

Part D Marketing Guideline Training Conference
Centers for Medicare & Medicaid Services (CMS) Speakers
CMS Headquarters, Baltimore, Maryland
June 3rd, 2005 (8:00am – 4:00pm)

Leslie V. Norwalk, Esq., is the Deputy Administrator for the Centers for Medicare & Medicaid Services (CMS). In this role she directs the complex and demanding task of implementing the hundreds of changes to be made under the Medicare Modernization Act. Ms. Norwalk continues to direct the day-to-day operations of Medicare, Medicaid, Child Health Insurance Programs, Survey and Certification of health care facilities and other federal health care initiatives, such as physician referral regulations, HIPAA and EMTALA. Prior to serving the Bush Administration, she practiced law in the Washington, D.C. office of Epstein Becker & Green, P.C. where she advised clients on a variety of health policy matters. She also served in the first Bush administration in the White House Office of Presidential Personnel. Ms. Norwalk, a native of Dayton, OH, earned a juris doctor degree from the George Mason University School of Law, where she was a Dean's Scholar and an editor of the *George Mason Law Review*. She earned a bachelor's degree, *cum laude*, in economics and international relations from Wellesley College.

Bob Donnelly is the director of the Medicare Drug Benefit Group in the Center for Beneficiary Choices at CMS. In this position, Mr. Donnelly has responsibility for the operational implementation of the Part D drug benefit. Prior to this position, Mr. Donnelly served as the Director of CMS's Health Plan Policy Group for 3 years, overseeing policies related to the Medicare Prescription Drug Benefit and Medicare Advantage (MA), as well as enrollment, appeals, and consumer protections for Part D, MA, and fee-for-service Medicare. Before becoming the group director, Mr. Donnelly was the director of the Division of Program Policy, dealing with Medicare+Choice benefit and payment policy. Prior to coming to CMS, Mr. Donnelly spent five years as a program examiner at the Office of Management and Budget, working primarily on Medicare and health reform issues. Mr. Donnelly has a master's degree in Public Policy from the University of Michigan.

Teresa DeCaro, R.N., M.S., is currently the Director of Drug Benefit Purchasing in the Center for Beneficiary Choices within the Centers for Medicare & Medicaid Services (CMS). Prior to that she was a senior policy advisor to the Director of the Center, and in that role she was a cross-agency team leader on the policy development and implementation of the Medicare prescription drug discount card program. Other policy areas on which she has previously advised include coverage and payment for new technology, value based purchasing and Medicare fee-for-service modernization, including under the previous administration she was the agency's co-lead on the Medicare fee-for-service components of the Clinton Health Care Reform Plan. Prior to that, as a senior research analyst she designed and conducted research studies and demonstrations of alternative payment and service delivery systems for the Medicare program. She began her career in health policy in 1990, at the Physician Payment Review Commission developing policy recommendations for the Medicare physician fee schedule. Throughout the 1980s she was a critical care staff nurse and manager in a variety of hospitals throughout the Washington-Baltimore area.

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Kim Caldwell, R.Ph., is the Division Director for Clinical and Economic Performance in the Center for Beneficiary Choices at CMS. In this role, he is helping to lead the development and implementation of the Medicare Part D drug benefit. He has served as Privacy Officer and VP of Pharmacy Regulations for an e-Prescribing company, VP of Clinical Operations and VP of Pharmacy Regulations for a national PBM and was both owner and pharmacist of an independent pharmacy. Prior to accepting his position with CMS, Mr. Caldwell was employed by Novartis Pharmaceuticals in the U.S. Managed Markets area. His public service commitments include serving a second term with the Texas State Board of Pharmacy and two terms on the Texas Statewide Health Coordinating Council. Mr. Caldwell received his Bachelor of Science in Pharmacy in 1974 from Southwestern Oklahoma State University.

Babette S. Edgar, Pharm.D., M.B.A., is the Director of the Division of Finance and Operations Medicare Drug Benefit Group. Dr. Edgar's current role includes directing and managing the formulary review process, benefit oversight, marketing operations, plan transition issues, licensure and solvency operations, and other financial and operational areas for the Medicare Drug benefit. Dr. Edgar has spent her previous 9 years in the pharmacy benefit management industry with management responsibilities in disease management, marketing, business development, sales, product development and clinical and formulary management. She has also been a Clinical Instructor for the past 13 years at the University of Maryland where she served four years as Assistant Professor full time in the Clinical Division. She also provided clinical services for geriatric psychiatry patients for over 8 years. She has published several peer reviewed articles and book chapters and has been invited to lecture at many professional association and other meetings. She has been involved with and served on committees for AMCP and ASHP. Dr. Edgar received her Bachelors degree in Pharmacy from Rutgers University College of Pharmacy, her Doctor of Pharmacy degree from Duquesne University, and her Masters in Business Administration from the University of Phoenix.

Tim Hoogerwerf has worked as a systems analyst on the Health Plan Management System (HPMS) in the Center for Beneficiary Choices (CBC), Division of Health Plan and Provider Data (DHPPD) at CMS since the fall of 2000. Mr. Hoogerwerf's HPMS modules include the HPMS Monitoring and Marketing Modules (both MA and PDP), PACE, TAMS, Contract Management, as well as providing support to a variety of HPMS modules and initiatives.

Part D Marketing Guideline Training Conference
BearingPoint Speakers
CMS Headquarters, Baltimore, Maryland
June 3rd, 2005 (8:00am – 4:00pm)

Mike Adelberg, M.A., M.P.P., is a Senior Manager with BearingPoint and has over 12 years of professional experience in health/aging policy and administration, including 10 years with the Centers for Medicare & Medicaid Services (CMS). Mr. Adelberg presently manages numerous CMS engagements that focus on quality assurance and the quality of Medicare information including several tasks to evaluate the effectiveness of Medicare outreach activities. During his CMS tenure, Mr. Adelberg was prominent in a number of program and policy areas that are directly germane to Part D Marketing including the complaints tracking system for the Medicare-Endorsed Drug Card Program and CMS standard operating procedures for Medicare+Choice plan nonrenewals. Mr. Adelberg is also an accomplished presenter and trainer. As the Associate Regional Administrator in CMS' Chicago Regional Office, Mr. Adelberg presented to large and sometimes negatively predisposed professional audiences on a variety of topics, including Medicare+Choice and the Medicare-Endorsed Drug Card. More important, Mr. Adelberg has led several large training efforts, including HCFA's "CBSU" (a one week crash course on Medicare and the organizations that support it for HCFA staff), and national trainings to the SHIPs on the Medicare Savings Programs and managed care while he was the Training and Outreach Task Leader for the SHIP program. Mr. Adelberg will serve as the overall engagement manager, offering strategic direction and assuring appropriate resources. He also personally directed the training task.

Tom Miglino is a Manager with BearingPoint. Mr. Miglino has managed an extensive material review team that to date has completed compliance verification for more than 5,000 documents. Key to this success was the development of a multidisciplined staffing model that accommodates shifting labor needs; the development and revision of operational guidelines; the drafting of model marketing materials for use by Medicare beneficiaries; and the development of knowledge-based tools for a wide variety of end users. Additionally, Mr. Miglino has extensive knowledge of marketing practices within both the private and public sectors and has spearheaded marketing campaigns from conception through fulfillment to post-implementation customer satisfaction assessment. As Project Manager, Mr. Miglino will oversee the development and implementation of all aspects related to the BearingPoint contract for the Medicare Prescription Drug Benefit, including development of the Part D Marketing Materials Guidelines, model materials, and marketing review process.

