



BFSF & FMV Leading Practices

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Meet the team with you today



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Overview

1

Bona fide service fees (“BFSFs”) & fair market value (“FMV”) overview

2

Leading practices & IRA considerations

3

Trends and tips for conducting and maintaining a successful BFSF & FMV analysis and process



Bona Fide Service Fee Definition and Test

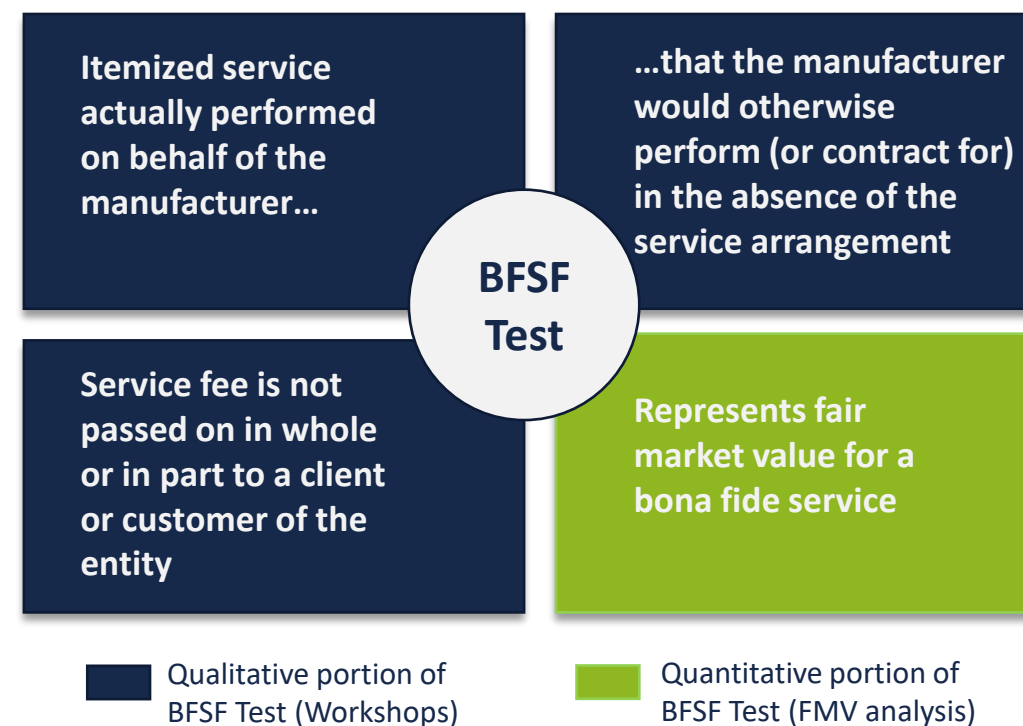
Fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a Company or customer of an entity, whether or not the entity takes title to the drug.

42 C.F.R. § 447.502 – Medicaid regulatory definition of BFSF

The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Discuss with your counsel and government pricing / BFSF / FMV advisors to ensure appropriate treatment of service fees in Non-FAMP calculations

Non-FAMP VA sub regulatory guidance



October 2006 Dear Manufacturer Letter:

