Assessing Future Regulatory and Compliance Developments –

The Current Landscape and Future Legislative Changes for Medicaid and Medicare Price Reporting Obligations

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Agenda

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- The Current Landscape and Possible Future Legislative Changes
  - Current Landscape: The DRA and Final Rule
  - Future Changes:
    - AMP/FUL Revisions
    - PHS/34OB Amendments
    - Price Reporting For Medical Devices
- Compliance Developments
  - Bundled Sales
  - Authorized Generics
  - Bona Fide Service Fees
  - Patient Programs: PAPs, Coupons, and Vouchers
  - Certification Requirements

The Current Landscape

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- Medicaid: The DRA and Final Rule
  - DRA: effective 2007 imposed statutory changes to Medicaid price reporting and outpatient drug reimbursement
  - Final Rule: effective Q4/07, defines detailed and extensive requirements regarding Average Manufacturer Price (AMP) and Best Price (BP) reporting
- DRA and Final Rule implementation has been focus of most price reporting groups for the past year
  - Implementation may not yet be complete
    - Certain aspects of implementation are very complex, and often require in-house IT/programming development
    - Programming and data issues may be identified as implementation proceeds
    - Policy/SOP documentation generally follows once operational issues have been resolved
  - Revisions to AMP from Final Rule may impact reimbursement as well
    - 5% threshold for ASP-based reimbursement
    - Enjoined/legislation prohibits AMP use for Medicaid reimbursement

Future Legislative Changes

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- Definition of AMP/Use for Medicaid Federal Upper Limits (FULs)
  - DRA/Final Rule re-define AMP and require its use to set FULs for multiple source drugs
  - NACDS litigation/MIPPA prevent use of AMPs to set FULs prior to 10/09
  - Future legislation may
    - Change definition of AMP, so fewer objections to its use in setting FULs
    - Prohibit (permanently) use of AMP in setting FULs
- PHS/340B Drug Pricing Program
  - Requires deep discounts to safety net providers, with discount tied to Medicaid rebate
  - Future legislation may
    - Expand entities entitled to discounts
    - Expand program from outpatient to also include inpatient drugs
- Price Reporting For Medical Devices?

Compliance Developments: The Bundled Sale Definition

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- Medicaid Requirement: *generally*, where a contract conditions a discount on any performance requirement linking more than one NDC-11, the manufacturer must reallocate discounts between the products before including those discounts in AMP/BP
- Medicare (ASP) Requirement: no mandate, but CMS expects manufacturers to use reasonable assumptions, which must be consistent with other business practices
- Implementation:
  - Required inventory and review of contractual and sales arrangements
  - Required creation of system (manual or automated) for reallocating discounts
  - Created possibility for
    - Increase in calculation complexity
    - Increase in risk of error
    - Decrease in predictability/control over Best Price
    - A Best Price that no longer may tie to a specific contract price/rebate rate
  - All in the context of a new certification requirement
- Option: contract simplification or separation

Compliance Developments: Authorized Generics

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- Medicaid Final Rule: Branded manufacturer may only include authorized generic (AG) in AMP if the branded manufacturer itself sells the product to the commercial market (wholesalers); for BP, branded manufacturer includes whatever price it sells the AG at to the next entity in the supply chain
- Implementation:
  - AMP: Where branded manufacturer sells to a secondary manufacturer, the branded manufacturer includes no AG data in AMP and the branded AMP stays high, at original branded amount
  - BP: Branded manufacturer includes (adjusted) transfer price to secondary manufacturer in the BP of the brand product, which sets a very low BP
  - URA: Very high, possibly in excess of AMP/WAC
- CMS: Discourages AG arrangements through increased rebates, and also promotes simplicity, avoids antitrust concerns
- Possible Alternative Business Model:
  - Can the branded manufacturer sell the product directly to the market so it can blend AMP with no transfer price?

Compliance Developments: Bona Fide Service Fees

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- Medicaid and Medicare Requirement: administrative and service fees are ineligible for AMP, BP, and ASP where definition of bona fide service fee satisfied:
  - Itemized, bona fide, service that is actually performed for the manufacturer, and that manufacturer itself otherwise would perform or contract for;
  - Payment represents fair market value
  - Fee is not passed on to customer of recipient
- Implementation:
  - Who at manufacturer is conducting this analysis?
  - Is FMV standard consistent across company, products, business units?
  - Is the price reporting area aware of all of the different fee arrangements that have to be analyzed under this definition?
  - *Definition applies even to entities that do not take title to product.*
- Option: Uniform standard for and centralized review of all fee arrangements subject to definition

Compliance Developments: Patient Programs

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- Medicaid Requirement: Patient Assistance Programs, and Patient Coupons and Vouchers now must satisfy specific criteria if they are to be excluded from AMP/BP
- Medicare Requirement: No parallel criteria, so reasonable assumption standard applies
- Implementation:
  - Inventory of all patient programs needed
  - Analysis must focus on both patient eligibility and benefits as well as contracts with any third party vendors that administer the programs
  - Are the income limits for your PAPs "low income" and consistent/rationale across products?
  - Have you analyzed your vendor contracts under the bona fide service fee definition?
- Option: Uniform standard for and centralized review of all patient programs.

Compliance Developments: Certification Requirements

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- Medicaid and Medicare Requirements: CEO, CFO, or delegee thereof must certify reports AMP, BP, and ASP data with each submission.
- Implementation:
  - Senior management now likely much more aware of these price points, their use, and drivers of fluctuations
  - Sub-certification process is best practice for ensuring full team ownership of accuracy and completeness
  - Certification requirement now generally results in most errors/restatements being disclosed to and discussed with certifier
  - Resource dedication is silver lining

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