Part D Marketing Guideline Training Conference
BearingPoint Speakers
CMS Headquarters, Baltimore, Maryland
June 3rd, 2005 (8:00am – 4:00pm)

Mori A. Hall, J.D., LL.M., a Senior Consultant with BearingPoint, has over 14 years of health care industry experience. Ms. Hall has served as a Project Lead for the Medicare Part D Oversight project, which involved regulatory element interpretation, oversight recommendations, data set compliance suggestions, and industry impact rationales. In addition, Ms. Hall was instrumental in drafting the revisions of the Medicare Endorsed Rx Discount Card Information and Outreach Materials Guidelines. Ms. Hall's experience as a health care attorney includes fraud and abuse investigations, drafting corrective action plans, developing corporate compliance programs within medical practices and medical centers. Recently, under the guidance of CMS, Ms. Hall contributed to the drafting of the Part D Marketing Guidelines, drawing upon her experience as a Team Leader from the Medicare Prescription Discount Drug Card project and several other consulting projects involving CMS program management and oversight.

Rita Alonis, J.D., is a Consultant with BearingPoint and brings with her over 10 years of combined work experience in the fields of law and health care. Ms. Alonis currently serves as the Sponsor Liaison for the Medicare Drug Discount Card Program in BearingPoint's Health Services Research and Management Group where she reviews vendor materials to ensure compliance with Medicare marketing regulations. Upon finding materials to be noncompliant, she advises vendors on how the materials may become compliant with regulatory requirements. As Sponsor Liaison, Ms. Alonis is also actively involved in the drafting and development of model marketing materials for use by Sponsors, as well as advising Sponsors on the submission and approval process. In addition to her role as Sponsor Liaison, Ms. Alonis is currently involved in the development of the Part D Marketing Materials Guidelines and model materials for the forthcoming Medicare Prescription Drug Benefit. Under this initiative, as the Senior Plan Communications Leader, Ms. Alonis will work closely with support staff to ensure that any questions, comments, or concerns from Plans are promptly and properly addressed and resolved.

Medicare Part D Plan Training

**Orientation for New Plans:
How to Successfully Work with CMS**



Bob Donnelly
Teresa DeCaro, RN, MS
Kim Caldwell, RPh
Babette Edgar, PharmD, MBA
Mel Sanders



Purpose of New Plan Orientation:

- Welcome New Plans as CMS Business Partners
- Provide an understanding of the MMA and the Part D Prescription Drug Benefit and Marketing Materials Guidelines
- Identify the roles and responsibilities of CMS and its partners
- Provide information on the approval and distribution process of marketing materials
- Discuss available resources that will assist plans in successfully marketing the Part D Drug Benefit

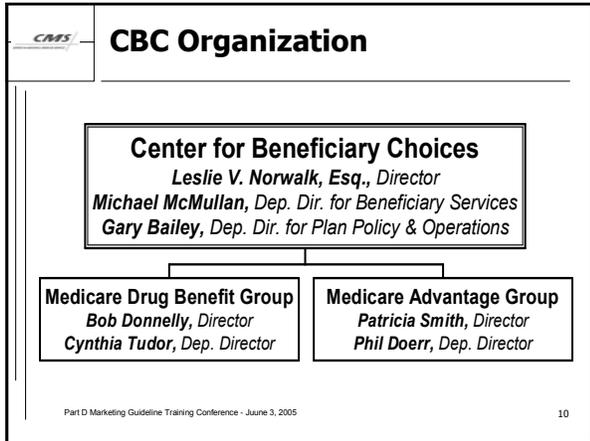
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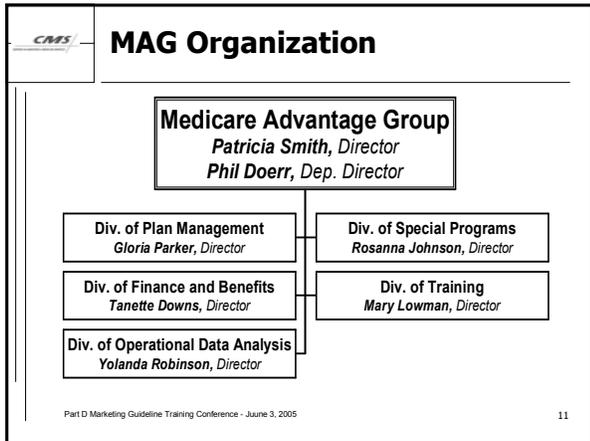


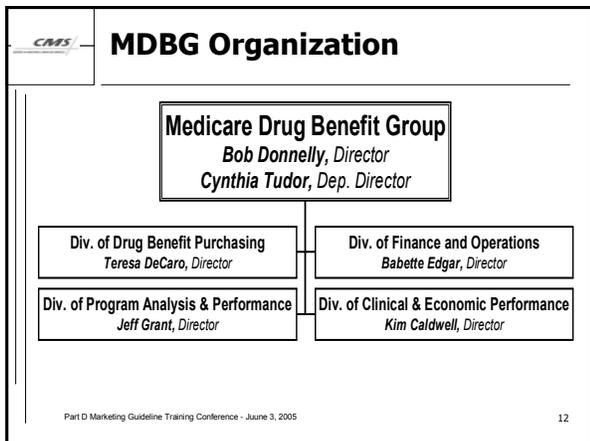
Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003



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Division of Drug Benefit Purchasing

- Application Development / Review / Annual Update
- Annual Renewal Process Development / Implementation
- Bid Negotiations Coordination
- Contracting
- Account Management
- Coordinate Among CMS staff in CO and RO Across Part C and D Responsibilities

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Thank You!

For further questions, contact:

Teresa DeCaro, RN, MS:
Division of Drug Benefit Purchasing
410-786-6604
Teresa.DeCaro@cms.hhs.gov

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Division of Clinical and Economic Performance

- Performance
- Quality
- Safety
- Drug Trend Analysis
- Cost Trend Analysis
- Population Specific Studies
- Comparative Studies (Submitted versus Actual)

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Division of Clinical and Economic Performance

- Coverage Determinations
 - Exceptions – Clinical
 - Exceptions – Tier Cost-sharing
 - Appeals
- Grievances
- Utilization Management
 - Step-Edits
 - Prior Authorizations
 - Quantity Limits

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Division of Clinical and Economic Performance

- Medication Therapy Management
- Electronic Prescribing
- Oversight:
 - Outliers
 - Fraud, Abuse, Waste
 - Audit team participants
- Market Intelligence Reports

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Thank You!

For further questions, contact:

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410-786-7518
Kim.Caldwell@cms.hhs.gov

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CMS **Division of Finance & Operations**

- Licensure and Solvency
- Formulary
- Benefit Design
- Marketing

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CMS **Role of CMS Regional Offices**

Regional Offices are located in 10 major cities around the United States and in Baltimore.

