

Assessing Future Regulatory and Compliance Developments –

The Current Landscape and Future Legislative, Regulatory and Contractual Changes for VA and DoD Purchases

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Agenda

- The Current Landscape and Possible Future Legislative and Regulatory Changes
 - DoD: Tricare Retail Pharmacy Program
- Compliance Developments
 - Annual Non-FAMP and FCP calculation
 - Contract Negotiations with VA

Overview - Tricare Retail

- DoD beneficiaries can have prescriptions filled at four venues:
 - Military Treatment Facilities (“MTFs”)
 - Mail Order pharmacy
 - Tricare Network Retail Pharmacies
 - Non-network Retail Pharmacies
- DoD pays Federal Ceiling Price (“FCP”) for pharmaceuticals to stock the MTFs and Mail Order pharmacies
- When DoD reimburses retail pharmacies for prescriptions filled for DoD beneficiaries, DoD pays “commercial prices” negotiated by the PBM
 - DoD only entitled to FCP when it purchases/procures product off the FSS contract or through depot contract
 - When DoD is acting as reimbursor/insurer on retail pharmacy prescriptions, it is not actually purchasing any product. Rather it is paying for product purchased by a DoD beneficiary

DoD Efforts to Obtain Discounts to Offset Retail Costs (2005-Present)

- **Voluntary Rebates (VARR)**

- DoD solicited offers from manufacturers to voluntarily provide rebates on retail pharmacy utilization

- **Rebates tied to Formulary Position (UF-VARR)**

- DoD has a Uniform Formulary to leverage buying power
 - Three tiers: generic, formulary, non-formulary
 - Subsets relating to MTFs: Basic Core Formulary (BCF) and Extended Core Formulary (ECF)
- Formulary position determined by cost and clinical efficacy
 - Cost efficacy considers price at 3 venues: MTF, TMOP, and Tricare Network retail pharmacies
- When class comes up for review, manufacturers can offer retail rebates to boost cost effectiveness determination compared with competing drugs and thereby get favorable formulary position
 - DoD may request multiple quotes contingent upon number of agents selected for UF, BCF, and/or ECF

- Manufacturers were free to set value of offered rebate (valued as a percentage off of WAC)

- **Blanket Purchase Agreements**

- Offer better than FCP pricing for MTF or TMOP in connection with class competition

National Defense Authorization Act for FY 2008

- 1/28/08: President signs National Defense Authorization Act (NDAA) for FY 2008 into law
- Section 703:
 - Treat Retail Pharmacy utilization as “part of DoD” for purposes of the VHCA statutory ceiling price
 - DoD must amend Uniform Formulary regulations to implement the statute
 - Does not specify how FCP-based pricing is to be obtained/accessed by DoD (assumption by industry is that DoD will again seek rebates based on utilization data provided to manufacturers)

TMA Actions Prior to Proposed Rule

- 2/1/08: TMA issues Dear Manufacturer Letter
 - States that NDAA “affirms” the government’s position that retail is subject to FCP
 - Informs industry that DoD expects “refunds” paid based on utilization beginning with 1/28/2008
 - Acknowledges the requirement to issue regulations, but seeks refunds prior to such regulations being promulgated
- Spring 2008: TMA updates its website with FAQs
 - “Refund” will be calculated as Annual Non-FAMP minus FCP times utilization
 - Asks companies to submit a Questionnaire to receive utilization data
 - Issues new Process and Procedures Guide discussing how to account for Tricare utilization in Non-FAMP
 - Note: Only VA is authorized to issue guidance regarding Non-FAMP calculations
- Industry Forum May 1, 2008
 - DoD acknowledges that until the regulation is implemented, only those manufacturers that have voluntary agreements with DoD (*i.e.*, VARR (Utilization) or UF VARRs) are required to pay rebates
 - UF VARRs for class competitions beginning 6/08 are to be based on Non-FAMP minus FCP
 - DoD says it will re-compete previously closed classes over the next 18-24 months

Recent Challenge to TMA Letter

- In June 2008, Coalition for Government Procurement filed suit in Federal court challenging TMA's 2/1/08 Dear Manufacturer letter
 - Seeks to enjoin DoD from conducting its formulary reviews according to the procedures laid out in the letter and in the updated Process and Procedures Guide
 - Purely procedural challenge: argues that DoD's interim implementation through a letter violated Section 703 and the APA
 - Section 703 expressly required a modification of the Pharmacy Benefits regulations
 - APA requires that substantive rules be issued through notice-and-comment rulemaking
- Oral argument took place on 9/10/08
- DoD agreed to stay any formulary decisions until following the oral argument
- Impact of the proposed rule (see next slide) on this lawsuit and/or DoD's formulary process and decisions?

