Developing an Effective Medicare Part D Compliance Program

HCCA Part D Compliance Conference
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What is Kaiser Permanente?

Founded in 1945, Kaiser Permanente is the nation’s largest integrated delivery system, serving over 8.5 million members in nine states and the District of Columbia. Kaiser Permanente serves almost 800,000 Medicare beneficiaries, almost 700,000 of whom live in California.

- More than 149,000 employees
- Nearly 13,000 physicians
- 34.6 million outpatient encounters annually
- More than 85,000 babies delivered annually
- Nearly 113 million prescriptions filled annually
- More than 450,000 surgeries performed annually
An Integrated Health Care Delivery System

HEALTH PLAN MEMBERS

KAISER FOUNDATION HEALTH PLAN

KAISER FOUNDATION HOSPITALS

PERMANENTE MEDICAL GROUPS

HOSPITAL SERVICES

MEDICAL SERVICES
Northern California

Type of Coverage
- 85.3% Commercial
- 13.0% Medicare
- 1.7% Medi-Cal

Ethnicity
- 59.4% Caucasian
- 14.6% Hispanic
- 13.3% Asian
- 5.6% African American
- 7.1% Other
Southern California

Type of Coverage

- 86% Commercial
- 10.1% Medicare
- 1.7% Medi-Cal
- 2.2% Special Programs
- 10.1% Medicare
- 2.2% Special Programs
- 1.7% Medi-Cal
- 86% Commercial

Ethnicity

- 52% Caucasian
- 7.8% Asian
- 25.7% Hispanic
- 10% African American
- 4.5% Other
- 52% Caucasian
- 25.7% Hispanic
- 10% African American
- 7.8% Asian
- 4.5% Other
Part D and Compliance Program Standards

As Implemented at Kaiser Permanente
Part D and Compliance Program Standards

- Regulatory requirements under 42 CFR § 423.504
- Prescription Drug Benefit Manual Chapter 9: Program to Control Fraud, Waste and Abuse
- May 25, 2007 proposed regulations at 72 Fed. Reg. 29368 (if finalized will take effect January 1, 2009)
- The Federal Sentencing Guidelines Chapter 8 § 8B2.1: Remedying Harm from Criminal Conduct, and Effective Compliance and Ethics Program
- The OIG “Seven Elements” – Compliance Program Guidance for Medicare+Choice Organizations at 64 Fed. Reg. 61893
Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents. It is updated daily by 6 a.m. and is published Monday through Friday, except Federal holidays.

http://www.gpoaccess.gov/fr/index.html

The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to Federal regulation. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis.

http://www.gpoaccess.gov/cfr/index.html
The Prescription Drug Benefit Manual (PDBM) is CMS’s guidance around the final rule for Part D. PDBM chapters address marketing; enrollment and disenrollment; benefits; drug and formulary requirements; grievances; quality improvement; fraud, waste and abuse and more.

Chapter 9 of the PDBM provides both interpretive rules and guidelines for Part D plan sponsors on how to implement the regulatory requirements under 42 CFR § 423.50(b)(4)(vi)(H) to have in place a comprehensive fraud and abuse plan to detect, correct and prevent fraud, waste and abuse as an element of their compliance plan.
■ Training – Specific requirements for downstream entity-level specialized training requirements
■ Self Reporting – Mandatory self-reporting of potential fraud and misconduct
■ Access to Books and Records – CMS will have access to books and records of Part D Plans’ business partners
OIG Compliance Program Guidance – The “Seven Elements”

1. Standards of Conduct/Policies and Procedures
2. Compliance Officer and Compliance Committee
3. Education and Training
4. Monitoring and Auditing
5. Reporting and Investigating
6. Enforcement and Discipline
7. Response and Prevention
The OIG’s “Seven Elements”
1. Standards of Conduct/Policies and Procedures

■ Code of Conduct
  - Standards of conduct for all affected employees that include a clear commitment to compliance by the organization’s senior leaders