- Boston
- Dallas
- New York
- Kansas City
- Philadelphia
- Denver
- Atlanta
- San Francisco
- Chicago
- Seattle

<http://www.cms.hhs.gov/about/regions/professionals.asp>

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CMS **Role of BearingPoint**

Supporting CMS in the:

- Development Part D marketing guidelines
- Establishment model marketing materials
- Review of PDP marketing materials
- Management of the PDP Marketing Resource Line

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Putting Faces to Names

Health Services Research & Management Group at BearingPoint

- Mike Adelberg, Engagement Director/Senior Trainer
- Tom Miglino, Project Manager
- Mori Hall, JD, LLM, Senior Guidelines Leader
- Rita Alonis, JD, Senior Plan Communications Leader
- Kelly Moriarty, Model Materials Leader
- Monica Sarmiento, MA, Senior Review Team Leader
- Jeremy Prose, Database and Document Controller

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Thank You!

For further questions, contact:

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Your CMS "Toolkit":

- Road Guide to Developing Your Relationship with CMS
- Key personnel and contact information
- Marketing Resources



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Road Guide to Developing Your Relationship with CMS...



Medicare Part D Plan Training

Welcome & Introduction



Leslie Norwalk, Esq.
Bob Donnelly
Babette Edgar, PharmD, MBA






Welcome !



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Conference Goals:

- **Provide a basic understanding of Part D Marketing Guidelines**
- **Develop marketing materials that comply with marketing guidelines**
- **Know which resources are available to Plans during the review process and how to best use them**
- **Provide opportunity to Plans to ask additional questions about the guidelines**

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Marketing Guidelines Training Overview

- CMS marketing guidelines are to assist Part D plans with:
 - Development of accurate marketing materials
 - Other aspects of marketing
- Part D Plans include PDPs and MA-PDs in the marketing guidelines.
- Sections within the marketing guidelines unique to a particular type of Part D Plan are identified as either PDP or MA-PD.

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Note to MA-PDs and Cost Plans

For guidance related to Marketing Materials, MA-PDs and Cost Plans should also refer to:

- The Medicare Managed Care Manual
- The Marketing Materials Guidelines for MA-PDs and PDPs



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Review Entities

- MA-PDs – Marketing material review will be performed by the ten CMS Regional Offices
- PDPs – Marketing materials are reviewed by CMS Designee

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Role of CMS Regional Offices

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<http://www.cms.hhs.gov/about/regions/professionals.asp>

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Role of BearingPoint

Supporting CMS in the:

- Development Part D Marketing Guidelines
- Establishment model marketing materials
- Review of PDP marketing materials
- Management of the PDP Marketing Resource Line

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Conference Agenda

- Orientation for New Plans
- Welcome & Introduction
- Marketing Guidelines Overview
- Marketing Materials Development
- Marketing Review Process
- Overview of HPMS
- Lunch
- Advertising
- Pre-Enrollment Materials
- Formulary
- Post-Enrollment Materials
- Q & A Panel
- Closing Remarks

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Framework of Presentations

- **Session Objectives**
- **Content**
- **Interactive Learning Activity**
- **Key Takeaways**
- **Contact information of the speaker**

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Question and Answer Panel

- **You may write your questions on index cards provided in the Welcome Packet.**
- **We will collect your questions at the end of each session.**
- **This afternoon, a CMS representative will address the most frequently asked questions.**



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Medicare Part D Plan Training

Marketing Guidelines Overview



CENTERS FOR MEDICARE & MEDICAID SERVICES



Mike Adelberg, MA, MPP



Session Content

- Purpose of Marketing Guidelines
- Definitions of Marketing Materials
- Plan Types
- Limitations
- Co-Branding Requirements
- HIPAA Provisions
- Licensure of PDPs

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General Overview

- CMS marketing guidelines are to assist Part D plans with:
 - Development of accurate marketing materials
 - Other aspects of marketing
- Part D Plans include PDPs and MA-PDs in the marketing guidelines.
- Sections within the marketing guidelines unique to a particular type of Part D Plan are identified as either PDP or MA-PD.

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Purpose of Marketing Guidelines

- Expedite CMS review process
- Allow Part D Plans to effectively manage their marketing resources
- Establish and ensure consistent marketing review standards
- Enable the development of beneficiary-friendly materials

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Purpose of Marketing Materials

Part D Marketing materials are intended to:

- Promote the Plan
- Provide enrollment information
- Explain benefits
- Describe the rules applicable to enrollees
- Explain how services are provided
- Communicate Part D Plan operational polices, rules, and procedures

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Explanatory Materials

Explanatory Materials are a subset of marketing materials which:

- Explain benefits, operational procedures, cost-sharing and other features of the plan
- Include Pre-Enrollment and Post-Enrollment materials
- Some examples include: Summary of Benefits, Evidence of Coverage, Pharmacy Directory, etc.

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Advertising

- Intended to attract or appeal to potential Part D Plan enrollees
- Intended for quick viewing by potential enrollees
- Examples include: TV, radio ads, outdoor ads, print ads, direct mail without an enrollment form, and event signage

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Pre-Enrollment Marketing Materials

- Provide more detail than included in an advertisement
- Generally used by prospective enrollees to decide on enrollment
- Examples include: direct mail and Summary of Benefits

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Post-Enrollment Marketing Materials

- Used by Plans to convey benefits or operational information to enrolled beneficiaries
- Includes all beneficiary notification materials
- Examples include: Evidence of Coverage, the Annual Notice of Change (ANOC), and the Pharmacy Directory

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Types of Plans Based on Service Area

National Plans (PDPs Only)

- Cover a minimum of the 34 PDP regions that include the 50 states and DC

Regional Plans (MA-PD Only)

- Coordinated care Plan structured as a PPO serving one or more entire MA regions (see guidelines)

Local Plans (MA-PD Only)

- Is not a Regional Plan and chooses the counties in which it operates (see guidelines)

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Plans based on Service Area-PDPs

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Plans Based on Service Area-MA-PDs

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Limitations on Distribution



No advertising outside of defined service area.

- May lead to corrective action by CMS
- If a Plan must advertise outside service area because it is unavoidable, then they *must* disclose their service area

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Co-Branding Defined

- Co-branding is defined as a relationship between two or more separate legal entities, one of which is a sponsoring Part D Plan.
- Sponsoring Part D Plan displays the name(s) or brand(s) of the co-branding entity or entities on its marketing materials to signify a business arrangement.

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Co-Branding Relationships

- Allow Part D Plan and its co-branding partner(s) to promote enrollment into the Plan
- Entered into independently from the contract that the Plan has with CMS.

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Co-Branding Relationships

Co-branding relationships that involve remuneration between parties in a position to influence the referral of Medicare-payable business should be carefully scrutinized by the Plan for compliance with the fraud and abuse laws, including the Federal anti-kickback statute.

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Co-Branding Requirements

Part D Plans may enter into co-branding arrangements by:

- Informing CMS of the relationship through the Plan Benefit Package (PBP) located in the HPMS
- Notifying CMS of changes in co-branding relationships through plan managers and updating information in HPMS
- Ensuring responsibility for co-branding partner(s) to adhere to applicable CMS policies and procedures
- Attesting that co-branding partners were provided marketing guidelines and agreed to follow all applicable guidelines
- Part D Plans may co-brand with State Pharmaceutical Assistance Programs (SPAPs)

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Use of Medigap Issuer Data

Media Issuers:

- May use existing information to market Part D Benefits to current enrollees
- Should consult their own legal counsel, to determine whether such marketing is permitted under HIPAA privacy rule or any other applicable Federal or State privacy laws
- If after consulting with counsel, the Medigap issuer, determines that marketing under this section is permitted, it must market to all its members (not just a subset).

