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2026 Physician Fee Schedule (PFS) Final Rule Tearsheet

Key Provisions of the Centers for Medicare & Medicaid Services CMS CY 2026 PFS Final Rule: Fair Market Value (FMV) and Bona Fide Service Fee (BFSF) Implications

#	Key Provision	Proposed Rule (CY 2026)	Final Rule (CY 2026)	Insights / Considerations	Future Implications
1	**Definition / Methodology for BFSFs & FMV (42 C.F.R. § 414.802)**	CMS proposed to revise the BFSF definition by: (a) specifying methodologies to calculate FMV; (b) time period after which reassessment of FMV is required; (c) requiring manufacturers to submit verification that a BFSF is not passed on (in whole or part) to clients/customer / affiliates.	CMS **did not finalize** the full methodology revisions and some of the more burdensome or prescriptive proposals (e.g., independent third-party valuator requirement, fixed reassessment period). CMS **finalized** documentation and submission requirements: (1) manufacturers must submit reasonable assumptions quarterly and (2) must submit certification for new BFSF arrangements (entered on / after Jan 1, 2026) that fees will not be passed on.	The four-part test for BFSFs remains unchanged. The major shift is in implementation burden for manufacturers. Whereas the proposed rule sought more prescriptive FMV methodology, use of independent third-party valuation providers, and FMV reassessment timing, the final rule retains flexibility for manufacturers but adds enhanced documentation and certification requirements.	Over time, CMS may issue further guidance on FMV methodology and process. Companies can expect evolving enforcement, increased scrutiny, and possibly more specific FMV standards relating to these more prescriptive items (e.g., independent third-party valuator requirement, fixed reassessment period).
2	**Reasonable Assumptions Submission for ASP Reporting including BFSFs**	CMS proposed that manufacturers must submit the FMV analyses of the BFSFs included in their ASP calculations to be submitted as part of quarterly ASP data submissions along with descriptions of methodologies utilized to determine FMV.	CMS **finalized** the requirement that manufacturers must submit a "reasonable assumptions letter" quarterly for **ALL** current, new, and renewed service contracts (including BFSFs) by the April 30, 2026, due date for Q1 2026 ASP data. The new "**reasonable assumptions letter**" is to include detailed summaries of methodologies utilized to determine FMV and provide information on the data sources, assumptions, and rationale supporting the applicable FMV determinations.	A new compliance and data-submission workflow will be required as manufacturers must document methodology, assumptions, FMV analyses, and maintain audit-ready files. CMS will provide a template of the "reasonable assumptions letter" for manufacturers to document their FMV analyses and encourages manufacturers to also document which service fees are volume/sales-based and which are not. Manufacturers will also need to ensure FMV determinations are up-to-date (if not, reassess FMV analyses, methodologies, and fee structures and update accordingly).	Expect increasing audit risk and enforcement. Compliance programs may wish to consider updating their quarterly reporting procedures. Over time, CMS may expand review or enforcement actions tied to these assumptions.
3	**Certification that BFSFs are not passed on to clients / customers / affiliates**	CMS proposed verification requirements (certifications) from manufacturers that BFSFs are not passed on (in whole or in part) to a client / customer or affiliate of the entity receiving the BFSF.	CMS **finalized** the requirement that manufacturers must obtain verification (certification) from BFSF recipients affirming that fees are not passed on. With this change, it will no longer be appropriate for a manufacturer to presume, in absence of any evidence or notice to the contrary, that a fee paid is not passed on to an affiliate, client, or customer of any entity. Now, for **new contracts entered on/after Jan 1, 2026**, manufacturers must submit a certification/warranty via ASP reporting portal that BFSFs will not be passed on. For pre-existing contracts (entered before Jan 1, 2026) the presumption may still apply.	Companies entering into new service contracts need to ensure certification language is included and record retention is aligned with CMS reporting portal requirements. Existing contracts may still require review to assess pass-through risk, and manufacturers should consider the level of diligence performed to verify assurances where pass-through fees may be nuanced. Research on client / customer affiliates is becoming ever more important as industry consolidation has rapidly occurred over last few years. CMS will provide a template for the certifications.	CMS may perform post-market audits to monitor for pass-through fees. The trend could move toward tighter definitions of pass-through and greater transparency obligations. Service providers and manufacturers should monitor for further guidance.
4	**Treatment of fees for tissue procurement /autologous cell-based immunotherapy / gene therapy**	CMS proposed beginning Jan 1, 2026, any preparatory procedures for tissue procurement paid by manufacturer must be included in the manufacturer's ASP; and such payments would not qualify as BFSFs (i.e., regarded as part of product cost).	CMS **finalized** continuation of the existing bundled payment policy for CAR-T and extended to autologous cell-based immunotherapy and gene therapy. The steps for manufacturing/procurement are included in product payment. CMS did *not* finalize all of the proposed BFSF changes for these services.	This signals that fees for tissue procurement and cell/gene therapy may be increasingly treated as part of **product cost** rather than separate service fees. Manufacturers need to evaluate their contracts and pricing arrangements accordingly.	As cell/gene therapies proliferate, expect CMS to further refine ASP inclusion rules and BFSF exclusions. Manufacturers should anticipate increased scrutiny on service arrangements embedded in therapy manufacturing.
5	**Definition of "bundled arrangement" and clarity on price concessions vs BFSFs**	CMS proposed the addition of a regulatory definition of "bundled arrangement" (where a rebate / discount or other price concession is conditioned on purchase of the same drug or other drugs / products, performance criteria, etc.) and to clarify how to allocate pricing for bundled arrangements when calculating ASP.	CMS **finalized** a definition of "bundled arrangement" in regulatory text, but removed some of the originally proposed phrases (e.g., "purchasing patterns" and "prior purchases") and limited guidance to allocation of pricing under the arrangement. CMS stated that certain other elements (like adopting the Medicaid definition of bundled sales) are not being finalized at this time.	Ambiguity remains in how CMS will treat bundled arrangements and what types of fees will be considered price concessions. Manufacturers are advised to maintain conservative documentation and evaluate service arrangements carefully.	Future rule-making may propose more granular definitions, which could retroactively affect arrangements. Continuous monitoring and contract structuring will be important.