■ Written Policies for Risk Areas
  - Marketing materials and personnel* †
  - The election process, enrollments* and disenrollments* †
  - Data collection and submission processes †
  - Benefits and beneficiary protections
  - Quality of care*
  - Cost sharing
  - Licensure
  - Claims processing †
  - Appeals and grievance procedures †

* OIG areas of “particular concern”
† Areas of recent heightened CMS scrutiny
Our Principles

Welcome to KP’s Principles of Responsibility 2007

Kaiser Permanente’s reputation, one of our most vital assets, depends on the ethical conduct of every person in the organization. The Principles of Responsibility (POR), the Kaiser Permanente code of conduct, serves as a guide for our daily decisions and actions, from how we take care of our members and patients to how we work with each other and our purchasers and vendors.

On this site you will find the Principles of Responsibility listed by each chapter, as well as available for downloading and printing. Other resources also are available, including Frequently Asked Questions about the POR, fact sheets that focus on many of the key issues faced daily in the workplace, and translations of some key POR resources, provided as a courtesy.

Taking the Principles of Responsibility to heart and applying them in your daily work life are essential to preserving the trust our stakeholders place in us, and the trust we place in each other.

The Principles of Responsibility document was updated under the direction of KP’s National Compliance, Ethics & Integrity Office, led by
Policies

Finding a Compliance Policy

All Compliance policies are located in the **KP Policy Library**.

To find a policy:

- Click on the **Policy Library tab** at the top of the page.
- Select national in the Region drop down menu in the upper left corner of the page.
- On the **Main tab**, click on the Category and Sub-category you want. A list of policy titles appears.
- For Example: **Compliance, Ethics and Integrity** (Category)
  - **Fraud, Waste, & Abuse** (Sub-category)
    - **National Fraud, Waste and Abuse Control NATL NOCO 11** (Sub-category)
- Click on the title of the policy you want to read, it may take a minute to load. A PDF copy of the policy is listed under the supporting documents section toward the bottom of each policy page.

If you don't know the category of the policy you are seeking, type a couple of keywords in the Search field on the upper right corner of the **KP Policy Library** page and click Search. A list of policies and a summary of each will appear in alphabetical order.
The OIG’s “Seven Elements”
2. Compliance Officer and Compliance Committee

- **Compliance Officer**
  - Should be a high level official within the organization
  - Ideally reports directly to the Board of Directors (BOD)
  - OIG does not recommend Compliance Officer report to Legal Counsel or Chief Financial Officer

- **Part D Compliance Officer**
  - CMS recommends Part D program sponsors dedicate a full-time employee to oversee the compliance program for Part D
  - Should report at least quarterly to the Compliance Officer, BOD, President/CEO and Compliance Committee on the status of the Part D compliance program implementation
  - Should ensure first tier entities and downstream entities and related entities are aware of and follow the requirements for Part D
  - Ensure the organization responds to reports of potential Part D fraud, waste and abuse
Compliance Committee

- Benefits from having perspectives of individuals with varying responsibilities in the organization, e.g., operations, finance, audit, human resources, utilization management, medicine, claims processing, information systems, legal, marketing, enrollment/disenrollment

Part D Compliance Committee

- Can operate within the structure of the existing compliance committee
- Should include people with varying but relevant backgrounds and reflect the size of the organization, e.g., pharmacists, registered nurses, pharmacy technicians, legal, auditors, information technology experts
- Must meet at least quarterly
- Must provide regular and ad hoc reports to the BOD
Risk Assessment

- **Information Feeding Risk Assessments – Internal**
  - Grievance and appeals data
  - CTM complaints
  - Performance monitoring/auditing
  - Hotline investigations

- **Information Feeding Risk Assessments – External**
  - Annual OIG Work Plan
  - CMS issuances (Annual Call Letter, HPMS and other CMS Program Memos, Part D Audit Guide, Chapter 9, etc.)
  - OIG guidance and enforcement actions
  - External audit findings
  - The Media
Medicare Audits Show Problems in Private Plans

By ROBERT PEAR
Published: October 7, 2007

WASHINGTON, Oct. 6 — Tens of thousands of Medicare recipients have been victims of deceptive sales tactics and had claims improperly denied by private insurers that run the system's huge new drug benefit program and offer other private insurance options encouraged by the Bush administration, a review of scores of federal audits has found.