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Health Insurance Portability and Accountability Act (HIPAA)



- Review Marketing Guidelines
- Refer to Department of Health and Human Services, Office of Civil Rights Web site address at: <http://www.hhs.gov/ocr/hipaa/>

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PDP State Licensure

- Title I of the MMA requires PDPs to:
 - Be licensed as a risk bearing entity in State or territory providing Part D Benefits or;
 - Obtain a license waiver from CMS in each State or territory it will operate PDP
- PDPs are prohibited from characterizing other PDPs with waivers as less stringent or less protective within marketing materials or any other type of communications.

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Key Takeaways

The Marketing Guidelines will assist in:

- Defining marketing materials and their use
- Understanding co-branding requirements
- Providing consistent review standards for Plans
- Developing consumer-friendly marketing materials that comply with CMS requirements

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Thank You!

For further questions, contact:

- **For PDPs:**
 - **PDP Marketing Resource Line**
 - **1-866-770-PLAN (7526). Activation date will be announced through HPMS.**

- **For MA-PDs:**
 - **Regional Office Contacts**

Medicare Part D Plan Training

Marketing Materials Development






Tom Miglino



Session Content

- **Plan responsibilities**
- **Prohibited terminology**
- **Model vs. standardized materials**
- **Internet marketing**
- **Studies & statistics**
- **Availability of alternative formats**
- **Contracting statement**

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Plan Responsibilities

- **Use the Health Plan Management System (HPMS) for marketing materials submission**
- **Ensure materials are consistent with Marketing Materials Guidelines**
- **Submit marketing materials with all necessary accompanying information**
- **Examine comments by reviewers and make corrections prior to resubmission of a disapproved material**

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Prohibited Terminology



Part D Plans *may not* :

- Use misleading or confusing terminology within marketing materials
- Misrepresent themselves or the Part D benefits and services they provide
- Claim recommendation or endorsement, by CMS

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Acceptable Terminology



A Part D Plan *may* explain:

- It is approved for participation in Medicare and/or
- It is contracted to administer the Part D benefit and/or
- Benefits and services are “Medicare-approved”

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Terminology

- “Medicare-approved”
 - Plans *may use* this term to describe their Part D Services.
- Plans should consult the Must Use/May Not Use Charts for specific guidance on permitted terms for the following:
 - Advertising Materials
 - Pre-Enrollment Materials
 - Post-Enrollment Materials
 - Internet Outreach
 - Dual Eligibles

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Model Materials

- Applies to certain Pre- and Post-Enrollment materials
- CMS has drafted model language
- Use of model language is optional
- Must be used without modification to qualify for the 10-day review period

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Standardized Language

- CMS drafted standardized language (Summary of Benefits only)
- Use is mandatory for Part D Plans
- Subject to 10-day marketing review

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Internet Marketing



- Part D Plans ***must*** have an Internet Web site.
- Web sites must be §508 Compliant. (See www.section508.gov.)

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Internet Marketing-URL Guidelines

Organizations *must*:

- Have a Web site or Web page dedicated to the Prescription Drug Benefit;
- Include the name of the particular Part D Plan on the site; and
- Clearly indicate that the Plan is a Medicare contractor.

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Internet Marketing-URL Guidelines

All marketing materials must include a Web address that connects the beneficiary either to:

- The corporate Web site or
- Directly to the Part D Web page.

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Internet Marketing-Other Lines of Business

- Plans *may* concurrently market other lines of business on the Internet with their Part D Plan products.
- Links for non-health related products or services *must*:
 - Be clearly labeled; and
 - Inform the beneficiary s/he will be leaving the Plan-specific Web site.

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Internet Marketing

Marketing materials placed on the Plan Web site must be a minimum 12-point Times New Roman-equivalent font.

- Refers to how the Plan codes the font on the Web page

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Internet Marketing-Web Content Requirements

- Plans should consult the guidelines for specific marketing requirements.
- Required content may be provided via links off the Part D Plan's Web pages.
- Links may consist of numerous pages, however, icons must clearly describe the information being accessed.

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Internet Marketing-Required Links

The following information must be accessible via a link:

- Summary of Benefits
- Enrollment Instructions and Forms
- Evidence of Coverage
- Privacy Notice

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Internet Marketing-Prohibited Links



Plans **may not** provide links to foreign drug sales on their Web sites.

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Internet Marketing-Must Use Chart

- Plans should refer to the Internet Must Use Chart for URL guidelines and Web site content requirements.
- Internet Must Use Chart is self-contained, however, Plans should refer to applicable sections for specifics on marketing requirements.

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Studies and Statistical Data

Plans may refer to results of studies or statistical data in relation to the following:

- Customer satisfaction
- Quality
- Cost
- Other reasons

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Studies

- Plans must provide specific study details, including:
 - Source
 - Date
- Unless it is a CMS study, Plans must provide:
 - Study sample size
 - Number surveyed

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CMS

Prohibition on Study and Statistical Data



Plans *may not* use study or statistical data to directly compare their Plan to another Part D Plan.

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CMS

Use of Superlatives

May be used:

- “One of the best”
- “Among the highest”
- “Among the highest rank”

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CMS

Use of Superlatives

May not be used, unless substantiated with supporting data:

- “The best”
- “Highest ranked”
- “Rated number one”

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CMS

Availability of Alternative Formats

- Plans must provide a disclosure on all Pre-and Post-Enrollment materials that alternative formats are available.
- Alternative formats include
 - Braille
 - Foreign languages
 - Audio tapes
 - Large print, etc.

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CMS

Contracting Statement

- Plan materials *must* include a statement either in the text of the materials or as a footnote that the Plan contracts with the Federal government.
- Statement must be contained in:
 - Advertising materials
 - Pre-Enrollment
 - Certain Post-Enrollment materials

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CMS

Key Takeaways

- **Model language used without modification is subject to the 10-day marketing review process.**
- **All Part D Plans must have an Internet Web site dedicated to the Prescription Drug Benefit.**
- **Plans should consult the Internet Must Use/Must Not Use Chart for URL and Web site content requirements.**

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CMS

Key Takeaways

Participants should understand:

- **Plan responsibilities for marketing**
- **Acceptable and prohibited terminology**
- **How model materials will be available for use**
- **Required use of standardized documents**
- **Use of studies and statistical data in marketing**
- **Alternative formats for marketing materials**
- **Requirements for inclusion of contracting statement**

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CMS

Thank You!

