Government Pricing Quarterly Update

January - April 2024

Author's note: *In this article, we provide insights into critical developments in pharmaceutical pricing, recent cases, and industry trends. Should you have any questions or thoughts to share, please feel free to reach out to us at* ***FCSNews@FederalComplianceSolutions.com****, and we would be glad to assist.*

Since the start of the year, new and revised regulations and guidance have been released, impacting drug manufacturer participation in government programs including the 340B Drug Pricing Program (340B Program), Medicaid Drug Rebate Program (MDRP), Medicare Part B, Medicare Part D Manufacturer Discount Program (MDP) and Coverage Gap Discount Program (CGDP), and Department of Veterans Affairs (VA) Federal Supply Schedule (FSS). The following is a summary of new and proposed changes, and how drug manufacturers can respond.

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1. 2024 Administrative Dispute Resolution (ADR) Final Rule

New regulation for manufacturers and 340B Covered Entities (CEs)

On April 19, 2024, the Department of Health and Human Services (HHS) issued a final rule for the Administrative Dispute Resolution (ADR) process (89 FR 28643, April 19, 2024), which will be effective June 18, 2024. HHS issued the final rule to correct policy and operational challenges encountered by the Health Resources and Services Administration (HRSA) since the 2020 final rule went into effect on January 13, 2021 (85 FR 80632, Dec. 14, 2020). The final rule retains certain provisions described in the proposed rule, including many requirements for filing a claim. However, input from industry stakeholders informed important changes to the published regulation.

What are the changes in the 2024 ADR Final Rule?

1. Removes onerous evidence and procedural requirements, establishing a more efficient ADR process.
2. Changes the review panel to include 340B Program subject-matter experts from the Office of Pharmacy Affairs (OPA).
3. Requires manufacturers and 340B Covered Entities (CEs) to "undertake good-faith efforts to resolve the disputed issues" prior to initiating the ADR process.
4. Limits the ADR process to issues regarding 340B Program overcharges, diversion, or duplicate discounts. Importantly, this includes "claims that a manufacturer has limited the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price."
5. Establishes a process to appeal or reconsider an ADR decision.

Key takeaways

- HRSA recognizes few manufacturers and CEs have initiated an ADR process to resolve 340B Program disputes. Although certain barriers have been removed or updated by the 2024 final rule, manufacturers are still required to complete a CE audit and must attempt good-faith negotiations before initiating the ADR process.
- CEs may be encouraged to initiate the ADR process against manufacturers with the final rule provision to include claims where access to Covered Outpatient Drugs (CODs) at the 340B Ceiling Price is limited, such as the case with contract pharmacy restrictions.

Questions and considerations

- Manufacturers with contract pharmacy restrictions should prepare to respond to CEs that initiate good faith efforts to resolve claims that their ability to purchase CODs is limited.
- Will the new ADR process increase the number of claims initiated by CEs?
- Will CEs join together and target certain manufacturers for restricting drugs at 340B Ceiling Price through contract pharmacies?

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2. Medicare Part D MDP:

a. Phase-In Eligibility Determination

Notice from CMS

In early April 2024, Centers for Medicare & Medicaid Services (CMS) sent a notice of phase-in determinations to manufacturers that entered into the Medicare Part D MDP and signed their Agreements by the March 1, 2024 deadline. CMS reviewed information provided by manufacturers, internal data, and publicly available sources against definitions in sections 1860D-14C(g)(4)(B)(ii) and 1860D-14C(g)(4)(C)(ii) of the Social Security Act to assign specified manufacturer and specified small manufacturer designations. Manufacturers with such designations are allowed lower discounts for applicable drugs marketed as of August 16, 2022 during the phase-in period, which ends in 2029 and 2031.

What to do now?

- Manufacturers in the Medicare Part D MDP should consider reviewing information used to determine the specified manufacturer or specified small manufacturer designation in the Health Plan Management System (HPMS).
- If a manufacturer disagrees with the determination, a recalculation request with rationale and supporting information may be submitted to CMS. The request must be received by CMS no later than 30 calendar days from the date of the determination notice.

b. Frequently Asked Questions (FAQs) from CMS

New guidance from CMS

On April 19, 2024, CMS sent a notice to manufacturers and Part D plan sponsors, responding to questions regarding recent guidance (i.e., Medicare Part D MDP Final Guidance and the Medicare Part D Manufacturer Discount Program: Methodology for Identifying Specified Manufacturers and Specified Small Manufacturers on November 17, 2023). Most questions focused on publication and management of the list of NDC-9s eligible for specified manufacturer or specified small manufacturer phase-ins. CMS will continue to update the FAQ list, as needed.