DoD Issues Proposed Rule

- Published on 7/25/08; comments due 9/23/08
- Proposes to adopt framework for voluntary rebate agreements tied to formulary placement similar to the interim UF-VARR procedures of recent months (does not appear to implicate the Master Agreement)
- Would require an agreement to provide FCP-based pricing as a precondition for formulary placement of a drug and its availability through TRRx without preauthorization (does not exclude from the Pharmacy Benefits Program)
 - Note: Non-formulary drugs are not to be stocked at MTFs, but are available through TMOP at a higher copay
- FCP pricing will be achieved through rebates based on a drug's TRRx utilization
- Rebate is the difference between the most recent annual Non-FAMP reported to the VA minus FCP (Optional: The difference between FCP and the direct commercial contract sales prices paid specifically attributable to the reported Tricare-paid pharmacies)
- DoD expects this rule to be retroactive (*i.e.*, require rebates back to 1/28/08)
- Not applicable to drugs for which Tricare is a second payer or those receiving an exemption from TMA

Submission of Comments to Proposed Rule

- Need for Definition of Scope and Terms of Rebate Agreement
 - Scope of covered drugs
 - Exclusions process?
 - Drug-by-drug basis or all covered drugs?
 - Disputes (process, burden of proof, limitations on stale claims)
 - Audit
 - Termination
- Start Date Should Not Reflect Back
 - Retrospective application to 1/28/08?
 - Application as of date of Rebate Agreement prevents fewer legal, logistical and financial hurdles
- Effect on Existing Agreements
 - Grandfathered-in?
 - Cancel and recompete?

Submission of Comments to Proposed Rule

- Impact on Other Pricing Programs
 - Proposed rule relies on and affects existing pricing programs outside of DoD's control
 - VA and CMS have yet to weigh in
- Consequences
 - Remedies for Failure to Contract?
 - TMA may take “any other action authorized by law” for failure to “enter into or honor” a voluntary agreement
 - Raises questions as to the “voluntariness” of the agreements
 - Preauthorization
 - Rule would subject non-FCP compliant drugs to preauthorization in TRRx
 - Discretionary under current regulations/mandatory under Proposed Rule

Next Steps and Unanswered Questions

- Recent DoD letter to Manufacturers (September 2008):
 - In effort to resolve Coalition litigation, allowing companies to submit UF-VARR with rebates less favorable than FCP until final rule is issued
 - Reserved right to retroactive rebates
- Without a final rule or contract, there is no legal obligation to pay rebates
 - Final rule could be months or years away
 - If manufacturers don't pay, should they accrue?
 - Highlights the complications with a retroactive requirement
- After a final rule, will TRRx utilization be excluded from Non-FAMP?
 - Depends on how “voluntary” the final rule is
 - e.g., will the rule require all covered drugs to be covered by an agreement or allow a drug-by-drug decision?
 - VA directed exclusion of TRRx utilization following 2004 letter when it was mandatory but later required those that paid voluntary rebates to include utilization and recalculate Non-FAMPs
 - VA has not yet provided guidance and will have to weigh in to answer these questions

2008 Annual Non-FAMP Filing

- Due November 17 (November 15 is a Saturday)
- All questions and issues submitted by Oct. 31
- VA to issue annual guidance letter re: calculation
- 2009 FCP
 - FSS Max Cap does not apply this year
 - Greatest impact for single pricers
 - Still apply the “Additional Discount”
 - Tracking customer-based price reductions still apply

New VA Contracts

- VA has issued a new solicitation
- Open solicitation – can submit any time
- Even if your company’s contract does not expire until 2010 or after, may consider renegotiating in 2009
 - All companies will be renegotiating in the next few years; may be back-up when your contract is expiring
 - Allows you to renegotiate tracking customers now
 - If you have unfavorable pricing, you can renegotiate
 - Depending on commercial pricing, can renegotiate OGA pricing in an amount higher than the CPI-U increase
 - Dual pricers: higher OGA prices mean higher FSS Max caps in 2010
- Required to submit Commercial Sales Practices Disclosure with new offer
 - Disclose all commercial pricing equal to or better than offered government price
 - VA expects disclosure to be “current, accurate, and complete”
 - Not required to offer “MFC” pricing

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