serve

Why fair market value?

Within the life sciences industry, companies are under scrutiny by regulators to provide a level of transparency and disclosure where spending on services is reported in accordance with several state laws and federal provisions.
These regulatory requirements include:

- Government pricing and bona fide service fee (BFSF) compliance in accordance with Centers for Medicare & Medicaid Services Average Manufacturer Price final rule.
- The corporate integrity agreement requires that payments to Health Care Professionals ("HCP") and Health Care Institutions ("HCI") be based on fair market value ("FMV").
- US Federal pricing regulations require that fee-for-service contracts with US customers are bona fide, and payments are at fair market value ("FMV") to not be considered a discount/rebate that should be included in the lowest federal price calculations [source: Medicaid Final Rule 4-part test].
- According to Health Law Resources, the US Anti-Kickback Statute safe harbors for services require that the fees are at FMV.
- An important element of anti-bribery & corruption diligence when working with a third party is to adequately document the development of FMV.

Potential implications of avoiding FMV pricing and analysis

Failing to pay FMV for services or a lack of a structured framework for determining pricing may result in non-compliance of regulatory requirements.

Non-compliance penalties may include:

- Large fines.
- Forced divestiture of subsidiaries or business units.
- Exclusion from government health care programs such as Medicare and Medicaid.
- Imprisonment of implicated individuals.

The Deloitte Difference

We have extensive experience working with outside counsel for our clients and assisting clients in assessing their fair market value circumstances with their regulatory requirements.

Deloitte FMV approach and framework

Health care organizations assess the bona fide nature of fee-for-service ("FFS") arrangements to help determine whether payments to third-party commercial vendors comply with regulatory requirements and to establish sound consultant and advisor payment practices. Unlike the HCP consulting obligations, publicly available cost/pricing data does not widely exist for third-party service providers. In addition, third-party contracts are often complex and differ in nature from one another adding greater variability in the approach to arriving at FMV.

The third-party vendor FFS obligations are typically valued by utilizing either a cost and/or market approach.
By leveraging our extensive experience with numerous FMV engagements, we have developed leading practices to estimate FMV utilizing the framework displayed below:

Deloitte FMV framework

	Cost approach	Market approach	FMV range
	Consider value based on bottom-up approach to recreate the service.	Consider value based on market comparability.	Estimates value by triangulating valuation approaches.
Method description	• Analysis of total costs incurred by industry participants to recreate the service activity. • May include elements of opportunity cost. • Includes building the value of individual elements within a service activity.	• Analysis of comparable services available in market. • Leveraged when: – Comparable market data is available. – Cost approach is not definitive. • Adjustments to account for differences between target/ comparable service.	• Considers applicability of both cost and market approaches based on specific service activity elements. • Output is FMV range by service activity.
Main components and inputs	• Direct costs. • Personnel costs. • Overhead costs.	• Comparable services. • Qualitative adjustments. • Independent surveys.	

The approach(es) utilized to identify the FMV range of value estimates for an FFS agreement will depend upon the complexity of the activity and its comparability to an economic exchange. While in some cases there may be relevant market data, we generally apply methods under the Cost Approach to develop the estimates. If the availability of information warrants further analysis, we consider other relevant approaches to value.

The Deloitte Difference

We believe the following Deloitte differentiators make us the leading valuation provider for life science manufacturers.

Our services help you to:

- Leverage our collective lessons and leading practices learned from these engagements to develop a more effective solution. Our team of professionals and subject matter specialists ("SMS"), provides us with what we see as high-quality insight into creating an effective FMV framework.
- Develop FMV menus and flexible frameworks for our clients, incorporate them into their processes, and ultimately provide training and knowledge transfer. We also have detailed knowledge and understanding of numerous FFS arrangements with third parties.

These sets of cross-sector experiences provide us with a greater appreciation of both our client's perspective and its counterparty in multiple FFS arrangements.

- Bring provider and payer perspectives to drive both FMV and strategic responses.
- Leverage our experience with regulatory and enforcement matters related to the Anti- Kickback Statute and False Claims Act for service payments to health care professionals and third parties. Additionally, our SMS' understand the implications of adjacent regulations, such as the PPACA that have mandated manufacturers and GPOs to report any payment or transfer of value to health care practitioners; we will bring this perspective to our engagements.
- Provide stakeholders direct contact with senior professionals that bring perspectives from multiple industry client experiences.
- Conduct efficient and streamlined project plans by leveraging our experience with benchmarking studies, surveys, interview templates, and valuation models to provide our clients with the tools to apply in future cases.

