

2011 MDRP Conference Presentation Summary

Presentation: Best Practices for Generic Companies Navigating Government Compliance

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With CMS final rules still currently not provided to the private industry, generic manufacturers must continue to operate in an ambiguous regulatory environment with limited budgets. Additionally, many generic manufacturers are in the process of or already have acquired authorized generic (AG) or branded products, further adding to the complexities. This document is intended to summarize the major points discussed in the 2011 MDRP Conference's Best Practices for Generic Companies Navigating Government Compliance presentation panel.

Market Landscape

- **Branded / Generic Calculation Differences** – While branded manufacturers participate in all facets of government programs, generic manufacturers participate in fewer government contracts and indirect agreements, but offer many more direct discounts:
 - **Government Participation** – Because the ownership of AG or branded products comes with responsibilities such as Best Price and the Federal Supply Schedule solicitation process, it is critical that a generic manufacturer takes into account all regulatory impact in the process of these acquisitions.
 - **Discount Payments** – In addition to the above challenges, generic manufacturers face the need to determine appropriate treatment of a slew of price concessions that do not have clear regulatory guidance, many of which branded manufacturers do not need to address. Discounts such as New Store Opening Promotions or Failure to Supply penalties are generally paid to all customers, and have the opposite effect on Average Manufacturer Price (AMP) and other calculated government prices (GP) than their branded counterparts. The net effect of these business channel and regulatory treatment differences is to generally increase AMP for branded products and decrease AMP for generics.
- **Shift in Revenue** – The government pricing participation differences listed earlier result from significant differences in business models between branded and generic manufacturers:
 - **Acquisitions and Authorized Generics** – Based on Alliance's poll of the generic participants at the MDRP Conference, many generic manufacturers

either have acquired or are in the process of acquiring AG or branded products. This shift in product mix is the result of pressure to generate more revenue, stave off increased competition, and recognition of the company's needs to diversify their product portfolio.

- **Market and Pricing Strategies** – As government reporting focuses on appropriately treating all transactions for inclusion/exclusion in price calculations, careful consideration must be taken of strategies behind a generic manufacturer's financial performance. As generics focus primarily on volume and price competition, it is necessary to monitor a branded product's patent expiration timeframe, enter the market first, and then maximize the retention of generic exclusivity. As generic exclusivity expires and competition enters the market, different forms of price drops, price countering, and volume-protection are taken, forming the strategies and price concessions that must all be taken into account from a regulatory perspective.

While the above merely summarizes some important market conditions, it is clear that generic manufacturers have many considerations to keep in mind in how they generate revenue and their associated impacts on regulatory compliance.

Regulatory Considerations

- **Regulatory Changes** – Due to the complexities of the U.S. healthcare system, government compliance is absolutely critical to the success of a generic manufacturer. To reach a level of compliance excellence, manufacturers will need to use a methodical approach to review ensure that appropriate handling, inclusion, and use of data is adhered. Some additional regulatory considerations follow:
 - **AMP Changes** – With the recent AMP Final Rules still not yet defined, generic and branded manufacturers alike must contend with appropriate treatment of their Retail vs. 51 products and whether they will adopt a new "top down" vs. "bottoms up" approach in their GP policies. Additionally, because GP policies are heavily

interrelated, a change in how AMP is calculated may significantly impact all government liability, whether it is in Medicaid or PHS 340B.

- **Litigation** – The need to comply with regulations to the best of a manufacturer’s ability is absolutely critical. As has been demonstrated with recent litigation cases of two prominent generic manufacturers, mistreatment of price concessions and not including them in the AMP calculation resulted in significant fines and penalties. Additionally, with the government’s trend to prosecute both companies and individuals responsible for GP certification, all sales and distribution price concessions must be reviewed in a GP calculation.

• **Government Program Additions** – As was introduced earlier, the process of becoming a branded manufacturer comes with many challenges. The following highlights major areas for review:

- **Best Price** – As a best price (BP) is the lowest commercial price in a period and Medicaid liability is impacted by the difference between AMP and the single transaction that sets the BP, it is critical that all discount types unique to generic manufacturers are considered for BP eligibility.
- **Federal Supply Schedule** – As branded manufacturers must participate in the Federal Supply Schedule (FSS), appropriate FSS contract awarding and processing must be followed to maximize value to the manufacturer. Important considerations in the FSS include the lack of a formal restatement process and the mandatory TRICARE refund payments, both of which imply high degrees of government compliance.
- **Medicare Part D and B** – AG and branded products have multiple considerations in the Medicare government program. In addition to the Part D coverage gap discount, some overlooked products that are not necessarily physician-administered may be prescribed through Medicare Part B, and therefore may require an ASP calculation. Examples of these products may include complementary products to physician-administered treatments.

