

Overview of CMS Authority for Part D Solicitations

Application Section	Authority
Management and Operations	<ul style="list-style-type: none"> • 42 CFR 423 Subpart K • 2007 Reporting Requirements
Experience and Capabilities	<ul style="list-style-type: none"> • 2007 Reporting Requirements • CMS Guidance issued via HPMS July 10, 2006
Licensure and Solvency	<ul style="list-style-type: none"> • 42 CFR 423.401 • 42 CFR 423.410 • CMS Guidance issued via HPMS September 29, 2006
Business Integrity	<ul style="list-style-type: none"> • 45 CFR Part 76
HPMS Part D Contacts	<ul style="list-style-type: none"> • CMS Guidance issued via HPMS September 9, 2006
Formulary/Pharmacy and Therapeutics Committee	<ul style="list-style-type: none"> • 42 CFR 423.120 (b) • Draft Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements • CMS Guidance issued via HPMS October 2, 2006 dated September 29, 2006 • CMS Guidance issued via HPMS December 5, 2006
Utilization Management Standards	<ul style="list-style-type: none"> • 42 CFR 423.153 (b) • Draft Prescription Drug Benefit Manual Chapter 7 – Medication Therapy Management and Quality Improvement Program
Quality Assurance and Patient Safety	<ul style="list-style-type: none"> • 42 CFR 423.153 (c) • Draft Prescription Drug Benefit Manual Chapter 7 – Medication Therapy Management and Quality Improvement Program
Medication Therapy Management	<ul style="list-style-type: none"> • 42 CFR 423.153 (d) • 2007 Reporting Requirements • Draft Prescription Drug Benefit Manual Chapter 7 – Medication Therapy Management and Quality Improvement Program • CMS Guidance issued via HPMS August 29, 2006
Electronic Prescription Program	<ul style="list-style-type: none"> • 42 CFR 423.159 • Draft Prescription Drug Benefit Manual Chapter 7 – Medication Therapy Management and Quality Improvement Program
Bids	<ul style="list-style-type: none"> • 42 CFR 423 Subpart F • CMS Guidance issued via HPMS June 1, 2006 • 2007 PDP Call Letter
Service Area/Regions	<ul style="list-style-type: none"> • 42 CFR 423.112
General Pharmacy Access	<ul style="list-style-type: none"> • 42 CFR 423.120 (a) • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections
Retail Pharmacy	<ul style="list-style-type: none"> • 42 CFR 423.120 (a) • 42 CFR 423.859 (c) • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections
Out of Network	<ul style="list-style-type: none"> • 42 CFR 423.124

Pharmacy	<ul style="list-style-type: none"> • CMS Guidance issued via HPMS May 9, 2006 dated May 8, 2006 • CMS Guidance issued via HPMS December 1, 2006 • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections
Mail Order Pharmacy	<ul style="list-style-type: none"> • 42 CFR 423.120 (a)(10) • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections
Home Infusion Pharmacy	<ul style="list-style-type: none"> • 42 CFR 423.120 (a)(4) • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections • CMS Guidance issued via HPMS March 10, 2006
Long-Term Care Pharmacy	<ul style="list-style-type: none"> • 42 CFR 423.120 (a)(5) • CMS Guidance issued via HPMS September 13, 2006 • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections
ITU Pharmacy	<ul style="list-style-type: none"> • 42 CFR 423.120 (a)(6) • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections
Specialty Pharmacy	<ul style="list-style-type: none"> • Draft Prescription Drug Benefit Manual Chapter 5 – Benefits and Beneficiary Protections • CMS Guidance issued via HPMS May 25, 2006
Enrollment and Eligibility	<ul style="list-style-type: none"> • 42 CFR 423.30 and 423.32 • Prescription Drug Benefit Manual Chapter 3 – PDP Enrollment and Disenrollment Guidance • CMS Guidance issued via HPMS July 19, 2006 • CMS Guidance issued via HPMS August 30, 2006
Complaints Tracking	<ul style="list-style-type: none"> • CMS Guidance issued via HPMS July 13, 2006 • CMS Guidance issued via HPMS November 16, 2006 • CMS Guidance issued via HPMS December 14, 2006
Medicare Prescription Drug Plan Finder	<ul style="list-style-type: none"> • CMS Guidance issued via HPMS July 17, 2006 • CMS Guidance issued via HPMS January 4, 2006
Grievances	<ul style="list-style-type: none"> • 42 CFR 423.564 • Prescription Drug Benefit Manual Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals • Part D QIC Reconsideration Procedures Manual
Exceptions and Appeals	<ul style="list-style-type: none"> • 42 CFR 423 Subpart M • Prescription Drug Benefit Manual Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals
Coordination of Benefits	<ul style="list-style-type: none"> • 42 CFR 423 Subpart J • Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits
Tracking Out-of-Pocket Costs	<ul style="list-style-type: none"> • 42 CFR 423 Subpart J • Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits
Medicare Secondary Payer	<ul style="list-style-type: none"> • 42 CFR 423.462 • Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits

Marketing/Beneficiary Communications	<ul style="list-style-type: none"> • 42 CFR 423.128 • Prescription Drug Benefit Manual Chapter 2 – Part C & D Marketing Guidelines • CMS Guidance issued via HPMS September 1, 2006 • CMS Guidance issued via HPMS September 5, 2006
Provider Communications	<ul style="list-style-type: none"> • Prescription Drug Benefit Manual Chapter 2 – Part C & D Marketing Guidelines
Compliance Plan	<ul style="list-style-type: none"> • 42 CFR 423.504(b)(4)(vi) • Prescription Drug Benefit Manual Chapter 9 – Fraud, Waste and Abuse
Reporting Requirements	<ul style="list-style-type: none"> • 42 CFR 423.514 • 2007 Reporting Requirements
Data Exchange Between Part D Sponsor and CMS	<ul style="list-style-type: none"> • 42 CFR 423.505 (c) & (k) • CMS Guidance issued via HPMS March 30, 2006 dated March 29, 2006
Upgrades of Health Information Technology	<ul style="list-style-type: none"> • 42 CFR 423.159 and 423.160
Health Insurance Portability and Accountability Act (HIPAA)	<ul style="list-style-type: none"> • 45 CFR Parts 160, 162 and 164 • CMS Guidance issued via HPMS June 9, 2006 • CMS Guidance issued via HPMS August 3, 2006
Prohibition on Use of SSN or Medicare ID number on Enrollee ID Cards	<ul style="list-style-type: none"> • Prescription Drug Benefit Manual Chapter 2 – Part C & D Marketing Guidelines
Record Retention	<ul style="list-style-type: none"> • 42 CFR 423.505 (d)
Claims Processing	<ul style="list-style-type: none"> • CMS Guidance issued May 22, 2006