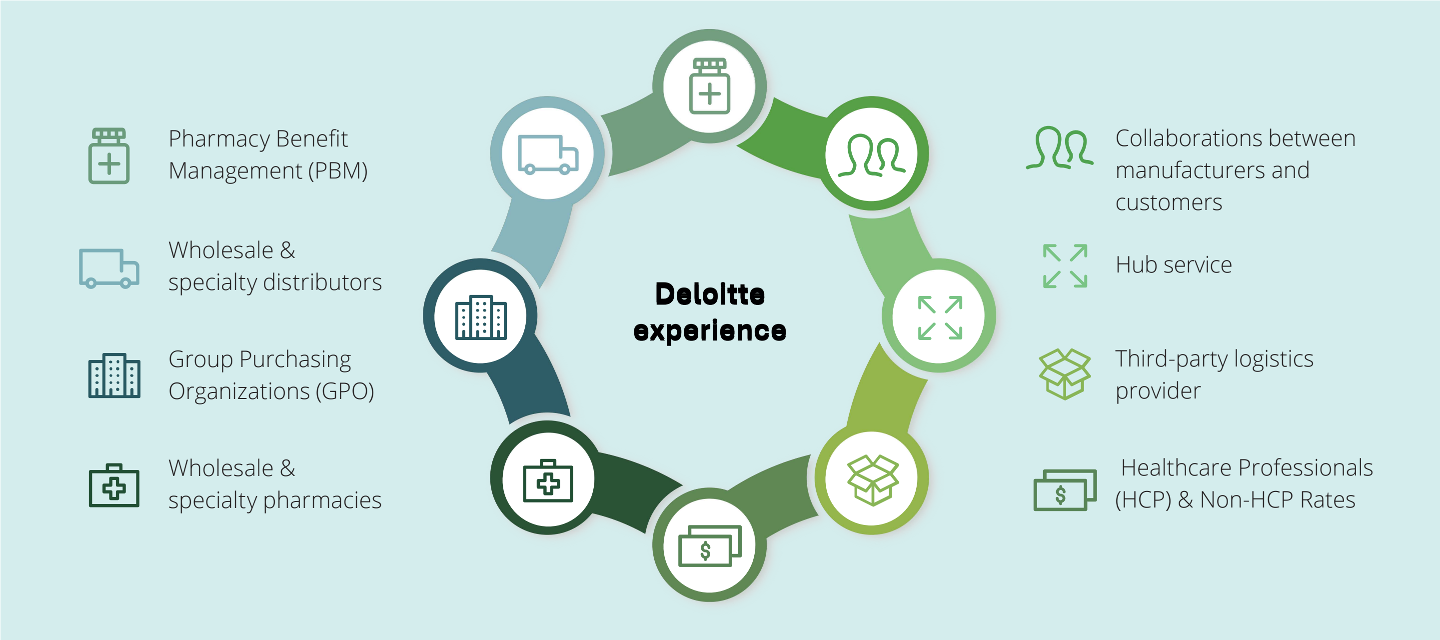
Types of services

- We estimated FMV of over 100 fee-for- service arrangements for over 60 manufacturers, as well as wholesalers, specialty pharmacies, PBMs, GPOs, and others.
- We developed FMV menu tools, which allowed for customization of a variety of FFS arrangements, including but not limited to data management and reporting and patient/physician outreach programs, reimbursement-related services, etc.
- We assisted group purchasing organizations (“GPOs”) estimate the FMV of administration fees and licensing fees.
- We developed broad channel strategy for manufacturers, including financial modeling of “exchange of value” between manufacturer and channel intermediaries.
- We developed broad strategies for future state distribution across channels and markets in the context of a rapidly changing product portfolio and a proliferation of specialty channels.

Transforming the valuation process

ValueD™ Value insights. Informed decisions.
ValueD is a powerful technology platform that leverages artificial intelligence (AI), market- based benchmarks, and our vast industry experience to improve the valuation process, cut through complexity, and provide deeper insights into how valuations are performed through a real-time dynamic view that our clients can use to improve their strategic decision-making.
Discover more about **ValueD** by visiting the following site: ValueD

Example types of fee-for-services valued:



This list of performed services and types of FFS Agreements assessed are not all encompassing.

Patient Assistance	Pharmacy-related	Distribution-related	Administrative
• Program management • Pharmacy dispensing • Drug ingredient costs • Data entry • Network and 1-800 number services • Letter and rebate check issuance, printing, handling • Data reports and web portal access • Co-pay, coupon, and voucher program • Patient Portal Design and Development • Patient Advocacy Programs	• Various types of nurse/ pharmacist calls • Benefit verification/ adjudication/ prior authorization • Various types of data including prescription purchase and dispensing data • Adverse events reporting • Mail Order Pharmacy Services • Customer service and support • Customer service training	• Inventory management & Stable purchases • Re-distribution • Drop ship • Order processing • EDI reporting • Chargeback processing • Product recall & Returns Processing • Pick, pack & ship • Special handling services • Customer support • Product Information Dissemination • REMS Services	• PBM administrative services (negotiating and contracting with clients, monitoring clients compliance with formulary requirements) • GPO administrative services (contracting with members and negotiating contracts) • Product information dissemination • Reimbursement Support Services • Program set-up and implementation • Account management

Marketing Services	HCP & Non-HCP Rates	Manufacturer Services provided to Customers	Other
• Email blasts • Banner ads, hyperlinks, microsites • Meeting and event planning • Trade show participation and presentations • Point of Sale Messaging • Shipment stuffers • Shelf-talkers/dispensers, brochure holders • Branded/Unbranded Videos/Radio Ads • Other rich media advertisements	• HCP titles: Cardiologist, Nurse, Endocrinologist, Dentist, Dermatologist, Internal Medicine, Rare Diseases, etc. • Non-HCP Titles: PhDs, Health Outcomes Specialists, Executive titles • Patient Rates for testimonies, patient advocacy groups, etc. • HCP Celebrity Rates	• Physician Educational Resources • Training Programs and Modules • Patient Educational Materials • Interactive Tools • Collaborations with AMCs, IDNs, physician practices, etc. • Sponsorships	• Managed Service Arrangements for Physician Practices • Joint venture arrangement between two manufacturers on distribution services • Clinical FMV • Data Services purchased from a variety of channels (SP, GPOs, Data Aggregators, HUBS, etc.)

At your service

The following professionals have extensive experience with FMV for FFS agreements and stand ready to serve you:

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