CMS Compliance Guide

A Complete Guide to Medicare Advantage, Part D, and Medicaid Managed Care Compliance

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1. Introduction to CMS Compliance

The Centers for Medicare & Medicaid Services (CMS) establishes and enforces regulations that govern how health plans and healthcare organizations deliver care to Medicare and Medicaid beneficiaries. Compliance with these regulations is not optional - it is a fundamental requirement for participation in federal healthcare programs.

This guide provides a comprehensive overview of the key compliance requirements for organizations participating in Medicare Advantage (Part C), Medicare Part D, and Medicaid managed care programs. Whether you are establishing a new compliance program or strengthening an existing one, this resource will help you understand your obligations and implement effective compliance strategies.

Why CMS Compliance Matters

- Protects beneficiaries by ensuring access to quality care and accurate information
- Reduces organizational risk of sanctions, civil monetary penalties (CMPs), and enrollment freezes
- Maintains eligibility for federal healthcare program participation
- Supports operational excellence and efficient care delivery
- Builds trust with regulators, providers, and members

Regulatory Framework

CMS compliance requirements are derived from multiple sources, including the Social Security Act, Code of Federal Regulations (42 CFR Parts 422, 423, and 438), annual Call Letters, Health Plan Management System (HPMS) memoranda, and sub-regulatory guidance. Organizations must monitor all of these sources for updates and changes that affect their operations.

2. Medicare Advantage (Part C) Requirements

Medicare Advantage organizations (MAOs) must comply with extensive requirements covering every aspect of plan operations, from marketing and enrollment to claims processing and quality improvement.

Benefit Design and Actuarial Requirements

- Annual bid submission and benefit package filing with CMS
- Actuarial equivalence to Original Medicare benefits
- Supplemental benefit offerings within regulatory guidelines
- Cost-sharing limits and out-of-pocket maximum compliance
- Mid-year benefit change restrictions

Network Adequacy

MAOs must maintain provider networks that meet CMS time and distance standards. This includes ensuring adequate access to primary care, specialists, hospitals, and other facility types based on the plan's service area.

- Time and distance standards by county type (large metro, metro, micro, rural, CEAC)
- Minimum provider-to-enrollee ratios for key specialties
- Written standards for timeliness of access to care
- Annual Health Service Delivery (HSD) table submissions
- Network change notification requirements

Marketing and Communications

- CMS review and approval of marketing materials via HPMS
- Prohibited marketing practices (unsolicited contacts, misleading statements)
- Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) distribution
- Translation and accessibility requirements for Limited English Proficiency (LEP) populations
- Third-party marketing organization (TPMO) oversight

Coverage Determinations and Appeals

MAOs must process organization determinations, reconsiderations, and appeals within strict CMS timeframes and provide proper notice to enrollees.

- Standard decisions: 14 calendar days (72 hours for expedited)
- Payment decisions: 60 calendar days
- Reconsiderations: 30 calendar days (72 hours for expedited)
- Proper written notice with appeal rights information
- Auto-forwarding to Independent Review Entity (IRE) for upheld denials

Quality Improvement

- Quality Improvement Program (QIP) with measurable goals
- Chronic Care Improvement Programs (CCIPs)
- HEDIS measure reporting and Stars Rating performance
- Health Risk Assessments (HRAs) for new enrollees
- Care coordination and transitions of care programs

3. Medicare Part D Compliance

Part D sponsors must comply with specific requirements governing prescription drug benefits, including formulary management, pharmacy network access, coverage determinations, and medication therapy management programs.

Formulary Requirements

- CMS formulary review and approval through the Formulary Reference File
- Minimum two drugs per USP therapeutic category and class
- All or substantially all drugs in six protected classes
- Formulary change notification requirements (60-day written notice)
- Transition supply policies for new enrollees and formulary changes
- Prior authorization, step therapy, and quantity limit criteria

Pharmacy Network Standards

- Convenient access standards (urban: within 1 mile, suburban: within 5 miles, rural: within 15 miles)
- Any Willing Pharmacy provisions
- Mail-order pharmacy options
- Long-term care pharmacy access
- I/T/U (Indian Health Service) pharmacy access

Coverage Determinations

Part D coverage determinations and exception requests must be processed within CMS timeframes:

- Standard: 72 hours from receipt
- Expedited: 24 hours from receipt
- Redeterminations: 7 calendar days (72 hours expedited)
- Effectuation within 72 hours of favorable decision
- Auto-forwarding to IRE for upheld coverage denials

Medication Therapy Management (MTM)

Part D sponsors must offer MTM programs to targeted beneficiaries that include:

- Comprehensive Medication Reviews (CMRs) annually

- Targeted Medication Reviews (TMRs) quarterly
- Written summaries of CMR findings (e.g., MAP - Medication Action Plan)
- Prescriber and pharmacist interventions
- Enrollment targeting based on CMS criteria (multiple chronic conditions, multiple Part D drugs, likely exceeding cost threshold)

Fraud, Waste, and Abuse (FWA)

- Prescription Drug Event (PDE) data accuracy and timely submission
- Pharmacy audit programs (desk and on-site)
- Prescriber validation and verification
- Monitoring for aberrant prescribing or dispensing patterns
- Coordination with CMS and OIG investigations

4. Medicaid Managed Care Regulations

Medicaid managed care organizations (MCOs) must comply with federal regulations under 42 CFR Part 438 as well as state-specific contract requirements. The 2016 Managed Care Final Rule significantly expanded federal oversight of Medicaid managed care programs.