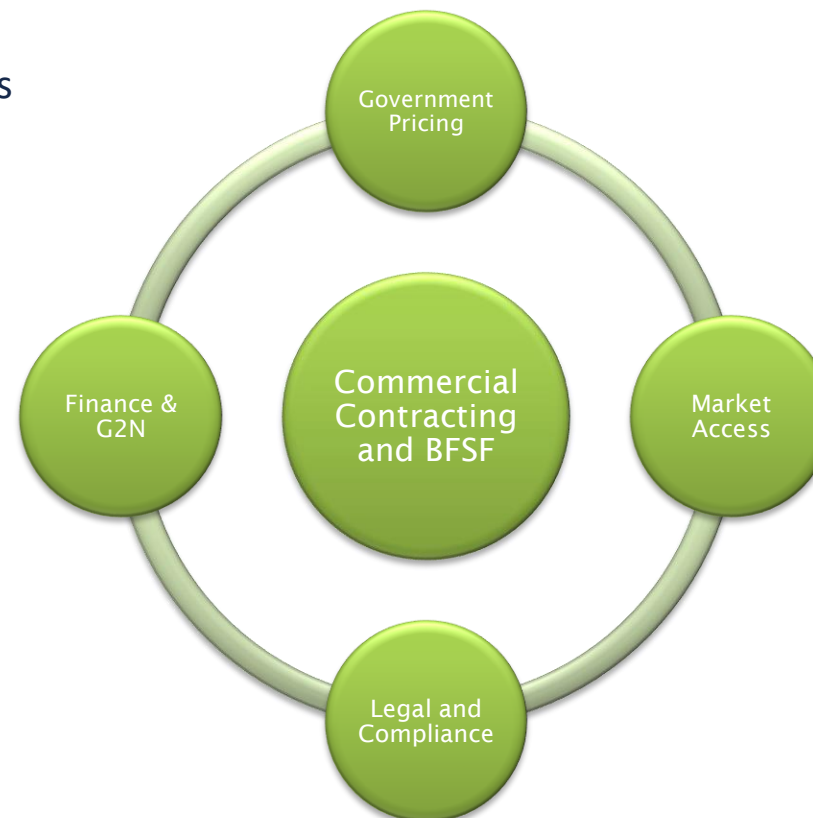
"...wholesaler fees associated with inventory management agreements, fees charged by general wholesalers to manufacturers that have chargeback arrangements with them, are excludable from non-FAMP, as long as they are defined services charges imposed on manufacturers generally."

October 2007 Dear Manufacturer Letter:

"...percent of sales incentive fees offered to wholesalers, in order to achieve business goals of the manufacturer, [are] not...IMA fees that are excludable from non-FAMP."

Do Bona Fide Service Fees Matter and Why?

- BFSF analysis is relevant to:
 - Government price reporting (AMP, BP, ASP, FSS)
 - Reimbursement rates and remuneration within supply chain arrangements
 - IRA rebates and price caps/ceilings based on Non-FAMP
 - Gross to net reporting
 - Compliance and legal exposure
- Legal risk:
 - Potential civil monetary penalties
 - Knowingly submitting false pricing or product data
 - Misrepresentation in the reporting of ASP data
 - Knowing and intentional 340B overcharges
 - Potential False Claims Act and other liability
 - E.g., potential Anti-Kickback Statute liability
- Enforcement
 - Settlements
 - Litigation
 - E.g., AstraZeneca and Cephalon paid \$46.5M, and \$7.5M, respectively, for allegedly underpaying MDRP rebates (allegation that they mischaracterized payments to wholesalers as non-bona fide service fees) (see also recent Eli Lilly case)
 - Cardinal



Entities That May Require BFSF Analysis

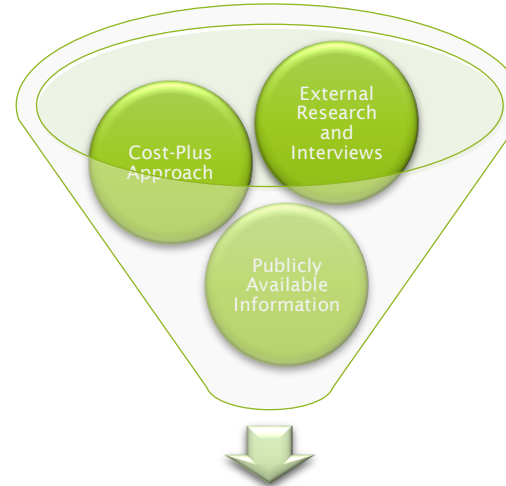
Below is an illustrative list of service arrangement types that may require analysis. Manufacturers must determine the ultimate list of entities that require this analysis:

- | | | | | | |
|---|--------------------------------|---|---|---|---|
| 1 | Pharmacy Benefit Managers |  | 5 | Patient Support Programs
(co-pay, coupon, voucher, and other HUB service arrangements) |  |
| 2 | Specialty Distributors |  | 6 | Third-Party Logistics Centers (3PL) |  |
| 3 | Group Purchasing Organizations |  | 7 | Pharmacies (specialty and non specialty) |  |
| 4 | Distributors and Wholesalers |  | 8 | Other service arrangements with customers and affiliated entities |  |

Fair Market Value Approach and Methodology

Cost Plus Approach

- The cost-plus approach considers the total direct and indirect costs as well as a level of overhead and profit that would be incurred by a market participant to recreate the activities.
- The cost-plus approach is based on the premise that the FMV of the service is driven by the opportunity cost of providing the service. Includes building the value of components in a service activity.



