Assessing Future Regulatory and Compliance Developments –

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

9th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

Allison D. Pugsley, Esq.

October 28, 2008
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 reimburer/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

- 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 issues 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