For further questions, contact:

- **For PDPs:**
 - **PDP Marketing Resource Line**
 - **1-866-770-PLAN (7526). Activation date will be announced through HPMS.**
- **For MA-PDs:**
 - **Regional Office Contacts**

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Medicare Part D Plan Training

Marketing Review Process




Mike Adelberg, MA, MPP






Session Content

- Reviewing entities
- Material disposition definitions
- Marketing review timeframes
- Resubmissions
- Revisions
- File & Use certification
- File & Use Eligibility
- Material ID system (PDPs)
- Multi-region plans
- Marketplace material review
- Materials not subject to review

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MARKETING REVIEW PROCESS
2



Reviewing Entities

- **MA-PDs – MA-PD Marketing material review will be performed by the ten CMS Regional Offices**
- **PDPs – Marketing materials are reviewed by the CMS designee**

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MARKETING REVIEW PROCESS
3

CMS

Materials Disposition Definitions

- **Approval**
- **Disapproval**
- **“Deemed” Approval**
- **Withdrawn by Organization**

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MARKETING REVIEW PROCESS
4

CMS

Materials Disposition Definitions

Approval

- Marketing materials are determined to be compliant with the marketing guidelines
- Approved materials remain approved unless:
 - They are altered by the Part D Plan
 - They become inaccurate due to changing conditions

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MARKETING REVIEW PROCESS
5

CMS

Materials Disposition Definitions

Disapproval

- Marketing materials are not compliant with the marketing guidelines and/or applicable regulations or law
- CMS will provide a specific reason for disapproval--with explanation--by email communication to the Plan

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MARKETING REVIEW PROCESS
6

CMS

Materials Disposition Definitions

Deemed

- If CMS does not approve or disapprove a marketing material within its appropriate review time frame, then it will be “deemed” approved.
- 45-day review materials will be “deemed” approved on the 46th day after submission
- 10-day review materials will be “deemed” approved on the 11th day after submission

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CMS

Materials Disposition Definitions

Withdrawn by Organization

- The Part D Plan may withdraw a marketing material submission prior to CMS approval or disapproval
- CMS does not have authority to withdraw a marketing submission

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CMS

Timeframes for Marketing Review

There are two timeframes for review:

- 45-day review
- 10-day review

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CMS

45 Day Review Period

The standard review time period given to materials is 45 days. Marketing materials receive 45-day review if:

- Standardized language or model language is not available
- Available model language has been modified by the Plan
- Neither File & Use Certification nor File & Use Eligible status is available

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CMS

10 day Review Period

Marketing materials receive an expedited review within 10 days if:

- Plan has used standardized language
- Plan has utilized model language without modification and has indicated this upon submission
- Neither File & Use Certification nor File & Use Eligible status is available

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CMS

10 day Review Period

Available only for certain material codes where model language is provided by CMS

- Requires Plans to affirmatively act
 - Plan must indicate upon submission that model language was utilized, *without modification*
- Without modification means:
 - The Part D Plan has used CMS model language verbatim and has only used its own language in areas where CMS has allowed the Plan to use its information
 - The Part D Plan has followed the sequence of information provided in the model

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CMS

Types of submission

There are three types of submissions:

- **Original:** first submitted version of a marketing material
- **Resubmission:** edited version of a previously submitted material that is still pending
- **Revision:** corrected version of a previously disapproved marketing material

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CMS

File & Use Certification - Part D Plans

- Plans must submit and certify that certain types of materials meet CMS marketing guidelines at least five days prior to use
- Plans must use model language without modification when available

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CMS

File & Use Certification – Part D Plans

- Organizations that do not have File & Use status must use the File & Use Certification Process for selected marketing material, unless the organization requests a waiver.
- Plans using the File & Use Certification process must submit and certify that certain types of materials meet CMS marketing guidelines at least five days prior to use.

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CMS

File & Use Certification Process

- Unless a waiver is requested, Plans must submit a File & Use Certification with the qualifying material five days prior to distribution
- CMS will verify that the marketing materials submitted qualify for File & Use Certification
- As each marketing material is submitted, the Plan must attest to the completeness and accuracy of the material through an electronic attestation

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CMS

File & Use Certification

<u>Qualified Materials</u>	<u>Materials Not Qualified</u>
<ul style="list-style-type: none"> • Advertising materials • Pharmacy directories • Formularies • Certain CMS letters used without modification. 	<ul style="list-style-type: none"> • Summary of Benefits • Evidence of Coverage • Member Handbooks • Annual Notice of Change • Enrollment Form • Disenrollment Form • Any other documents CMS defines.

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CMS

File & Use Certification

- Plans could potentially lose File & Use Certification privileges if:
 - Materials are used that do not meet marketing guideline requirements; and/or
 - The plan fails to file two or more materials at least five calendar days prior to distribution or publication
- If revoked, the Plan must wait at least 6 months to regain file and use privilege.
 - If revoked twice, the Plan must wait one year from the date of revocation

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CMS

File & Use Certification Retrospective Monitoring

- Once a Plan is in the File & Use Certification process, CMS will monitor compliance on a retrospective basis
- CMS will select a random sample of qualified materials that were submitted under the File & Use Certification process
- Additionally, CMS will investigate any complaints received regarding marketing materials to determine possible non-compliance with the marketing guidelines

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CMS

File & Use Eligible

- Designed to streamline the marketing review process
- Available for some types of materials for Plans that have continually met a particular standard of performance
- Plans are able to publish and distribute certain materials without prior approval

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CMS

Key Dates

June 7

Part D Plans may begin submitting marketing materials for review

October 1

Part D Plans may begin releasing their marketing materials into the marketplace

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CMS

Health Plan Management System (HPMS)

Part D Plans must submit marketing materials to the appropriate CMS Regional Office or the CMS Designee through the HPMS. There are two modules:

- PDP Marketing Module is an automated tool that is used to enter, track, and maintain marketing materials that organizations submit to CMS for review
- MA-PD Marketing Module is fully explained in the "User's Guide"

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CMS

Materials Not Subject to Review

The following materials are not subject to review:

- Privacy notices
- Press releases
- Newsletters
- Blank letterhead
- General health promotion materials that do not contain marketing material
- Non-Medicare beneficiary-specific materials
- Customer service correspondence addressing issues unique to individual members

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CMS

Marketing Review for Multi-Region Organizations

- For MA-PD organizations that operate in more than one of the CMS MA Regions, their marketing review approach will be determined by the agreement made between the organization and the CMS Multi-Region Team management
- Multi-Region MA-PDs must:
 - Ensure materials submitted are consistent with the Marketing Guidelines
 - Distribute final copies of national marketing materials to the lead and local ROs with a dated cover identifying the recipients according to CMS timelines

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CMS

Review of Materials in the Marketplace

- **Marketplace review consists of:**
 - Review of on-site marketing facilities, products, and activities
 - Random review of actual marketing pieces used in/by the media
 - “For-cause” review of materials and activities when complaints are made

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CMS

Marketing Material ID System-PDPs Only

- Each PDP is assigned a unique identifier - S number (XXXX)
- CMS requires a unique material ID for each submitted material:
 - Material ID must begin with Plan's PDP contract number
 - Followed by a hyphen (“-”)
 - PDP may chose a series of alphanumeric characters following the hyphen

Example: 1234-XXXXX

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CMS

Marketing Material ID System-MA-PDs Only

MA-PDs should refer to Chapter 3 of the Medicare Managed Care Manual for guidance.

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CMS

Key Takeaways

- All marketing materials are subject to 45 day review unless certain exceptions apply.
- Plans are responsible for ensuring that submitted and approved marketing materials do not contain typographical or grammatical errors.
- File & Use Certification: Plans submit and certify that certain types of materials meet CMS marketing guidelines at least five days prior to use.
- File & Use Eligible: Available for some types of materials for Plans that have continually met a particular standard of performance.

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CMS

Key Takeaways

- **Marketing materials can be approved, disapproved, deemed approved, or withdrawn by the Plan.**
- **CMS requires a unique material ID for each submitted material.**

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CMS

Thank You!