Key Federal Requirements (42 CFR 438)

- Actuarial soundness of capitation rates (438.4)
- Network adequacy standards (438.68)
- Access to services and timely access standards (438.206)
- Grievance and appeal system requirements (438.400-438.424)
- Quality Assessment and Performance Improvement (QAPI) programs (438.330)
- External Quality Review Organization (EQRO) participation
- Program integrity and FWA requirements (438.600-438.610)

Enrollee Rights and Protections

- Freedom of choice among network providers
- Access to out-of-network providers when network is insufficient
- Second opinion rights
- Advance directive information
- Continued services during appeal and transition periods
- Cultural competency and language access requirements

State-Specific Considerations

While federal regulations establish minimum standards, state Medicaid agencies often impose additional requirements through managed care contracts. Organizations must understand and comply with both levels of regulation. Key state-specific areas include:

- Performance measure requirements and quality incentive programs
- Encounter data submission specifications and timelines
- Provider credentialing and re-credentialing standards
- Utilization management program requirements
- Population health management expectations
- Value-based payment arrangements

5. Key Compliance Program Elements

CMS requires Medicare Advantage and Part D sponsors to maintain comprehensive compliance programs that include seven core elements, as outlined in Chapter 9 of the Medicare Managed Care Manual and Chapter 21 of the Prescription Drug Benefit Manual.

Element 1: Written Policies and Procedures

Organizations must maintain written compliance policies and procedures that address all regulatory requirements, are regularly updated, and are accessible to all workforce members. Policies should cover standards of conduct, regulatory requirements, and operational processes.

Element 2: Compliance Officer and Committee

A designated Compliance Officer must report directly to the CEO and the Board of Directors. The Compliance Officer must not be subordinate to the General Counsel or CFO and must have sufficient authority, resources, and access to information to fulfill their responsibilities.

Element 3: Training and Education

- General compliance training for all employees, contractors, and governing body within 90 days of hire
- Annual refresher training for all workforce members
- Specialized FWA training based on role and responsibilities
- Training completion tracking and documentation

Element 4: Effective Communication

- Open lines of communication between compliance staff and workforce
- Reporting mechanisms (hotline, email, web portal) for compliance concerns
- Non-retaliation/non-intimidation policies for reporters
- Regular compliance communications and updates to workforce

Element 5: Internal Monitoring and Auditing

Organizations must conduct regular internal monitoring and auditing to identify compliance risks, detect potential violations, and verify effectiveness of controls.

- Annual compliance audit work plan based on risk assessment

- Ongoing operational monitoring activities
- First Tier, Downstream, and Related Entity (FDR) oversight and auditing
- Corrective action tracking and effectiveness verification

Element 6: Enforcement and Discipline

- Consistent enforcement of compliance standards across all levels
- Fair and equitable disciplinary guidelines for violations
- OIG/GSA exclusion list screening (monthly for new hires, monthly ongoing)
- Documentation of all compliance investigations and outcomes

Element 7: Corrective Action Procedures

- Prompt response to identified compliance issues
- Root cause analysis for significant violations
- Corrective Action Plans (CAPs) with measurable milestones
- Effectiveness monitoring and sustainment verification
- Self-reporting to CMS when required

6. CMS Audits and Enforcement

Types of CMS Audits

CMS conducts multiple types of audits and reviews:

- Program Audits: Comprehensive review of plan operations across multiple areas
- Financial Audits: Review of bid submissions and financial reporting
- RADV (Risk Adjustment Data Validation): Verifies accuracy of diagnosis coding
- Performance Audits: Focused on specific operational areas (e.g., ODAG, Part D)
- Secret Shopper Surveys: Unannounced calls to test member service accuracy

Common Audit Focus Areas

- Coverage determinations and appeals timeliness and accuracy
- Grievance handling and resolution
- Provider directory accuracy
- Claims processing timeliness and accuracy
- Formulary administration and transition processes
- Marketing material compliance
- Compliance program effectiveness

Enforcement Actions

CMS has a range of enforcement tools available when organizations fail to meet compliance requirements:

- Warning Letters and Notices of Non-Compliance
- Corrective Action Plans (CAPs) with mandatory reporting
- Civil Monetary Penalties (CMPs) up to $100,000+ per violation
- Enrollment and Marketing Sanctions (suspension of enrollment)
- Intermediate Sanctions
- Contract Non-Renewal or Termination

Key Insight: In CY2024, CMS imposed over $50 million in CMPs against Medicare Advantage and Part D organizations. The most common violations involved untimely coverage determinations, failure to provide required notices, and inaccurate provider directories.

