

## **Part D Administrative Contract Flowdowns**

**By  
Kenneth M. Bruntel  
Crowell & Moring, LLP**

**Presented to the  
American Health Lawyers Association  
Mid-Year Meeting  
Hollywood, FL  
May 2007**

- Threshold Question No. 1: What is a Flowdown?
  - A statutory, regulatory, contractual, or other requirement imposed on Part D Plans that must or should also be imposed on certain PDP vendors
- Threshold Question No. 2: To Which Vendors Do Flowdowns Apply?
  - No Part D guidance
  - Draft Prescription Drug Benefit Manual Ch. 9 defined “Subcontractor”, but final Ch. 9 deleted definition and used “downstream entity” throughout

- Who gets Part D Flowdowns?
  - Every downstream entity?
  - If not all, which ones?
- Managed Care Manual, Ch. 11, § 100.5 (<http://www.cms.hhs.gov/manuals/downloads/mc86c11.pdf>) “core functions” analysis: “contract administration and management, marketing, utilization management, quality assurance, applications processing, enrollment and disenrollment functions, claims processing, adjudicating Medicare organization determinations, appeals and grievances, and credentialing...”
- Non-core functions, e.g., IT hardware and software, office, supplies, furniture, facilities, etc., excluded

- Source of Flowdowns – No one location
  - Regulations
  - Application
    - Attestations
    - Appendix V Certification
    - Appendix VI Crosswalk
  - Call Letter
  - Contract

- Regulatory Flowdowns 42 CFR § 423.505(i)
  - (2)(i) Audit rights
  - (2)(ii) Document retention
  - (3)(i) Enrollee protections
  - (3)(ii) Accountability for delegations
  - (3)(iii) Compliance with PDP contract requirements
  - (4)(i) Written delegations and reporting
  - (4)(ii) Remedies for unsatisfactory performance
  - (4)(iii) Compliance with all applicable Federal laws, regulations and CMS instructions
  - (5) PDP sponsor's right to approve, disapprove, or terminate delegated selection of providers

- Regulatory Flowdowns - continued
  - 42 CFR § 423.505(j) – Any other terms CMS finds “necessary and appropriate”
  - 42 CFR § 423.505(k) – Certification of Claims Data
    - “if the claims data are generated by a ...subcontractor...subcontractor must similarly certify (based on best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.”

- Part D Application

([http://www.cms.hhs.gov/PrescriptionDrugCovContra/04/RxContracting\\_ApplicationGuidance.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovContra/04/RxContracting_ApplicationGuidance.asp#TopOfPage) )

- Attestations, e.g., 3.1.5. Business Integrity

“A.1. Applicant...or subcontractors and subcontractor staff agree that they are bound by 46 CFR Part 76 and attest that they are not excluded....”

- Appendix V – “Certification by Prescription Drug Plan Organization that Subcontracts Meet the Requirements of Section 3.1.2D” and include:

- A.3 - Flowdown clauses from PDP contract
- A.8 - Compliance with Federal laws, etc.
- A.9 - Compliance with Federal and State privacy and security requirements
- A.10 - Contain all 42 CFR 423.505(i) requirements

# Part D Flowdowns

- Part D Application – continued
  - Appendix VI Crosswalk

Appendix VI  
Crosswalk of Section 3.1.2D Requirements in Subcontracts submitted as Attachments to Section 3.1.2

**INSTRUCTIONS:** Applicants must complete the following chart for each subcontract submitted under Section 3.1.2D. Applicants must identify where specifically in each contract the following elements are found.

Section	Requirements	Location in Subcontract by Page number and Section
3.1.2D1	The parties to the contract.	xx
3.1.2D2	The functions to be performed by the subcontractor, as well as any reporting requirements the subcontractor has to the Applicant identified in Section 3.1.2C of the application.	xx
3.1.2D3	Language clearly indicating that the subcontractor has agreed to participate in your Medicare Prescription Drug Benefit program (except for a network pharmacy if the existing contract would allow participation in this program), and flow-down clause.	xx
3.1.2D4	Language describing the services to be performed in a manner that encompasses the services required to support the Medicare Prescription Drug Benefit program.	xx
3.1.2D5	The payment the subcontractor will receive for performance under the contract, if applicable.	xx
3.1.2D6	Are for a term of at least the one-year contract period for which application is submitted.	xx
3.1.2D7	Are signed by a representative of each party with legal authority to bind the entity.	xx
3.1.2D8	Language obligating the subcontractor to abide by all applicable Federal and State laws and regulations and CMS instructions.	xx
3.1.2D9	Language obligating the subcontractor to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for the program at 42 CFR §423.136.	xx
3.1.2D10	Language ensuring that the subcontractor will make its books and other records available in accordance with 42 CFR §423.505(i)(2), which generally states these regulations give HHS, the Comptroller General, or their designees the right to inspect.	xx
3.1.2D11	Language stating that the subcontractor will ensure that beneficiaries are not held liable for fees that are the responsibility of the Applicant.	xx
3.1.2D12	Language stating that if the Applicant, upon becoming a Part D sponsor, delegates an activity or responsibility to the subcontractor, that such activity or responsibility may be revoked if CMS or the Part D sponsor determines the subcontractor has not performed satisfactorily. The subcontract may include remedies in lieu of revocation to address this requirement.	xx
3.1.2D13	Language specifying that the Applicant, upon becoming a Part D sponsor, will monitor the performance of the subcontractor on an ongoing basis.	xx
3.1.2D14	Language that the Part D sponsor retains the right to approve, suspend, or terminate any arrangement with a pharmacy if the subcontractor will establish the pharmacy network or select pharmacies to be included in the network.	xx

- Call Letter Flowdowns
  - 2007 Part D call letter provides that contracts would require plan sponsors to submit “financial and organizational conflicts of interest reports to CMS, pursuant to instructions to be issued by CMS.”
  - No such instructions forthcoming, except that Chapter 9 (*Part D Program to Control Fraud Waste and Abuse*), § 50.2.1.2, p. 24 of the Prescription Drug Benefit Manual provides: “the Sponsor should obtain certifications from first tier entities...that these entities will require its managers, officers and directors responsible for the administration and delivery of Part D benefits to sign a conflict of interest statement, attestation, or certification at the time of hire and annually thereafter certifying that the manger, officer or director is free from any conflict of interest in administering or delivering Part D benefits.”
  - No such requirement in 2008 Combined Call Letter.

- Additional Contract Flowdowns (MA-PD Contracts, § H)
  - Program Integrity

“The MA Organization agrees to provide notice based on best knowledge, information and belief to CMS of any integrity items related to payments from government entities, both federal and state, for healthcare or prescription drug services. These items include any investigations, legal actions or matters subject to arbitration brought involving the MA Organization (or MA Organization's firm if applicable) and its subcontractors (excluding contracted network providers), including any key management or executive staff, or any major shareholder (5% or more), by a government agency (state or federal) on matters relating to payments from government entities, both federal and state, for healthcare and/or prescription drug services. In providing the notice, the sponsor shall keep the government informed of when the integrity item is initiated and when it is closed. Notice should be provided of the details concerning any resolution and monetary payments as well as any settlement agreements or corporate integrity agreements.”

- Additional Contract Flowdowns (MA-PD Contracts, § H)
  - Program Integrity - continued
    - The MA Organization agrees to provide notice based on best knowledge, information and belief to CMS in the event the MA Organization or any of its subcontractors is criminally convicted or has a civil judgment entered against it for fraudulent or is sanctioned under any Federal program involving the provision of health care or prescription drug services.