For further questions, contact:

- **For PDPs:**
 - PDP Marketing Resource Line
 - 1-866-770-PLAN (7526). Activation date will be announced through HPMS.
- **For MA-PDs:**
 - Regional Office Contacts

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Medicare Part D Plan Training

**Health Plan Management System (HPMS)
System Overview**



Tim Hoogerwerf
Systems Analyst,
Center for Beneficiary Choices (CBC)
CMS






Session Content

- Introduction
- HPMS Overview
- Live Walkthrough of the HPMS PDP Marketing Module
- Accessing HPMS
- HPMS Contacts
- Questions

Medicare Part D Marketing Guideline Training Conference – June 3, 2005

2



What is the HPMS

- A web-enabled information system that supports the ongoing operations of the Medicare Advantage programs by facilitating electronic communication between CMS and plans.
- CMS has enhanced the HPMS to support the operations of the new Medicare prescription drug benefit program.

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3

CMS

What PDP Marketing Functions will be in the HPMS

PDP Organizations will use the HPMS PDP Marketing Module to:

- Log the Upload of New Marketing Materials
- Log the Upload of Material Revisions
- Log the Upload of Material Resubmissions
- Search for an Existing Material
- View and Print Reports

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CMS

Demonstration

Live demonstration of the HPMS PDP Marketing Module.

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CMS

HPMS Access

- **By default, ALL existing HPMS PDP users have been granted access to the HPMS PDP Marketing Module.**
 - New users will need to follow the instructions below.
- **HPMS is a web-enabled Extranet application that resides within the Medicare Data Communications Network (MDCN).**
- **HPMS requires a CMS user ID/password and the Microsoft Internet Explorer web browser version 5.1 or higher.**
- **The user access form can be found at:**
<http://www.cms.hhs.gov/mdcn/access.pdf>

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CMS

HPMS Connectivity Options

Three alternatives for accessing HPMS:

- Internet access via a Secure Socket Layer Virtual Private Network (SSL VPN) using your corporate Internet Service Provider (ISP) at <https://gateway.cms.hhs.gov>;
- T-1 lease line access via AT&T Global Network Services (AGNS) at <http://32.91.239.68>; or
- Dial-up access via AGNS at <http://32.91.239.68>.

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CMS

HPMS Contacts

Name	Phone Number / E-Mail	Responsibilities
Lori Robinson	410-786-1826 LRobinson1@cms.hhs.gov	Director, Division of Health Plan and Provider Data (DHPPD)
Ana Nunez-Poole	410-786-3300 Ana.nunezpoole@cms.hhs.gov	Lead Technical Analyst, HPMS.
Susan Watson	410-786-1822 swatson@cms.hhs.gov	Lead developer, HPMS PDP Marketing Module, HPMS MA Marketing Module, Deeming.
Tim Hoogerwerf	410-786-9962 THoogerwerf@cms.hhs.gov	Systems analyst for online application, marketing, MA plan monitoring, and PACE
Don Freeburger	410-786-4586 DFreeburger@cms.hhs.gov	Systems analyst for HPMS connectivity, user access, and user IDs
Neetu Jhagwani	410-786-2548 NJhagwani@cms.hhs.gov	Systems analyst for HPMS user access and user IDs
HPMS Help Desk	1-800-220-2028 hpms@nerdvana.fu.com	Support for all HPMS technical issues

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CMS

Thank You!

For further questions, contact:

- **For PDPs:**
 - PDP Marketing Resource Line
 - 1-866-770-PLAN (7526). Activation date will be announced through HPMS.
- **For MA-PDs:**
 - Regional Office Contacts

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Medicare Part D Plan Training

Advertising






Tom Miglino



Session Content

- Definition of Advertising
- Examples of Advertising materials
- Product Endorsements and Testimonials
- Drawing/Prizes/Giveaways
- Radio/TV spots
- Telemarketing

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MARKETING MATERIAL DEVELOPMENT GUIDELINES
Advertising
2



Prohibited Terminology



Part D Plans *may not* :

- Use misleading terminology within marketing materials
- Misrepresent the Part D Benefits and services it provides
- Claim it is recommended or endorsed by CMS

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MARKETING MATERIAL DEVELOPMENT GUIDELINES
Advertising
3

CMS

Acceptable Terminology



A Part D Plan **may** explain that:

- It is approved for participation in Medicare
- It is contracted to administer the Part D Benefit
- Its benefits and services are “Medicare-approved”

Medicare Part D Marketing Guideline Training Conference-June 3, 2005 MARKETING MATERIAL DEVELOPMENT GUIDELINES Advertising 4

CMS

Definition of Advertising

- Intended to attract or appeal to potential Part D Plan enrollees
- Outdoor Advertising (ODA) is designed to motivate an individual to call for more information
- Intended for quick review
- **Examples:** TV, radio ads, outdoor ads, print ads, direct mail without an enrollment form, and event signage.



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CMS

Product Endorsements/Testimonials

- Content **must** comply with CMS Marketing Guidelines
- Speaker must identify Part D Plan by name
- If an individual is paid to promote the Plan, “paid endorsement” must be clearly stated
- If an individual is paid to portray a real or fictitious situation, “Paid Actor Portrayal” must be clearly stated

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CMS

Product Endorsements/Testimonials

- If a Medicare beneficiary offers an endorsement, the individual must be a current Plan enrollee
- Use negative testimonials about other Plans
- Guidance regarding actual providers appearing in advertisements is forthcoming

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CMS

Drawings/Prizes/Giveaways



- Part D Plans are prohibited from using free gifts and prizes as an inducement to enroll
- Any gratuity must be made available to all participants regardless of enrollment
- Any gift must be valued at less than \$15

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CMS

Drawings/Prizes/Giveaways

- Part D Plans offering drawings, prizes, or giveaways must state the following in 12-point font:
- “Eligible for free drawing and prizes with no obligation”
- “Free drawing without obligation”
- Plans cannot state “Eligible for free drawing and prizes”

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CMS

Radio and TV Spots

Both Radio and TV spots:

- **Must include the Part D Plan's toll-free number**
- **Do not have to mention the date the script was approved by CMS**
- **Final scripts must be submitted to CMS under File & Use Certification**

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Advertising 10

CMS

Radio Spots

- **Do not need to include the Plan's TTY/TDD number**
- **If disclaimers are required, they may be worked into the script**

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Advertising 11

CMS

TV Spots

- **Must include the TTY/TDD number**
- **Required disclaimers (e.g., "paid endorsement") must be worked into the script or shown on the crawl**

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Advertising 12

CMS

Contracting Statement



All advertising materials (EXCEPT banners, banner-like ads, and outdoor advertising) **must** include a statement that the Plan contracts with the Federal government.

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CMS

Telemarketing

- Part D Plans **may** conduct outbound telemarketing for health related products.
- Part D Plans **may not** conduct outbound telemarketing for non-health related products **unless** the beneficiary has provided prior **written authorization**.

