

## Subcontractor Liability

Will Downstream Delegation  
Send You Up the Creek?



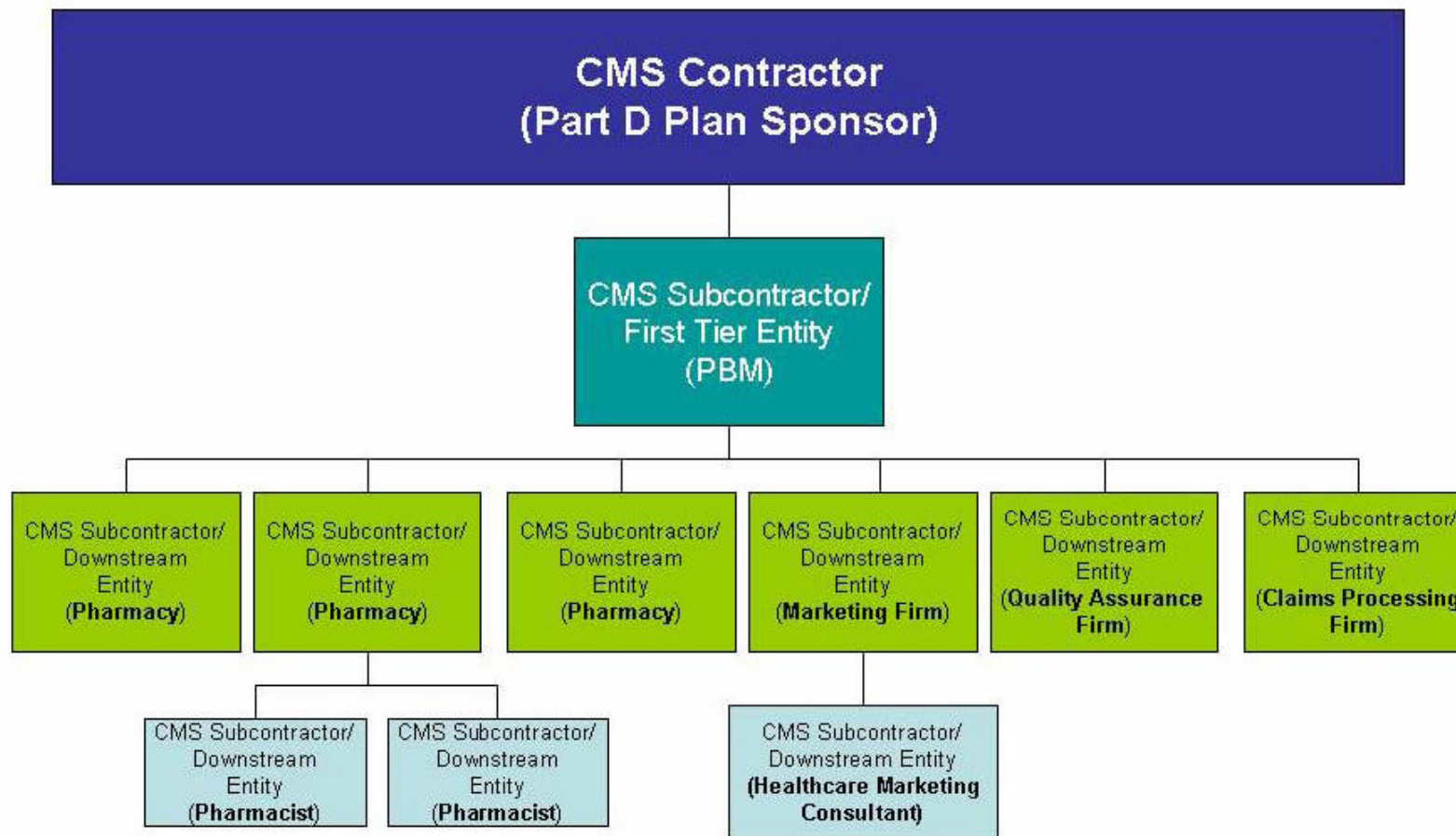
**Crowell & Moring LLP's  
Medicare Part D Webinar:  
Fraud, Waste and Abuse**