The problems, described in 91 audit reports reviewed by The New York Times, include the improper termination of coverage for people with H.I.V. and AIDS, huge backlogs of claims and complaints, and a failure to answer telephone calls from consumers, doctors and
3. Education and Training

- **General Sessions**
  - Annual training emphasizing the organization’s commitment to compliance; should include a message about the importance of complying with fraud and abuse laws

- **Specialized Training**
  - Training for individuals working in areas identified as risk areas
    - Marketing
    - Enrollment/Disenrollment
    - Appeals and Grievances

- **Part D Specialized Training**
  - Required for employees and downstream entity staff involved with the program sponsor’s Part D activities
    - Sponsors may require downstream entities to have their own specialized compliance training, or where there are sufficient organizational similarities the Sponsor may choose to make its training available to the downstream entities
Kaiser Permanente Specialized Training Curriculum Model

Level 1
Introduction and Overview

Level 2
Specific Compliance Standards

Level 3
Operational Job Training

Level 4
Focus – (“Remediation”) Training
Introduction to Medicare

Click here to begin the course.
Overview

Medicare Part D: Marketing

The voluntary prescription drug benefit, known as Part D, became available to Medicare beneficiaries on January 1, 2006. This benefit is available through private at-risk prescription drug plans offering drug-only coverage or Medicare Advantage plans offering integrated prescription drug and healthcare coverage. Together these plans are referred to as Part D sponsors. Part D sponsors were authorized to begin marketing to beneficiaries on October 1, 2005. The CMS Marketing Guidelines are available to assist sponsors in all marketing activities. These Guidelines set forth very precise requirements for marketing activities.

After completing this course, you will be able to identify the marketing materials that are regulated by the Centers for Medicare and Medicaid Services (CMS), the information that must be included in the materials, and how the CMS approval process works. You will also be able to identify what role providers
Part D Sponsors should develop a monitoring and auditing work plan that addresses the risks associated with the Part D benefit. The work plan should include:

- Risk assessment
- Audit schedule and methodology

The monitoring system should include a mechanism to ensure the Part D Compliance Officer and Committee receive regular reports on performance, and updates on issues such as systems and staffing.

The Part D Compliance Officer should provide updates on the monitoring results to the Compliance Committee and senior leadership.

Part D Sponsors are responsible for the monitoring and auditing of downstream entities.

- PBM oversight is critical
Our Program

Medicare Performance Monitoring Program

A Medicare Performance Monitoring Program for all Kaiser Permanente regions is being implemented as required by the Office of Inspector General (OIG) for Medicare participating programs.

What is the Medicare Performance Monitoring Program?

A Medicare Performance Monitoring Program is rolling out throughout the organization to ensure KP is meeting Medicare’s regulatory requirements. All Kaiser Permanente functional areas with responsibilities related to Part C and Part D, will implement metrics based on Centers for Medicare and Medicaid Services (CMS) audit guidelines that can be measured and tracked on an ongoing basis.

The Program requires designated functional areas to periodically assess their compliance with particular Medicare requirements. The results of those assessments are entered into metrics within a common software platform called ActiveStrategy, are approved by assigned individuals, and are then available for certain compliance and operations personnel to monitor.

This work helps KP track Medicare metrics in real-time to fix any internal deficiencies early on rather than waiting for findings CMS identifies in its audits.