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CMS

Telemarketing

Telemarketers **may**:

- Solicit requests for pre-enrollment information
- Describe benefits
- Alert existing beneficiaries to new benefits or health-related offers
- Conduct follow-up calls
- Field questions regarding the program

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CMS

Telemarketing

Plans must adhere to:

- The Federal Trade Commission Requirements for Sellers and Telemarketers
- All applicable state laws

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CMS

Telemarketing

Plans ***must***:

- Comply with the National Do-Not-Call Registry
- Honor “do not call again” requests
- Abide by Federal and State Calling Hours

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CMS

Telemarketing

Enrollment is not allowed by outbound telemarketers

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CMS

Telemarketing

- **Scripts must be reviewed and approved by CMS prior to use in the marketplace**
- **Plans are not required to adhere to a specific format for submission of the script to CMS**

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Advertising
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CMS

Telemarketing

Part D Plans conducting telemarketing:

- Must include a privacy statement in scripts notifying beneficiaries that they are not required to provide any information to the Plan representative and the information provided will in no way affect the beneficiary's membership
- Are prohibited from requesting any beneficiary identification numbers
- Are allowed to say they are contracted with Medicare to provide Prescription Drug Benefits or that they are a Medicare-Approved MA-PD or PDP
- Cannot use language in outbound scripts that implies endorsement by Medicare, calling on behalf of Medicare, or calling for Medicare

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Advertising
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CMS

Key Takeaways

- **The content of endorsements and testimonials must comply with CMS Marketing Guidelines.**
- **Any gratuity offered by a Part D Plan must be available to all participants regardless of enrollment.**
- **Final scripts for Radio and TV spots must be submitted to CMS under File & Use Certification**
- **Outbound telemarketing is permitted for health related services. Outbound telemarketing is not permitted for non-health related products without written consent.**

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Advertising
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CMS

Key Takeaways

Participants should understand:

- **Acceptable and prohibited terminology**
- **Product endorsement and testimonial guidelines**
- **Requirements for radio and TV spots**
- **Requirements for inclusion of a contracting statement**
- **Guidelines for outbound telemarketing to potential beneficiaries**

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Advertising
22

CMS

Thank You!

For further questions, contact:

- **For PDPs:**
 - **PDP Marketing Resource Line**
 - **1-866-770-PLAN (7526). Activation date will be announced through HPMS.**
- **For MA-PDs:**
 - **Regional Office Contacts**

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Advertising
23

Medicare Part D Plan Training

Pre-Enrollment Materials



Rita Alonis, JD






Session Content

- **Understand general guidance for Pre-Enrollment materials**
- **Distinguish Pre-Enrollment materials from other marketing materials**
- **Determine applicable sections of the Marketing Guidelines to follow when creating Pre-Enrollment materials**

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MARKETING MATERIAL DEVELOPMENT GUIDELINES
Pre-Enrollment Materials



Purpose of Pre-Enrollment Guidance

To ensure that:

- **Beneficiaries have enough information to make an informed choice**
- **Beneficiaries have access to Plan resources (toll-free numbers, mailing addresses, etc.)**
- **Pre-Enrollment materials are not misleading**

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MARKETING MATERIAL DEVELOPMENT GUIDELINES
Pre-Enrollment Materials

CMS

Pre-Enrollment Materials vs. Advertisements

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Pre-Enrollment Materials 4

CMS

Pre-Enrollment Materials

- Marketing materials that provide more detail on a Plan than an advertisement
- Used by potential enrollees to decide whether or not to enroll in a plan
- Must include components required by the guidelines
- Examples:
 - Summary of Benefits
 - Formulary
- May be distributed with advertising materials

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Pre-Enrollment Materials 5

CMS

Advertisements

- **Designed to attract or to appeal to potential enrollees**
- **Includes:**
 - **Product endorsements or testimonials**
 - **Materials used in conjunction with Drawings/Prizes/Giveaways**
 - **Radio and television spots**
 - **Banner, banner-like ads, and ODA**

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Pre-Enrollment Materials 6

CMS

**Pre-Enrollment Materials
vs.
Post Enrollment Materials**

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Pre-Enrollment Materials 7

CMS

**Pre- and Post-Enrollment Materials:
Similarities and Differences**

<u>Pre-Enrollment</u>	<u>Post-Enrollment</u>
<ul style="list-style-type: none"> • Summary of Benefits • Formulary 	<ul style="list-style-type: none"> • Summary of Benefits • Formulary • Member Handbook • Annual Mailings • ID Card • Pharmacy Directories • Mail Order Prescription Drug Services

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Pre-Enrollment Materials 8

CMS

**By the end of Specific Guidance of
Pre-Enrollment Materials, you will be able to:**

- Understand what information is required in Pre-Enrollment materials
- Identify required and optional Pre-Enrollment materials

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Pre-Enrollment Materials 9

CMS

Information Required in Pre-Enrollment Materials

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Pre-Enrollment Materials
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CMS

Required Information

- Eligibility Requirements
- Prescription Drug Services
- Contracting Statement
- Program Description
- Premiums

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Pre-Enrollment Materials
11

CMS

Eligibility Requirements: Part D Plans

Pre-Enrollment materials must clearly state that an eligible beneficiary is one who:

- Is entitled to Medicare benefits under Part A or enrolled in Part B; and
- Must reside in the service area of the Part D Plan

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Pre-Enrollment Materials
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CMS

Eligibility Requirements: PDPs Only

PDPs must also state that the beneficiary:

- **May be enrolled in only one Part D Plan at a time**
- **May NOT enroll in a PDP if already enrolled in an MA Plan, unless he/she is a member of a Private Fee-for-Service MA Plan (PFFS) or a Medical Savings Account MA Plan (MSA)**

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Eligibility Requirements: MA-PDs Only

MA-PDs must also state that:

- **Their Medicare Prescription Drug Benefit is only available to members of the MA-PD Plan.**
- **If a beneficiary is already enrolled in a MA-PD Plan, the enrollee must receive their Medicare Prescription Drug Benefit through that Plan.**

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Eligibility Requirements: 1876 Cost Plans

1876 Cost Plans must state that Medicare beneficiaries may be enrolled in only one Part D Plan at a time.

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CMS

Prescription Drug Services:

If the Plan mentions Prescription Drug Benefits in the material, the Plan must:

- Inform the beneficiaries of the types of pharmacies in the network
- Note that benefits are only available at the Plan's Network Pharmacies
- Provide contact information

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Contracting Statement

“[Plan Name] contracts with the Federal Government” must appear in:

- The text of the material; or
- As a footnote

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Program Description

Must include:

- “[Program Name] is a Prescription Drug Plan that is approved by Medicare”
- Plan Service Area
- Statement that enrollees must use network pharmacies to receive Plan benefits

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Premiums

Must include:

“You must continue to pay your Medicare Part B premium if not otherwise paid for under Medicaid or by another third party.”

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CMS

Scenario 1 – Is this material missing any required information?

A Plan would like to distribute a brochure describing Part D benefits offered. The brochure includes:

- A description of available pharmacy services, types of pharmacies within the Plan network, and availability of mail order services
- A disclaimer that benefits are only available at network pharmacies
- Out-of-network access information
- Program description
- Contracting statement
- Premium information

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Required Pre-Enrollment Materials

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Required Pre-Enrollment Materials

- **Cover Letter**
- **Enrollment Instructions and Forms***
- **Summary of Benefits (SB)***
- **Written notice that the Plan's contract with CMS may result in termination of the beneficiary's enrollment in the Plan or reduction in the Plan's service area.**

* Model or standard language forthcoming

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Summary of Benefits (SB)

- **Primary Pre-Enrollment document**
- **Provides an easy means of plan benefit comparison**
- **Stand alone marketing document consisting of 3 sections**

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Three Sections of the Summary of Benefits

- **Section 1 - Introduction**
- **Section 2 - Comparison Matrix**
- **Section 3 - Free Form Text**

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**SB: General Instructions
(PDPs Only)**

- Adhere to language and format of SB
- PDP organizations offering more than one Plan
- PDP organizations offering Plans with identical benefits in different regions

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Summary of Benefits: PDP Only

Section 1

- Must incorporate information exactly as written in the standardized document
- Must include:
 - "If you have special needs, this document may be available in other formats"

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CMS

Summary of Benefits: PDP Only

Section 2

- SB comparison matrix generated by the PBP in chart format with the required language
- Order/content of information presented in the benefit comparison matrix must be the same as information presented in the PBP (exception for Section 3)

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CMS

**Summary of Benefits: PDP Only
(continued)**

Section 3

- Optional Section, no specific format, content limited to further discussion of covered Part D benefits from Section II
- Must reference the benefit comparison matrix (Section 2) if speaking of covered benefits
 - “See [page#] for additional information about [benefit category].”