What to do now?

- Manufacturers should monitor for notices from CMS and the FAQ list for additional Medicare Part D MDP guidance.

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3. 2023 Medicaid Proposed Rule – Get a jump start on changes!

Proposed regulation from CMS

In March, CMS submitted the proposed rule "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" to the Office of Management and Budget (OMB) for review. The contents of the final regulation are not yet known, but manufacturers can take action now to manage areas of their organization with heightened exposure to these regulatory impacts.

Publication of the final rule in the Federal Register is expected by June 2024

The proposed rule includes provisions, if finalized, that could significantly impact drug manufacturer government program prices, commercial discount strategies, compliance activities, and innovation. Certain provisions pose particular challenges or considerations:

- Implementation of discount stacking across customers for Best Price (BP) determination.
- Revised definition for misclassification of drugs, with new penalties for non-compliance.
- Change to the definition of "internal investigation", limiting restatements beyond the 12-quarter price reporting period.

What to do now?

Inform relevant stakeholders and evaluate impact:

- Engage government pricing (GP), contracting, finance, legal, compliance, and regulatory affairs teams to inform relevant stakeholders of the regulation timeline; continue to monitor developments regarding the publication of the final rule.
- Understand the proposed regulation and consider operational, financial, strategic, systems, and resourcing impact.
- Identify policies, procedures, methodologies, reasonable assumptions, and system design documents that may be affected. Further evaluate controlled documents to determine inclusion of recent latest law, regulation, or guidance.

Best Price (BP) Stacking

What is the proposed regulation?

- CMS proposes to "clarify" the definition of BP to require the aggregation of discounts associated with a final price, even if they were received by different entities.
- The current BP definition is typically interpreted by manufacturers as an evaluation of each single entity as a separate BP candidate. This interpretation is based on regulation, which defines BP as:

  "…the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States…" (42 CFR 447.505)
- The change from stacking discounts to a single entity to stacking all arrangements on a single transaction will be challenging to implement and may result in significantly higher Medicaid rebate payments and lower 340B Ceiling Prices.
- Read further in-depth analysis from FCS Insights & News :
  - CMS Proposed Rule on Stacking for BP
  - MDRP Summit 2023: BP Stacking Proposal

What to do now?

- Evaluate current single entity stacking relationships and consider:
  - How are stacking relationships identified?
  - Is stacking documented in policies and procedures?
  - Have customers been evaluated to identify potential corporate relationships that may represent a single entity and require discount stacking?
  - Is the GP calculation system configured to calculate BP with stacked discounts (if so, how are transactions linked)?
- Communicate proposed rule changes to stakeholders and assess potential impact:
  - GP and contracting teams - understand which discounts may need to be aggregated and any potential matching logic to stack discounts appropriately
  - Technology – understand potential system requirements and limitations
  - Brand teams – understand how discount strategies will impact BP candidates
  - Finance – understand potential impact on Medicaid rebate accruals
- Consider reasonable assumptions regarding the ability to track discounts through the supply chain for stacking across multiple entities.

Misclassification of Drugs

What is the proposed regulation?

- CMS proposes to define a product misclassification as "the incorrect drug product information related to a COD is being used by the manufacturer" or "is paying rebates to States at a level other than that supported by statute and regulation."
- Penalties for failure to resolve misclassification of drugs in the required timeframe include civil monetary penalties and suspension of the drug from the MDRP.
- CMS will review drug classification data from the Food and Drug Administration (FDA) against product setup in MDP to identify manufacturers that may be incorrectly lowering their rebate obligation, on an "as needed" basis.

What to do now?

- Access and download the FDA's data sources:
  - Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE)
  - FDA's drugs@fda web page
- Compare product master to FDA data, including:
  - Drug classification (i.e., single source drug, innovator multiple source drug, non-innovator multiple source).
  - Drug information, including dosage form, strength, and billing unit.
- Identify and resolve misaligned data attributes.

Internal Investigations

What is the proposed regulation?

- CMS proposes to define "internal investigation" to limit the exception to the 12-quarter rule for price reporting with the following:

  "a manufacturer's investigation of its AMP, best price, customary prompt pay discounts or nominal prices that have been previously certified in MDRP that results in a finding made by the manufacturer of fraud, abuse or violation of law or regulation."
- Current regulation provides a broader exception to the 12-quarter price reporting rule, which allows for restatements when "the change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation" (42 CFR 447.510(b)(1)(v)).
- CMS highlights that the existing language has enabled manufacturers to recover significant dollars due to methodology changes outside the 12-quarter price reporting period, where the original calculation was consistent with statute and regulation. The proposed change will limit manufacturers from taking such action.