Thursday February 23, 2006

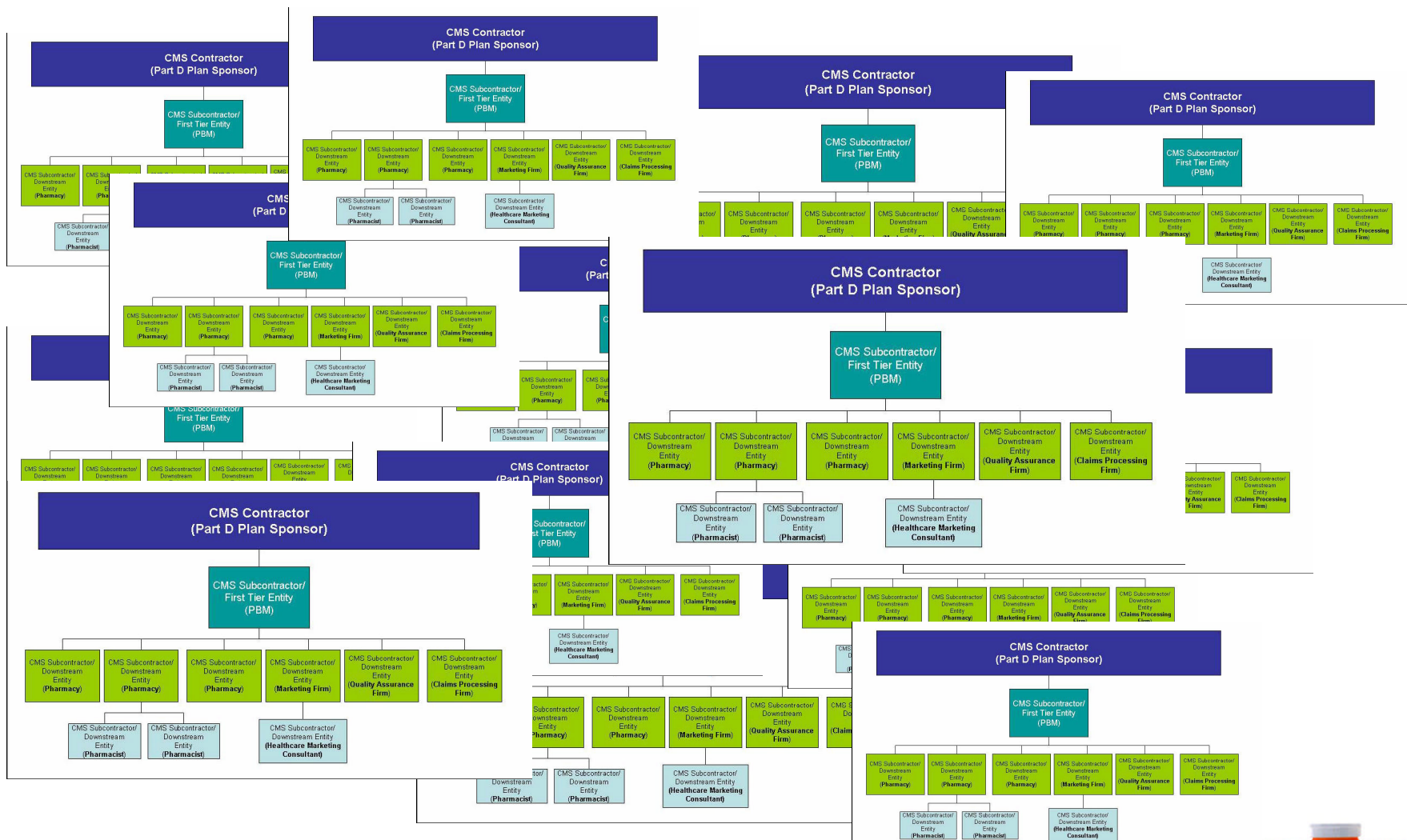
- Section 40 of FWA Guidance – only 4 pages
- But 120+ “subcontractor” references throughout FWA Guidance
- Compliance initiatives must extend downstream in numerous respects
- Hard Questions – How to enforce? Who pays?



# Stakeholder Relationship Flow Chart (p.13): In a vacuum it may be straightforward, but...



# ... the reality is a lot more complicated



- Monitoring and auditing
- Training
- Internal exclusion list checks
- Data certifications
- Code of Conduct certifications
- Conflict of Interest certifications
- Renegotiating contracts?



- Part D sponsor “maintains ultimate responsibility for ... fully complying with ... its contract with CMS” (42 CFR § 423.505(i))
- Subcontracts with “downstream entities” extend to “the level of the ultimate provider of ... health ... services.” (42 CFR § 423.501)
- Contracts must specify that Part D sponsor “on an ongoing basis monitors the performance of the parties.” (42 CFR § 423.505(i)(4)(iii))



- Compliance program may not be delegated
  - » Part D Compliance Officer position
  - » Compliance Committee
- Contracts with subcontractors must enable revocation at CMS' request
- Subcontractors must certify accuracy of data, and acknowledge that data will be used for purposes of obtaining Federal reimbursement



- Subcontractor reports of non-compliance, misconduct
  - » System for receiving reports
  - » Confidential, anonymous reporting mechanisms
  - » Non-retaliation
  - » Mandatory reporting
- Responding to subcontractor compliance questions and concerns
  - » Hotline inquiries
  - » Timely response
  - » Follow-up investigation process, progress reports





- Monitoring and Auditing of Subcontractors
  - » Regular reporting process, review
  - » Routine and random audits
  - » Workplan – how many to be audited for the year
  - » Audits should include on-site visits, interviews
  - » State licensure standards
  - » Rebate, discount arrangements
  - » Payment reports
  - » Drug utilization reports
  - » Prescribing patterns by physician
  - » Geographic zip reports (doctor shopping)



- **OIG/GSA exclusion list review (2x/year min.)**
  - » Should include subcontractor officers and managers
  - » Subcontractors should be contractually required to check on own employees, Board members 2x/year
- **Code of Conduct**
  - » Subcontractor officers, directors, and managers should certify compliance on behalf of employees
- **Training**
  - » Should occur when “subcontractor works in an area previously found to be non-compliant ... or implicated in past misconduct”



- **Conflicts of Interest**
  - » Subcontractor officers, directors, and managers involved in Part D administration must certify at time of hire, annually thereafter
  - » Should designate a system to determine if outside employment opportunities by these individuals creates a conflict
- **Internal Special Investigation Units (SIUs)**
  - » Deemed “crucial” to identifying subcontractor FWA
- **Corrective Action Plans**
  - » Where subcontractor commits misconduct, elements should be detailed in written agreement