FMV Results and Market Insights

Typically, either the **cost-plus approach** or the **market approach**, or a **combination of the two approaches**, is used to develop a range of FMV estimates for service arrangements.

Market Approach

- The market or sales comparison approach is a general way of estimating the value of a business or tangible or intangible asset using one or more methods that compare the subject to similar investments or assets that have been sold or offered for sale. Sales or offering prices for the comparable investments or assets are adjusted to reflect the differences between the investment or asset being valued and the comparable investments or assets.
- Used when comparable market data is available or when cost approach is not definitive. Key inputs include; agreement type, execution date, service type, service performed, product type and manufacturer size and type.

CMS Relevant FMV Guidance

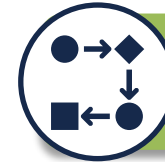
- CMS refrains from defining “Fair Market Value.” Instead, the agency says “we believe the determination of fair market value is by nature subjective [A]ny documentation can be used, provided that it makes clear the methodologies or factors ... [S]uch determination of fair market value and documentation be made contemporaneously with the manufacturer’s agreement to pay the fee.” 81 Fed. Reg. 5170, 5180 (Feb. 1, 2016).
- In Preamble to the Medicare Part B Final Rule, CMS states that “bona fide service fees means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities.” 71 Fed. Reg. 69624, 69669 (Dec. 1, 2006)

BFSF Hot Topics and Trends



Regulatory (external)

- **Inflation Reduction Act** and importance of BFSF to various statutory provisions
- **OIG Survey** of Manufacturer ASP Data
- **Reasonable assumptions.** OIG 2019 survey found that almost all manufacturers (91%) adopt reasonable assumptions around BFSFs in connection with BP or AMP reporting:
 - More than half of manufacturers requested additional agency guidance around BFSFs
 - FMV determination
 - Pass through (e.g., what is considered evidence or notice of pass through)
 - Specific questions around admin fees to PBMs



Process (internal)

- **Determining which entities require analysis** (i.e., do affiliates of trade partners require analysis, what about entities that only aggregate data, etc.)
- **Understanding criteria** to determine if a service is Bona Fide
 - E.g., what services are bona fide services? What services are really on behalf of the manufacturer? Are the services sufficiently itemized? What are reasonable steps to take regarding pass through?
- **How to navigate VASF determination**
 - What guidance should be relied upon? Do you rely on CMS guidance, VA guidance, a mix, or make assumptions?
 - What kind of BFSF/VASF documentation and process should manufacturers have in place?

Examples of Vertical Integration

The table below highlights vertical integration in the PBM and specialty pharmacy sector*. Note this is just an example list and there are many others including distributors being affiliated with data aggregators, patient assistance programs, etc.. It's important to know your vendors.



1. Since 2021, Prime's Blue Cross and Blue Shield plans have had the option to use Express Scripts or AllianceRx Walgreens Pharmacy for mail/specialty pharmacy services. In Dec. 2021, Walgreens purchased Prime Therapeutics' 45% ownership interest, so this business had no PBM ownership as of 2022. Effective June 2022, the company was rebranded as AllianceRx Walgreens Pharmacy.

2. Centene has announced that it would outsource its PBM operations to Express Scripts in 2024. In 2023, Centene rebranded its pharmacy benefit subsidiary as Centene Pharmacy Services.

3. In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.

4. Since 2020, Prime has sourced formulary rebates via Ascent Health Services. In 2021, Humana began sourcing formulary rebates via Ascent Health Services for its commercial plans.

5. Previously known as Evernorth Care Group and Cigna Medical Group.

6. In 2021, Cigna's Evernorth business acquired MDLIVE.

7. In 2022, Cigna invested \$2.7 billion for an estimated 14% ownership stake in VillageMD. Walgreens owns a majority of VillageMD.

8. In September 2022, CVS Health announced its acquisition of Signify Health. In February 2023, CVS announced its acquisition of Oak Street Health. Both transactions closed in 2023.