EXPERIENCE AT WORK

Ankura's valuation experts have consulted with life sciences clients for over 15 years to provide compliance guidance and supportable fair market value analyses in connection with the complex relationships underlying payments to customers.

Our assistance has included scenarios involving pre-commercialization to mature products and all major therapeutic areas, including orphan drug categories. In addition, our valuation experience covers a broad array of products (branded, generic, infused) and services for regulatory compliance and government pricing purposes and includes the following:

- **Arrangements with third-party healthcare professionals (HCPs) for consulting, speaker programs, advisory boards, focus groups, etc.**

- **Bona fide services provided by the following market access participants:**
  - **3PL and 3PL Title Model**
  - **Wholesale and Specialty Distributors**
    - Inventory Management
    - Data Reporting (852/867/844)
    - Order Processing (Administrative)
    - Cash/Financial/Accounts Receivable Management
    - Contract and Chargeback Administration
    - Returns Processing
    - National Logistics
    - Drop Shipment
  - **Specialty Infusion Providers**
    - Case Management
    - In-home Nurse Visits
  - **Copay and Voucher Program Administrators**
  - **HUB and Other Market Access Providers**
  - **Specialty Pharmacies**
    - Program Setup and IT Development
    - Data Reporting (Dispense/Status/Inventory)
    - Program Management
    - Case Management
    - Adherence/Welcome Calls
    - Distribution of Welcome Kits / Educational Materials / Brochures
  - **Group purchasing organizations (GPOs)**
    - Administrative Services
    - Sponsorships, Exhibitor Space, and Other Marketing Opportunities
  - **Reimbursement Support Centers**

- **Arrangements in connection with de-identified clinical patient data and other data purchases or collaborations with research institutions, providers, and other data providers.**
- **HEOR studies, clinical trial services, investigator sponsored trial services, and other research activities.**

GET IN TOUCH

CJ DeKreek
Managing Director
+1.404.575.3899
cj.dekreek@ankura.com

Katherine C. Norris
Senior Managing Director
+1.808.229.3748
katherine.norris@ankura.com

Kevin Lanier
Senior Director
+1.404.575.3862
kevin.lanier@ankura.com