What are some of the functional areas impacted?
5. Reporting and Investigating

- Part D Sponsors should have a system in place to receive, record and respond to compliance questions or reports of potential non-compliance (e.g. hotlines or mail drops)
- Part D Sponsors are responsible for “effective lines of communication” at the downstream entity level
- Part D Sponsors should develop prompt follow-up investigation procedures
  - Must allow anonymity
  - Must ensure non- retaliation against callers
Kaiser Permanente Hotline

A phone call has more power than you think.

CALL THE COMPLIANCE HOTLINE: 1(888) 774-9100

For more information, see your Principles of Responsibility booklet, or visit www.kp.org/compliance

ANONYMOUS. AVAILABLE 24/7.
TRAINED PROFESSIONALS.
TOLL-FREE.
FOLLOW YOUR NOSE.

PREVENT FRAUD, WASTE & ABUSE

Talk to your manager/supervisor, compliance officer, or HR representative, or CALL THE COMPLIANCE HOTLINE 1-888-774-9100

MEMBERS AND PATIENTS SHOULD CALL MEMBER SERVICES IF YOU HAVE CONCERNS.

For more information see your Principles of Responsibility booklet or visit kp.org/compliance

COMPLIANCE. THAT'S RIGHT!
Prevent Fraud, Waste & Abuse

WE SHOULD be as careful with our resources as we are with the care we give.
Make good decisions about purchasing and using medical equipment, office supplies, and vendor services, and follow all Kaiser Permanente policies and procedures. We can all help prevent fraud, waste, and abuse. Every roll counts!

IT ADDS UP.

PREVENT FRAUD, WASTE & ABUSE

Talk to your manager/supervisor, compliance officer, or HR representative, or
CALL THE COMPLIANCE HOTLINE
1-888-774-9100

MEMBERS AND PATIENTS SHOULD CALL MEMBER SERVICES IF YOU HAVE CONCERNS
For more information see your Principles of Responsibility booklet or visit kp.org/compliance

COMPLIANCE. THAT'S RIGHT!
Follow Scope of Practice Rules

WE ALL HAVE A JOB TO DO.

FOLLOW SCOPE OF PRACTICE RULES

Talk to your manager/supervisor, compliance officer, or HR representative, or CALL THE COMPLIANCE HOTLINE

1-888-774-9100

MEMBERS AND PATIENTS SHOULD CALL MEMBER SERVICES IF YOU HAVE CONCERNS

For more information see your Principles of Responsibility booklet or visit kp.org/compliance

COMPLIANCE. THAT'S RIGHT!
To help communicate a strong organizational commitment to compliance, the CEO, COO, General Counsel, Compliance Officer and other senior officials should be involved in the development of the standards of conduct.

The Part D Sponsor must enforce standards through well-publicized disciplinary guidelines:
- Job descriptions
- Progressive disciplinary P&Ps

All employees should be informed the violation of standards may result in disciplinary action, up to and including termination.
The OIG’s “Seven Elements”
7. Response and Prevention

- The OIG encourages self-reporting
- Although self-reporting is voluntary, CMS has emphasized its importance
  - Part D Sponsors should report fraud; especially when it is alleged or confirmed at the downstream entity level
  - Kaiser Permanente has put into place a Special Investigations Unit – a dedicated task force – to conduct special investigations into suspected and/or alleged prescription drug fraud, waste and abuse
- Plans should develop corrective action plans emphasizing remediation training and ongoing monitoring
- Plans should document progressive disciplinary action
Any suspected fraud, waste or abuse cases should be referred to the Medicare Drug Integrity Contractor (MEDIC)

Cases that should be referred include:

- Potential criminal, civil or administrative law violations
- Allegations extending beyond the MAPD/PDP involving multiple health plans, multiple states or widespread schemes
- Allegations involving known patterns of fraud that may have already come to the attention of law enforcement
- Patterns of fraud or abuse threatening the life or wellbeing of beneficiaries
- Schemes posing a large financial risk to Medicare or Medicare beneficiaries
CMS Partial Audit of Kaiser Permanente’s California Regions’ Part D Program

Part D Elements Audited
Chapter 2 (Provider Communication): Element PC02

Provision of Notice Regarding Formulary Changes

The Part D sponsor must provide at least 60 days notice to all authorized prescribers, network pharmacies, and pharmacists prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to all authorized prescribers, network pharmacies, and pharmacists.

