Pharmacy Benefit Manager (PBM) final rule delayed again: What now?

Bona fide service fee trends and considerations for pharmaceutical manufacturers

By Emily Ashton and Paul Silver

With a new administration, government leaders continue to focus on health care spending and drug pricing in the United States.

On November 30, 2020, the Department of Health and Human Services (HHS) published a final rule to address concerns of the current rebate-based system increasing financial burdens for beneficiaries. The goal of this legislation was to create a more transparent drug pricing system that would lower high prescription drug prices and lower out-of-pocket costs.[1] However, on January 30, 2021, an order was issued that postpones the provisions of the final rule until January 1, 2023.[2]

Summary of the PBM final rule

The final rule, issued by the HHS Office of Inspector General (OIG), finalizes a new safe harbor for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations (MCOs) that meet certain criteria.[3] It also amends safe harbor regulation so that percent-

[1] 42 C.F.R. Part 1001.I.A
[2] Pharmaceutical Care Management v. HHS - Civil Action No. 21-95 (JDB)
[3] 42 C.F.R. Part 1001.952(cc)

based administrative fees to pharmacy benefit managers (PBMs) will no longer be protected from liability under the federal Anti-Kickback Statute of the Social Security Act. Instead, the final rule creates a new safe harbor for fixed fees paid to PBMs.[4]

According to the final rule, in order to receive protection, the proposed safe harbor would require that:

- The services and compensation be **set out in a written agreement**
- The compensation be consistent with fair market value in an arm's length transaction; the payment be fixed; not based on a percentage of sales; and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans, for which payment may be made in whole or in part under Medicare, Medicaid, or other federal health care programs
- The **PBM makes annual written disclosures to each health plan** with which it contracts regarding the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan, and make such disclosures to the Secretary upon request.

It is important to note that the final rule does not clarify a definition of "fixed" fees (or what the value of the fee may be), and does not list services that may fall under its purview. Furthermore, it suggests that manufacturers should use "generally accepted valuation methodologies and principles in any determination of 'fair market value'".[5] The final rule also notes that the CMS definition of "bona fide service fees" (BFSF) is outside the scope of the rule; as such, manufacturers still need to follow CMS BFSF guidance as well.[6]

What does this mean for manufacturers and what now?

While the PBM final rule is delayed and may even change as it goes through the court process, it is important for manufacturers to continue to evaluate their current service arrangements (including PBM agreements) from a BFSF and fair market value (FMV) perspective. The CMS BFSF guidance is still a requirement and is critical to the accuracy of government pricing (GP) calculations, the integrity of price reporting, and other regulatory requirements regardless of the outcome and timing of the PBM final rule.

Refresher on BFSF test components[7]

1. The fee is paid for a bona fide, itemized service actually performed on behalf of the manufacturer
2. The manufacturer would otherwise perform (or contract for) the service in the absence of the service arrangement
3. The fee is not passed on in whole or in part to a client or customer of the service-providing entity, whether or not the entity takes title to the drug
4. The fee represents FMV for the service

Example arrangements that may require BFSF/FMV analysis

Fee for service (FFS) arrangements with entities to which a service fee is paid must be evaluated from a BFSF perspective, including FMV.

Key trends and items to consider relating to BFSF/FMV

In light of COVID-19 and other industry drivers, a number of trends continue including:

- Shift toward digital/virtual services and offerings
- Increased high-touch services, especially for specialty products
- Continued focus on pricing/contracting service arrangements and overall health care spending
- Continued vertical integration throughout the industry, including supply chain partners
- Ongoing focus on importance of data/data analytics and how data is utilized
- Focus on value and overall patient journey instead of volume

[1] Copay Coupon and Voucher Programs

[2] Collaboration arrangements may include Real World Data/Evidence that may be used for development of tools and technologies that may be used by hospitals or physicians

[4] 42 C.F.R. Part 1001.952(dd)
[5] 42 C.F.R. Part 1001.III.A.xiii
[6] 42 C.F.R. Part 1001.III.D.ii
[7] 42 C.F.R. § 447.502

Items to consider and recap

- Keep an eye out for updates regarding PBM final rule, 340B, and guidance from new administration
- Plan and strategize for potential outcomes of new rules and regulations to ensure your company is ready to implement and operationalize any changes
- Continue performing BFSF evaluations for all service arrangements and note that FMV may be required for other legal or compliance/regulatory reasons, including compliance with anti-kickback regulation
- Manufacturers should consider the following options to enhance their service arrangements and overall BFSF/FMV process, including:
  - Identifying ownership of the BFSF/FMV process and location for information to be stored, especially when multiple departments may be requesting FMV.
  - Ensuring clearer itemization of services within contracts to better track metrics and performance, and more easily penalize service providers if not met.
  - Building time for BFSF/FMV analysis into the initial contracting process rather than evaluating it retroactively or when the contract is ready to be signed – it is a good practice to work with your FMV team (internal or external) and let them know when you are in the concept phase. That way, the teams can advise and work with your business timing requirements.
  - Performing periodic BFSF/FMV trainings so business units and teams are aware of company process, points of contact, and what types of arrangements/services may require BFSF/FMV analysis.
  - Monitoring and tracking performance of service providers and striving to enhance overall performance.
  - Performing analytics and integrating with gross-to-net and government pricing teams to evaluate impacts of arrangements.

We welcome your own experiences, challenges, and questions related to commercial contracting and BFSF/FMV evaluation—please comment or send a message.

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Where can I find more information?

For more information on the Final Rule:

HHS Rebate Rule Discount and PBM Service Fee Final Rule

Pharmaceutical Care Management v. HHS - Civil Action No. 21-95 (JDB)