7. Annual Compliance Calendar

Maintaining an annual compliance calendar helps organizations stay ahead of key deadlines and regulatory submissions. Below are major milestones for Medicare Advantage and Part D organizations.

Q1: January - March

- Annual compliance training completion (within 90 days of plan year start)
- Annual ANOC/EOC mailing verification and documentation
- OIG/GSA exclusion list screening (ongoing monthly)
- Q4 prior year compliance program effectiveness assessment
- Annual risk assessment update and audit work plan development

Q2: April - June

- Bid preparation and actuarial analysis for upcoming plan year
- HEDIS data collection and submission (June deadline)
- Provider directory accuracy validation
- Network adequacy assessment and gap analysis
- FDR compliance oversight reviews

Q3: July - September

- Bid submission to CMS (first Monday in June - approval in August/September)
- Annual marketing material development and CMS submission for review
- Formulary updates and transition planning
- Readiness review preparation for new contract year
- Annual compliance program description update

Q4: October - December

- Annual Enrollment Period (AEP) - October 15 through December 7
- Annual compliance training delivery for upcoming year
- ANOC/EOC distribution (by September 30)
- Provider network updates and credentialing for new year
- Year-end compliance program reporting to Board

8. Common Compliance Pitfalls

Based on CMS audit findings and enforcement actions, the following areas consistently present compliance challenges for health plans:

Coverage Determinations and Appeals

- Failing to meet processing timeframes (most common CMP basis)
- Inadequate denial notices lacking specific clinical rationale
- Not auto-forwarding unfavorable reconsiderations to the IRE
- Applying incorrect urgency classification for expedited requests
- Failing to effectuate favorable decisions within required timeframes

Provider Directory Accuracy

- Listing providers who are no longer accepting new patients
- Incorrect office addresses, phone numbers, or specialties
- Failure to update online directories within required timeframes
- Not removing terminated providers promptly

FDR Oversight

- Insufficient monitoring of delegated entity performance
- Lack of FDR compliance training verification
- Missing or incomplete delegation agreements
- Failure to conduct downstream entity audits

Data Integrity

- Inaccurate encounter data or PDE submissions
- Risk adjustment coding errors
- Incomplete or untimely reporting to CMS
- Provider credentialing data gaps

9. Building a Culture of Compliance

Effective compliance programs go beyond meeting minimum regulatory requirements. Organizations that build a true culture of compliance experience fewer violations, better audit outcomes, and stronger operational performance.

Leadership Commitment

- Board and C-suite actively engaged in compliance oversight
- Compliance officer has direct access to CEO and Board
- Adequate resources allocated to compliance function
- Tone from the top emphasizes ethical behavior and regulatory adherence

Employee Engagement

- Compliance training that is relevant, practical, and engaging
- Clear expectations communicated at all levels
- Recognition for compliance achievements and proactive reporting
- Safe environment for raising concerns without fear of retaliation

Continuous Improvement

- Regular assessment of compliance program effectiveness
- Benchmarking against industry best practices
- Lessons learned from audit findings and industry enforcement trends
- Proactive monitoring of regulatory changes and emerging requirements
- Investment in compliance technology and automation

Best Practice: Organizations with the strongest compliance cultures conduct regular "compliance health checks" - structured self-assessments that evaluate program maturity across all seven elements and identify opportunities for improvement before regulators do.

10. Resources and Next Steps

Key CMS Resources

- CMS.gov - Medicare Managed Care Manual (Chapters 2-21)
- CMS.gov - Prescription Drug Benefit Manual
- CMS HPMS (Health Plan Management System) memoranda
- Annual Call Letter and Rate Announcements
- Medicare Communications and Marketing Guidelines (MCMG)
- 42 CFR Parts 422, 423, and 438

Industry Resources

- Health Care Compliance Association (HCCA)
- National Committee for Quality Assurance (NCQA)
- AHIP (America's Health Insurance Plans)
- OIG Work Plan and Special Fraud Alerts
- State Medicaid agency websites and managed care contracts

How Ginete Can Help

Ginete Healthcare Consulting Group provides comprehensive compliance support for health plans and healthcare organizations, including:

- Compliance program assessments and gap analyses
- CMS audit preparation and mock audits
- Policy and procedure development and review
- FDR oversight program design and implementation
- Corrective Action Plan development and monitoring
- Compliance training program development
- Regulatory change management and impact analysis

Ready to strengthen your compliance program? Contact Ginete Healthcare Consulting Group:
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