42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d)

Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
Chapter 3 (Marketing and Beneficiary Information): Element MR06

Plan Responsibility for Persons Employed or Contracted to Perform Marketing

The Part D sponsor must have a compensation structure that meets CMS requirements for any person directly employed or contracted to market the plan. The Part D sponsor must utilize only state licensed, certified, or registered individuals to perform marketing on behalf of the Part D sponsor, whether as an employee or under contract directly or downstream, if a state has such a marketing requirement, and it must conduct monitoring activities to ensure that individuals marketing on behalf of the Part D sponsor comply with all applicable Part D laws, all other Federal health care laws, and CMS policies, including CMS marketing guidelines, to ensure that beneficiaries receive truthful and accurate information.

Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
Chapter 3 (Marketing and Beneficiary Information): Element MR09

Provision of Notices Regarding Formulary Changes
Prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug, the Part D sponsor must provide a written notice to affected enrollees at least 60 days prior to the date the change becomes effective, or provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed, and written notice of the formulary change at the time an affected enrollee requests a refill of the Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to the affected enrollees.

42 CFR § 423.120(b)(5)(i-iii); § 423.120(b)(7); § 423.578(d)
Medicare Marketing Guidelines for MAs, MA-PDs, PDPs, and 1876 Cost Plans
Chapter 6 (Pharmacy Access): Element PH03

Access to Long-Term Care Pharmacies
The Part D sponsor must offer standard contracting terms and conditions, including performance and service criteria, to all long-term care (LTC) pharmacies in its Part D plan service area. The Part D sponsor must contract with a sufficient number of LTC pharmacies to provide all of its plans’ institutionalized enrollees convenient access to their Part D benefits.

42 CFR § 423.120(a)(5)
MA-PD Solicitation
Long Term Care Guidance
Chapter 7 (Formulary, Transition Process, and Pharmacy & Therapeutics Committee Formulary): Element FM03

Provision of Notice Regarding Formulary Changes
The Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (SPAPs), and entities providing other prescription drug coverage prior to removing a covered Part D drug from its formulary or making any changes to the preferred or tiered cost-sharing status of a covered Part D drug. If the change involves immediate removal of a Part D drug deemed unsafe by the Food and Drug Administration (FDA) or removed from the market by the manufacturer, the Part D sponsor must provide retrospective notice to the parties listed above.

42 CFR § 423.120(b)(5)(i); § 423.120(b)(5)(iii); § 423.578(d)
Medicare Marketing Guidelines for MA, MA-PDs, PDPs, and 1876 Cost Plans
Chapter 7 (Formulary, Transition Process, and Pharmacy & Therapeutics Committee Formulary): Element TP02

Transition Process for Residents of Long-Term Care Facilities
The Part D sponsor must have and implement an appropriate transition process in accordance with CMS requirements for addressing the unique needs of long-term care (LTC) facility residents prescribed Part D drugs that are not on its formulary or that are on its formulary but require prior authorization or step therapy.

42 CFR § 423.120(b)(3)
MA-PD Solicitation
*Information for Part D Sponsors on Requirements for a Transition Process*
*Transition Process Requirements for Part D Sponsors*
Chapter 11 (First-Tier and Downstream Contracts / Maintenance of Records): Element CN05

Required Contract Provisions: Long-Term Care Pharmacies
The Part D sponsor’s written contracts with network long-term care pharmacies must include the CMS-specified performance and service criteria for long-term care pharmacies.

42 CFR § 423.120(a)(5)
MA-PD Solicitation
Long Term Care Guidance
Chapter 13 (Grievances, Coverage Determinations, and Appeals):
All Elements

42 CFR § 423