9. Previously known as IngenioRx.

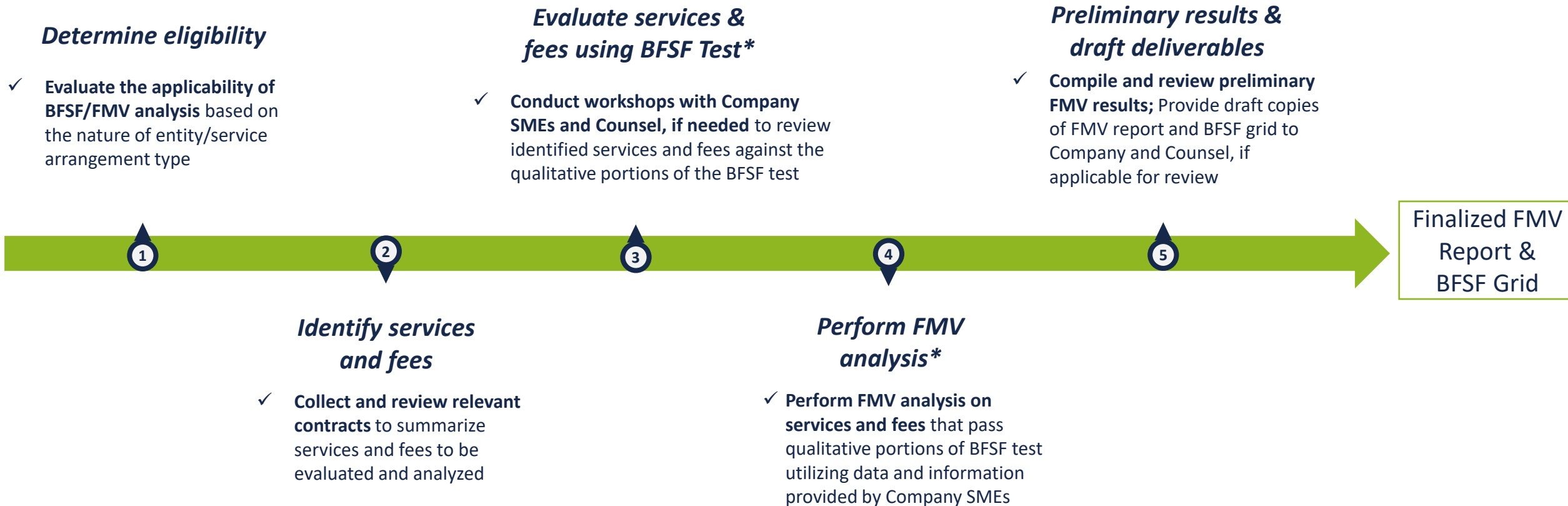
10. In 2021, Partners in Primary Care and Family Physicians Group businesses were rebranded as CenterWell Senior Primary Care.

11. In 2022, Kindred at Home was rebranded as CenterWell Home Health. In 2022, Humana announced an agreement to divest its majority interest in Kindred at Home's Hospice and Personal Care Divisions to Clayton, Dubilier & Rice. Humana also announced plans to close a majority of its SeniorBridge home care locations.

Source: *The 2023 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Exhibit 234. Companies are listed alphabetically by corporate name.

= Recent changes

Hypothetical BFSF/FMV Process Overview



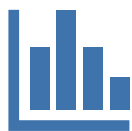
* Note the FMV may be performed at the same time as the BFSF qualitative tests are being evaluated. Additionally, the qualitative elements of the BFSF may change from time to time (e.g., a company might receive evidence of pass-through, and this may affect the BFSF analysis).

Best Practices



- Designate a process owner to manage end-to-end BFSF/FMV analysis
- Develop and follow a consistent BFSF/FMV approach
- Document policies, evaluation results, and reasonable assumptions

- Incorporate BFSF and FMV as part of overall contracting process
- Engage early with BFSF/FMV partners before fee negotiation and assess GP impact

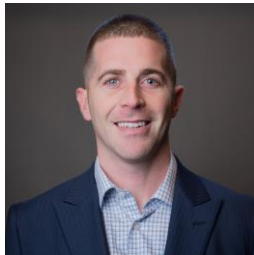


- Keep the FMV models up-to-date and relevant
 - Periodically refresh every 2-3 years to reflect market/ economic /regulatory changes
 - Look out for new, unique fee-for-services

- Provide periodic trainings at least once a year to stakeholders involved in the process and seek legal advice as needed
- Consider leveraging technology and systems to gain operational efficiency



Questions



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