Product Master Data Management:

Considerations, Common Pitfalls and Key Takeaways for Manufacturers Participating in Medicaid

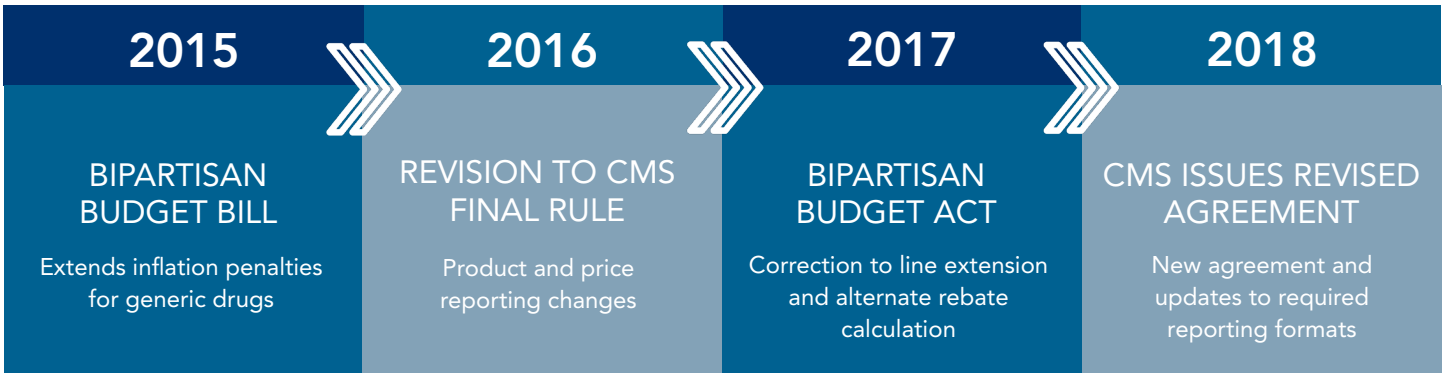
Recent market and enforcement trends in healthcare further exemplify the transition from a volume to value-based marketplace, as well as the complexities to contain the increasing costs of drugs in the new paradigm. The costs of branded prescription drugs are rising at an alarming rate that is unsustainable. Agency enforcement efforts highlight that more authority is needed for imposition of penalties and corrective actions to recover overpayments under Medicaid. Concurrently, legislation enacted, and regulatory changes continue to target cost containment of prescription drugs subsidized by Medicaid and Medicare.

Under the Medicaid Program, these changes have been further defined and clarified in the revised National Drug Rebate Agreement ("NDRA"). The amendment also requires manufacturers to verify that their products reconcile and match FDA drug listings and updates to reflect recent changes and corrections to reporting. As a result, the reconciliation and validation of the product master, long considered a best practice for manufacturers, is now a necessary and required action.

Legislative Actions and Regulatory Changes

In keeping with bi-partisan goals to shift, offset, and contain the rising costs of prescriptions drugs, recent regulatory actions continue to target the implementation of improvements to the Medicaid Program.

Some of the resulting changes have a significant impact on product master, data management, and liability due under the Medicaid Program, and are outlined below.



Overview of Product Reporting

Although interagency coordination between Center for Medicaid and Medicare Services ("CMS") and Food and Drug Administration ("FDA") is certainly not new, current efforts have furthered strengthened their existing partnership. Recent notifications announcing parallel review efforts and resource sharing continue to promote their joint commitment to reporting transparency, compliance and data integrity.

Notably, the FDA has formalized the process to update and certify drug listings annually, while CMS has issued the revised NDRA, which requires verification by participating manufacturers that all products are listed and match the FDA's NDC Structured Product Labeling Data Elements ("NSDE") file. For each product that is listed with the FDA that does not meet the definition of a covered drug and therefore is excluded under Medicaid, CMS also requires manufacturers to note the rationale for exclusion. CMS has restructured this process to effectuate the revised agreements or to reinstate manufacturers previously terminated from the Medicaid Program.

Product Master Management

A company's product master is one of the foundational pillars upon which the accuracy of government price reporting is structured. Product master data management is centralized within the commercial organization and managed in conjunction with government pricing. Updates to the product master are the initial trigger for product and baseline price reporting and the primary connection between transactional data for monthly and quarterly price reporting submitted to CMS.

Furthermore, CMS and FDA publicly disclose information reported by manufacturers, including CMS' active product listing and reporting status on a quarterly basis and current drug listings are updated and published daily by the FDA. Key considerations to ensure reporting requirements are met and data integrity is sustained are highlighted below.

Key Considerations

DATA SOURCES

- FDA is the source for product data reported to CMS
- Annual certification of FDA NDC Listings
- CMS publishes active products and reporting status quarterly

PRODUCT MASTER

- New drug indicators
- Line extension designation
- Baseline pricing for generics
- 5i product designations and thresholds
- Market entry and purchase date

REPORTING

- Process and system controls to reduce data errors
- CMS reinstatement process
- Verification against FDA information and Listing

Common Pitfalls and Key Takeaways

Silos between regulatory and commercial

Lack of due diligence (i.e. transfer of ownership)

Insufficient controls to reduce errors, omissions, and inconsistencies

Decentralized master data management

The accuracy and completeness of the product master throughout the product's lifecycle is paramount to calculating prices paid by and rebates due to the government.

An evolving regulatory landscape, increasing scrutiny of rising drug prices, and enforcement efforts around product data integrity further underscore the importance of proactively assessing, reconciling and validating product master data.

A few key takeaways from the revised agreements for MDRP participating manufacturers include:

- Proactive collaboration and communication with the regulatory department to manage changes and updates to the product master.
- Product master alignment to certified drug listings reported to the FDA and Drug Data Reporting ("DDR") for Medicaid as required by CMS.
- Establishment of processes and controls to centralize product records and the management of master data.
- Verify completion and accuracy of product information, as outlined in the reporting format required under the revised agreement for Medicaid.
- Document the validation results to support the verification of the product master for reporting required by CMS, including:
    - Updates to the drug status for Drug Efficacy Study Implementation ("DESI") drugs,
    - Product information and drug categorization matches the current drug listings reported to the FDA,
    - Line extension indicators are defined and applied,
    - Revisions to market entry dates
    - Baseline pricing for generics, and
    - Transfers of ownership updates.
- Retain documentation of the validation results to support the verification required for new manufacturers requesting an agreement to participate in Medicaid.
- CMS' review and approval of covered drug listings, including the rationale for product exclusions is required to effectuate the revised agreement.

The assessment, reconciliation, and validation effort will help to avoid common pitfalls, which are likely to lead to revenue leakage, penalties and/or costly remediation and restatements.

About the author:

Christina Spicer has 18 years of industry experience in life sciences, encompassing 13 years as a management consultant. She is an Associate Director in the Commercial Strategy, Operations and Compliance Practice at EVERSANA specializing in regulatory compliance, transparency disclosures, and government price reporting. In this capacity, Christina helps clients design, harmonize and integrate business processes and innovative solutions to support operational excellence and compliance in commercial operations. Further, Christina has extensive consulting experience in organizational transformation projects related to mergers and acquisitions, joint ventures and divestitures; commercialization and product launches; and new regulations or settlement agreements.