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Compliance Update

New CMS Requirements for Average Sales Price Reporting: What Pharmaceutical Manufacturers Need to Do by April 30

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The Calendar Year 2026 Physician Fee Schedule Final Rule includes several targeted, but material, changes to the average sales price (ASP) calculation and reporting that directly impact pharmaceutical manufacturers, with requirements becoming operationally effective by April 30. While ASP calculation and reporting itself is not new, the Final Rule increases expectations from the Centers for Medicare & Medicaid Services (CMS) around data completeness, methodological rigor and accountability.

Manufacturers should consider the following key changes in documentation requirements introduced in the Final Rule:

- **Manufacturers must submit fair market value (FMV) methodologies for all bona fide services, along with reasonable assumptions.** Companies should create an inventory of documentation for all bona fide services and ensure that their FMV analysis was prepared specifically for their company and each relevant service (i.e., not carried forward from a prior company or created via informal benchmarking). CMS' draft instructions for documenting reasonable assumptions are available [here](#); while the templates provided at this link are under review, final versions should be made available prior to the Q1 2026 ASP reporting deadline of April 30.
- **Manufacturers must submit documentation confirming that bona fide service fees are not passed through to downstream entities.** For third-party service agreements that are entered into or renewed on or after January 1, companies must obtain a certification or warranty from the third-party entity providing the services confirming that the associated fee will not be passed through, in whole or in part, to its downstream clients or customers. Manufacturers should:
 - Begin identifying which service fee arrangements trigger this requirement and evaluate whether existing documentation will support the necessary certifications.
 - Continue to assess how certifications are obtained, who within the organization is responsible for oversight and how exceptions will be addressed if third parties are unwilling or unable to provide the requested certification or warranty.

CMS has released related frequently asked questions, which are available [here](#). Although the effective date is April 30, CMS has signaled an expectation that manufacturers will use the period leading up to the effective date to remediate gaps, enhance controls and validate methodologies supporting ASP reporting.



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