What to do now?

- Evaluate the sufficiency of the current control framework and the ability to identify potential calculation errors, including the price calculation validation and certification processes.
- Consider modifications to the timing of GP calculation audit and monitoring to avoid restatements beyond the 12-quarter price reporting period.

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4. Government Program Calculation and Reporting Updates

a. 1Q 2024 Unit Rebate Amount (URA) Considerations: AMP Cap Removal and Consumer Price Index – Urban (CPI-U) Decrease

AMP cap removal in effect

Beginning with the 1Q 2024 URA calculation due April 30, 2024, Medicaid rebates will no longer be capped at 100 percent of quarterly AMP. The American Rescue Plan Act of 2021 removed the AMP cap, which is expected to increase Medicaid rebates or move manufacturers to limit the rate of price increases for certain single source, innovator multiple source, and non-innovator multiple source drugs.

CPI-U decrease for 1Q 2024 Additional Rebate Calculation

Manufacturers should be aware the URA Additional Rebate may apply to cases where AMP increases, stays the same, or even decreases this quarter.

➢ 1Q 2024 Quarterly CPI-U is 306.746, which down from the 4Q 2023 Quarterly CPI-U of 307.789.

What to do now?

In preparation for the reporting deadline, manufactures should confirm the AMP cap has been removed from the 1Q 2024 URA calculation and a process is in place to monitor potential future impact:

- Confirm implementation of AMP cap removal, including:
  - GP system configuration change to remove AMP cap.
  - GP calculation policy, methodology, and process documents were updated to reflect the revised URA calculation, effective January 1, 2024.
  - Medicaid liability forecast reflects changes to URA.
- Evaluate the impact of AMP cap removal on the 1Q 2024 URA and inform relevant pricing and contracting, finance, and brand team stakeholders of impacted products.
- Continue to evaluate and manage impact of AMP cap removal, including:
  - Analyze drugs with high list price or high rebates to determine whether URA is close to AMP and potential for URA to exceed AMP.
  - Assess products that incur additional rebates to understand the driver of the additional rebates and potential for those rebates to grow.
  - Assess options to reduce prices and or apply other strategies to mitigate higher Medicaid rebate liability.
  - Monitor product demand and availability, which may be influenced by higher Medicaid rebates.

b. Office of Pharmacy Affairs Information System (OPAIS) 340B Pricing Component

New reporting process

On April 8, 2024, the Office of Pharmacy Affairs (OPA) informed manufacturers of enhancements to the Pricing Component website application for quarterly submission and reconciliation of 340B pricing data. Changes include the ability to designate an NDC as an "inner NDC", not available for sale during the reporting period. The designation defaults to the assignment submitted to First Data Bank. Additionally, manufacturers may submit corrections to previously published prices, including the prior quarter's Average Manufacturer Price (AMP) or URA.

What to do now?

- Review and correct "inner NDC" designation for 1Q 2024 price submission, if appropriate.
- Review the updated user guide released by the OPA, which includes instructions for enhancements to the 340B OPAIS pricing component website.

c. CMS Average Sales Price (ASP) Data Collection System

New reporting process

On April 1, 2024, CMS launched the new ASP Data Collection System, which provides enhancements to the ASP reporting process. Key changes include updated data fields (e.g., unit and strength type), new data templates, the capability to manage financial data tasks, and an improved user experience.

What to do now?

- Review information and training for the ASP Data Collection System posted to the CMS ASP Education and Outreach Page.
- **Submit 1Q 2024 ASP data through the CMS Enterprise Portal by April 30.**
- Review information on the new ASP Regulations and Policy Page, with references and links to ASP-related statutes, regulations, rules, and guidance.

d. Federal Acquisition Service (FAS) Sales Reporting Portal (SRP) for FSS Sales Reporting and Industrial Funding Fee (IFF) Payment

New reporting process

On April 1, 2024, the General Services Administration (GSA) launched the new FAS SRP for FSS sales reporting and IFF payments. The portal replaces the VA Sales Reporting System (SRS) as part of GSA's effort to modernize systems, standardize processes, and streamline the user experience. An important change is a shortened deadline for reporting sales and remitting IFF payment to 30 days, which aligns to current GSA practice.

What to do now?

