Bona Fide Service Fees & Fair Market Value

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Presentation Overview

➢ Fees vs. Price Concessions
➢ Definition of BFSFs
➢ BFSFs vs. Personal Services and GPO Safe Harbors to the AKS
➢ Getting to FMV
➢ BFSFs in Medicare Part D?
➢ Final Thoughts
➢ Questions
Fees vs. Price Concessions

- Classification always relevant for drug price reporting

- FCA exposure related to incorrect classification particularly true when resulting in lower rebates/higher prices to government

- Conservative approach before DRA Final Rule/ACA treat service fees as price concessions
  - Could go either way for Brands depending on AMP-BP

- Heightened importance after ACA given mandate to use AMP as reimbursement metric
4-Part Test under Medicaid

- 4-part test in Final DRA Rule remains applicable to BP

- 2012 AMP Proposed Rule would extend/continue use of 4-part test for AMP as well

1. Paid by a Manufacturer to an Entity
2. Fair Market Value for Bona Fide, Itemized Service Actually Performed on Behalf of Manufacturer
3. Manufacturer Would Otherwise Perform or Contract for Service in Absence of Service Arrangement
4. Not Passed on in Whole or in Part to Client or Customer of Entity, Whether or Not Entity Takes Title to Drug
ACA “Examples” of BFSFs

- ACA expressly excludes bona fide service fees paid by manufacturers to wholesalers or RCPs, including (but not limited to):
  - distribution service fees
  - inventory management fees
  - product stocking allowances
  - fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)

- Denoted “examples” per 2012 AMP Proposed Rule
Extends to GPO Admin. Fees

- 2012 AMP Proposed Rule specifically extended the 4-part BFSF test to GPO admin. fees
  - Reiterates that fees paid to entities that do not take title to drug can be BFSFs
  - Extend to PBMs and Managed Care customers?
  - No presumption that if 3% or less the fee is FMV or than more than 3% is not FMV
Other BFSF Definitions

✔ Medicare Part B uses same 4-part test as Medicaid
  ▪ Technically, final AMP rule could promulgate a different test for Medicaid, but unlikely given AMP/ASP substitution

✔ BUT….Not the VA/FSS program
  ▪ Fair Market Value for defined services
  ▪ Imposed on Manufacturers “generally”
  ▪ Cannot be Percent-of-sales incentive fees offered to wholesalers or distributors to achieve a business goal
Other BFSF Definitions

➢ Under the VA guidance, certain common percentage-based fees to wholesalers are NOT BFSFs
  ▪ Trade show fees
  ▪ Marketing fees
  ▪ Stocking allowances
Beware of AKS Exposure

- Just because a fee qualifies as a BFSF, does not mean it’s safe harbored under the AKS

- Personal Services Safe Harbor
  - Written Agreement
  - Itemized services
  - Compensation if FMV, set in advance and not based on the volume or value of referrals or business other generated under federal health care programs-
  - Compensation is reasonable to accomplish business purposes

- Does not apply to percentage-based fees as based on volume of purchases
Beware of AKS Exposure

➢ Just because a fee qualifies as a BFSF, does not mean its safe harbored under the AKS

➢ GPO Safe Harbor
  ▪ Applies to percentage-based fees
  ▪ Specific disclosure requirements if greater than 3%
  ▪ Must meet the definition of GPO, members cannot be affiliates
    - Advisory Opinion 13-09
    - OIG Compliance Guidance suggests applicable for PBM administrative fees
What is FMV?

- CMS has not offered any definition or guidance on FMV

- 2012 AMP Proposed Rule- manufactures must make reasonable assumptions on FMV and document assumptions

- US ex rel. Streck v. Allergan, No. 08-5135 (E.D. Pa)- manufacturers must make a “good faith effort” to evaluate the fees paid
Assessing FMV

- FMV can be a range, need not be the same fee for similar customers in order to be a BFSF
  - FMV service fee can be percentage-based

- Most manufacturers have developed ranges or databases for common service fees often with assistance from third party financial consultants
  - Periodic updates
Assessing FMV

Benchmarking Approach

- Outward looking across the industry
- What do other manufacturers pay for such services?
- Considers types and sizes of manufacturers, types of agreements, specified services
- Range of payments
Assessing FMV

Cost-based Approach

- Inward looking
- What would it cost a manufacturer to perform the service itself?
- Useful for specialty services for unique products- limited distribution, specialty products, REMS
What if part of a fee is FMV?

- Can treat portion that is FMV as a BFSF and remainder as price concession
  - OIG Advisory Opinion 13-09 seems to favor splitting between discounts/fees in context of GPO admin. fees passed-through

OR

- Can treat entire amount as price concession

Need to document approach and apply consistently to all customer fees
Not Passed Through

What if you don’t know if its passed through or not passed through?

- 71 Federal Register 69, 624 (Dec. 1, 2006)- “a manufacturer may presume, in the absence of any evidence to the contrary, that the fee paid is not passed on to a client or customer of any entity”

- Medicare Part B/ASP context, adopted for Medicaid in preamble to Final DRA Rule
Not Passed Through

- **Best Practice is to obtain representation of retention in contracts with customers**
  - Review public GPO websites about retention
  - Train national account managers on pass-through issues related to managed care/PBM/GPOs
Not Passed Through

➢ If a portion is passed through, obtain split from customer for use in classifying portion as BFSF and portion as price concession

▪ Customer should certify such split in writing
▪ Treat entire amount as price concession if you know some is passed through but cannot obtain split
▪ OIG required GPO to make split publicly available in Advisory Opinion 13-09
BFSFs in Medicare Part D

➢ Term always used related to Direct and Indirect Remuneration (DIR) reporting by Medicare Part D plans

➢ Recently used in Medical Loss Ratio context for Medicare Advantage plans

➢ Part D adopts the 4-part test used by Medicaid
BFSFs in Medicare Part D

- May 28, 2014- CMS issues DIR reporting requirements for 2013

- Contains BFSF designation as usual

- Expands requirement in 2012 guidance that Medicare Part D plans document determination of BFSFs, particularly assumptions, methodology and rationale used to determine FMV

- CMS comment suggests could obtain this from a manufacturer or have independent assessment
  - Requests to certify that fees are FMV
Final Thoughts

➢ Will the Final AMP Rule answer any more questions about BFSFs including FMV?
  ▪ Wait and see
  ▪ Doubtful on FMV

➢ Consistency is key - develop and consistently apply a rationale to distinguish BFSF and price concession
  ▪ Must document each application of such analysis for every fee to a customer- wholesaler, pharmacy, GPO, PBM or managed care entity
  ▪ Retain such documented analysis for 10 years or longer according to record retention policy
Final Thoughts

- Remember the VA/FSS BFSF test is different and Medicaid could vary from Medicare B depending on the final AMP rule though not likely

- Document and support FMV

- Include provision to address retention of fees deemed BFSFs
  - If a portion passed-through obtain documentation of split or treat entire fee as price concession
Final Thoughts

- Expect OIG and CMS comparison of BFSF classifications among programs including Medicare Part D
  - Be prepared to explain differing treatments by differing parties
Questions

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