• **Pricing, Reimbursement, and Reporting Impact** – In addition to market condition changes and government program considerations, generic manufacturers must also take into account different challenges in ongoing reporting and financial impact:

- **Change in Reimbursement** – As it has been speculated by multiple private sector sources, CMS’s recent regulatory change to focus AMP around the Retail Community Pharmacy will generally increase AMP to be closer to the Wholesale Acquisition Cost. Increases to AMP may therefore imply increased Medicaid liability, and potential decreases to PHS profitability.
- **Different AMP Methodologies** – As the current AMP regulations are not yet finalized, it is additionally postulated that generic and brand manufacturers may be held responsible to use two different types of AMP calculation methodologies in their submissions to CMS: those for Retail products, and those to 5I products with discrete Class of Trade (CoT) and other data identifiers.
- **Changes Over Time** – Because generic manufacturers have a higher proportion of overall revenue through direct sales channels than branded manufacturers, increasingly varied direct discounting strategies will proportionately impact AMP.

• **Unique Discount Types** – A generic manufacturer may employ multiple discounts in its normal course of business with different treatment in GP calculations. To help clarify these calculation methodologies, please see below a summary that suggests some common filtering criteria for AMP. Additionally, because each manufacturer’s business practices and GP policies are different, the following should be reviewed with legal counsel to ensure appropriate treatment before adoption:

Payment Type	AMP Inclusion
Pricing Differentials	YES
Shelf Stock Adjustments	YES
Price Protections	YES
Promo – Advertising	NO
Promo – Booth Fees	NO
Promo – Trade Show Allow.	YES
Promo – New Store Openings	YES
Promo – Stocking Allowances	NO
Failure to Supply	NO
Redistribution Fees	??
Marketing Fees	YES
3rd Party Contract Service Fees	YES
Broker Commissions	NO

In addition to the regulatory considerations described above, generic manufacturers have a slew of ongoing operational challenges to face. To aid the successful completion of these challenges, the presentation team has assembled the following set of tips and suggestions.

Trends, Accelerators, and Tips

- **Managed Medicaid Volume Increases** – Managed Medicaid and increased significance of State Pharmacy Assistance Programs (SPAPs) and Supplemental agreements represent workload increases for the Medicaid rebate claims processing team. This challenge is compounded by the need to validate the same prescription is not being invoiced on both the standard Federal Medicaid and the Managed Medicaid invoices.
- **Distribution Channels and Impact on GP** – Because brand and generic manufacturers operate through different sales channels, a GP methodology should take both into account. For example, significant changes between months on whether products are shipped through wholesalers or sold through direct pharmacies may significantly skew a smoothing valuation, thereby significantly impacting the outcome of the AMP and other related GP.
- **Membership Management** – To assist in maintaining positive cash flow, a generic manufacturer must heavily scrutinize its Gross to Net process. This need is further compounded by the fact that typical generic manufacturers have significantly lower profit margins than their branded counterparts. In order to properly maintain strong financial performance, commercial and PHS 340B membership management, transaction monitoring, and contract reviews must all be performed. Additionally, generic manufacturers acquiring branded products must also focus even greater scrutiny on PHS 340B membership, as a single erroneously processed PHS transaction could trigger a lower BP, a higher Rebate Per Unit, and a lower PHS price in the future.
- **Organizational Design and Resource Availability** – Generic manufacturers often face simple administrative challenges, such as not having enough hours to complete all assigned government compliance tasks before looming deadlines. As a result, slowdowns in price calculations and payment processing may occur. To help circumvent these types of challenges, generic manufacturers should perform an assessment of their major bottlenecks in government participation to identify improvement areas such as:

- **Departmental Separations** – Different companies may have different organizational structures to address government participation. In many cases, where the GP department is structured can impact the overall efficiency of the organization. For example, assigning CoTs without input from the GP department may significantly hamper the overall compliance structure of a firm.
- **Physical Location Challenges** – Having different government participation job functions in different physical locations can prove challenging to an organization as well. For example, out-of-state payment processing centers create an administrative slowdown for a pricing and reimbursement office. Often, a redesigned business process can avoid such situations as multi-day delays in check requests.
- **Communication with Government Agencies** – While compliance with the above regulations may seem challenging, communication with the appropriate government agencies can greatly speed up compliance.
 - **Medicaid** – Many states participating in the Medicaid program offer their Medicaid claims in electronic format, whether through email, diskettes, or on websites. Often, a phone call with a state Medicaid officer is all that is needed to begin the process of receiving claims data in electronic format, avoiding laborious manual claims entries.
 - **Federal Supply Schedule** – Navigating the FSS is a complicated process. Fortunately, the Department of Veterans Affairs has been proactive in its ability to provide feedback to manufacturers. A generic manufacturer that chooses to acquire AG or branded products should establish solid working relationships with VA Contracting Officers.

In total, while generic manufacturers face a significant number of challenges, it is often the case that a solution exists for each challenge. It is Alliance's hope that in delineating some of the high level approaches to government participation, that more generic manufacturers are able to derive value from government programs.