- Evaluate impact of the reporting time period change from 60 days to 30 days and implement process and documentation updates.
- **Submit 1Q 2024 FSS sales and 1Q 2024 IFF payment through the new FAS SRP portal by April 30.**
- Review the updated Quickstart guide released by the FAS, which includes instructions for reporting and payment through the new portal.

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5. SUSTAIN Act

Discussion Draft 340B Program Reform

On February 2, 2024, the Senate released a discussion draft of a bill to reform the 340B Program. Titled "Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act" or "SUSTAIN 340B Act", the discussion draft outlines 340B Program changes based on a Request for Information on June 16, 2023, and meetings with stakeholders. Provisions in the discussion draft include:

- Removal of drug manufacturer restrictions to contract pharmacies (e.g., site limitations or claims data requirements).
- Definition of a patient.
- Clarification of child site eligibility.
- Transparency reporting requirement for CEs to disclose 340B Program metrics (e.g., number of prescriptions filled and cost of charity care).
- Enhanced program integrity through audits of covered entities, including the contract pharmacies and child sites, and manufacturers.
- Establishment of a 340B Program data clearinghouse to identify and prevent duplicate discounts.
- Requirements to ensure equitable treatment of CEs, contract pharmacies, and beneficiaries by group health plans and pharmacy benefit managers.
- CE user fee payments to HRSA for administering the 340B Program.

Comments to the discussion draft were submitted by April 1, 2024. The Senate Committee will use feedback from 340B Program stakeholders to inform the law-making.

6. Bona Fide Service Fees

There continues to be a lot of focus on pharma manufacturers and their arrangements with third-party service providers and how the fees are treated in government pricing (i.e., included as a price concession or excluded as a Bona Fide Service Fee (BFSF). We've included a quick refresher on BFSF and a few key considerations (see our recent BFSF blog for additional details and insights)

Quick Refresher on BFSF

Pursuant to 42C.F.R.§447.502, the definition of BFSF for purposes of Average Manufacturers Price (AMP), Best Price (BP), and Average Sales Price (ASP):

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.

BFSF Test Components

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 Fair Market Value (FMV) for the service.

What to do now and Key Considerations to Mitigate Risk?

- ✓ Inventory your contracts and evaluate if you have sufficient BFSF documentation.
- ✓ Document your BFSF evaluation, follow your BFSF process, perform FMV, and ensure that fees and other payments (including admin fees, credit card fees, distribution fees, data fees, other service fees, etc..) are treated appropriately based on the results of the BFSF evaluation. As a reminder, there is no conservative approach for BFSF (i.e., depending on your product, what's conservative in one government program may be aggressive in another). Note we generally recommend checking with counsel; especially for new or complex arrangements, if it's your first evaluation, or if it's a sensitive matter that should be performed under privilege.
- ✓ Develop processes and incorporate tools (i.e., checklist/questionnaires/FMV estimators) to help facilitate and incorporate BFSF evaluations in contracting process. This is a key item to help ensure that service arrangements are being evaluated not only from a fair market value perspective but taking a close look at the qualitative prongs of the test (i.e., is this a service on our behalf, is their pass-through evidence or notice, services itemized in the contract) and having a framework in place for the evaluation including when to seek counsel advice. In practice, we've seen it work well when manufacturers incorporate BFSF review as part of the contracting process to ensure appropriate stakeholders are aligned and there are no surprises when it comes to government pricing or gross to net. Also, for large manufacturers and or manufacturers that do a lot of contracting, think about ways to modernize and streamline the process.
- ✓ Perform periodic BFSF/FMV training so business teams are aware of process and mindful of current rules, regulations, and that the company creates and maintains documentation of the BFSF analysis and treats the fees appropriately in government pricing.

- ✓ Monitor and track performance of service providers and overall spend and evaluate whether there's an opportunity to mitigate risks.
- ✓ If you're contracts allow the vendor to invoice net of service fees, discounts, and other adjustment on their invoices, ensure that you're reviewing them and treating the fees appropriately. Note this is an area that is commonly overlooked especially as it relates to items like price appreciation credits. It's important to note that CMS has made clear that price appreciation credits are not BFSF and should be included in calculations
- ✓ Perform periodic government pricing assessments to ensure calculations are accurate and complete, appropriate reasonable assumptions and methodology are documented, policies and procedures are current, and service fee treatment in calculations aligns to BFSF documentation and that all service arrangements are reviewed.
- ✓ If you've already performed FMV and BFSF evaluation, keep track and perform periodic refreshes as needed. We typically recommend every 2-3 years, unless something significantly changes (i.e., sales or service changes, new rules/guidance, etc.).

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