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CMS

**Summary of Benefits:
MA-PD and Cost Plans**

- Must comply with requirements as described in Chapter 3 of the Medicare Managed Care Manual
- Generally mirrors standardized Summary of Benefits for PDPs
- Medicare Managed Care Manual:
http://www.cms.hhs.gov/manuals/116_mmc/mc86toc.asp

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**Optional Pre-Enrollment
Materials**

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Optional Pre-Enrollment Materials

- Pharmacy Directory
- Formulary
- Description of Drug Utilization Management
- Description of Medication Therapy Management Program (MTMP)

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Pharmacy Directory

- Geographic areas, but all directories together cover entire service area
- Chain pharmacies
- Non-chain pharmacies
- Disclaimers

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Formulary – Section 423.128 (c)(v)

- Comprehensive
- Abridged
- Special requirements

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CMS

Drug Utilization MTMP Descriptions

- May be included in Pre-enrollment Materials
- Plans can include:
 - Number of drugs or disease states included in the program
 - Description of utilization management methods, such as
 - Prior Authorization
 - Quantity Limits
 - Step Therapy

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Key Takeaways

- Beneficiaries have the resources and information they need to make an informed choice
- Categories of Pre-Enrollment, Advertising, and Post-Enrollment materials often overlap
- Refer to applicable sections within the Marketing Guidelines for specific content requirements

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Key Takeaways

Prospective beneficiaries must receive a Pre-Enrollment packet that contains, at a minimum:

- Cover Letter
- Enrollment Instructions and Forms
- Summary of Benefits
- Written notice to beneficiaries of possible termination of CMS's contract or reduction in the Plan's service area

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 **Thank you!**

For further questions, contact:

- **For PDPs:**
 - **PDP Marketing Resource Line**
 - **1-866-770-PLAN (7526). Activation date will be announced through HPMS.**
- **For MA-PDs:**
 - **Regional Office Contacts**

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Medicare Part D Plan Training

Formulary Review



Babette Edgar, PharmD, MBA
Director of the Division of Finance and Operations Medicare Drug Benefit Group
CMS






Formulary Review: Rationale

MMA requires CMS to review Part D formularies to ensure

- **Beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states**
- **Formulary design does not discriminate or substantially discourage enrollment of certain groups**



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Pre-Enrollment and Post-Enrollment Materials



Guiding Principles for Formulary Review

- **Relying on Existing Best Practices**
- **Provide Access to Medically Necessary Drugs**
- **Flexibility**
- **Administrative Efficiency**



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Pre-Enrollment and Post-Enrollment Materials

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Formulary Review: Approach

- Ensure the inclusion of a broad distribution of therapeutic categories and classes
- Utilize reasonable benchmarks to check that drug lists are robust
- Review tiering and utilization management strategies
- Identify potential outliers at each review step for further CMS investigation
- Obtain reasonable clinical justification when outliers appear to create access problems

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Formulary Information: Written Materials

Abridged Formulary

- Formulary definition and instructions of use
- Required Statements
- Formulary chart #1: Therapeutic Category/Class
 - Drug Name, brand name capitalized, generic in lower case italics. May enter generic name next to brand name
 - Tier Placement
 - UM edit if applicable
- Formulary chart #2: Alphabetical Listing

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Formulary Information: Written Materials

Comprehensive Formulary

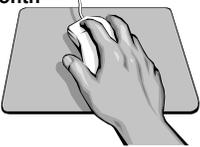
- Must be available by request
- Include same statements and explanations as abridged

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Website Options

- **Electronic copy of abridged and comprehensive formularies available for view and/or print**
- **Formulary search capability**
 - Includes same criteria as written formulary
- **Must be updated once a month**



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Review of Materials

- **File and Use Certification**
 - Abridged
 - Comprehensive
- **Re-review not required for updated formularies**
- **45 Day Review**
 - Other formulary documents



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Formulary Changes

- **Deletion of drug, change in tier cost sharing status**
- **Required communication**
 - Timeframe- 60 days
 - Content
 - Audiences



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Pre-Enrollment and Post-Enrollment Materials
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Thank you!

For further questions, contact:

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Medicare Part D Plan Training

Post-Enrollment Materials




Mori A. Hall, JD, LLM






Session Content

- **Purpose of Post-Enrollment materials**
- **Review process**
- **Required Post-Enrollment materials**
- **Specific Guidance on Post-Enrollment materials**

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MARKETING MATERIAL DEVELOPMENT GUIDELINES
Post-Enrollment Materials



Purpose of Post-Enrollment Materials

- **Used by Part D Plans to convey benefit or operational information to enrollees**
- **Includes all notification forms and letters, sections of a Plan's newsletter used to communicate with enrollees regarding membership policies and procedures**

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Post-Enrollment Materials

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Distribution at Time of Enrollment

Part D Plans **must** distribute the following materials to beneficiaries at the time of enrollment:

- Evidence of Coverage
- Summary of Benefits
- Formulary
- Pharmacy Directory
- ID Card

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Annual Distribution to Enrollees

The following materials **must** be distributed to enrollees annually:

- Annual Notice of Change
- Summary of Benefits
- Evidence of Coverage
- Formulary

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Explanation of Benefits

- An Explanation of Benefits (EOB) must be distributed at least monthly to enrollees for the months in which enrollees use their Part D benefits.
- The EOB must include:
 - Items or services for which payments was made
 - Notice of enrollee's right to request an itemized statement
 - Year-to-date statement of Part D Benefits provided in relation to the current year deductible and Initial Coverage Limit (ICL)
 - Cumulative year-to-date total of incurred costs
 - Applicable formulary changes

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Pop Quiz

Which one of the materials below may **NOT** be part of the Post-Enrollment materials sent to beneficiaries?

- A) Formulary
- B) Acceptance Letter
- C) Enrollment Form
- D) Pharmacy Directory
- E) Member Handbook

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Annual Notice of Change (ANOC)

- By October 31st of the current year, all Part D Plans are required to give members notice of program changes taking place on January 1 of the upcoming year.
- Model ANOC:
 - MA-PD – Available in the draft Medicare Advantage Marketing Guidelines
 - PDP – Will be developed during summer 2005

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Out of Network Pharmacy Access

Plans must include information within their marketing materials that inform individuals that they will have adequate access to covered Part D drugs dispensed on a non-routine basis by out-of-network pharmacies when the enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy.



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Mail Order Prescription Drug Service

Part D Plans must include a description of any mail order services that are offered, including:

- **The maximum expected turnaround time for processing and shipment**
- **A description of the process for enrollees to obtain a prescription if a mail order is delayed**
- **A toll-free telephone number (including toll-free TTY/TDD) to call if there are questions**

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Evidence of Coverage

EOC must include comprehensive information on the following:

- Service Area
- Benefits
- Premiums
- Cost-Sharing
- Network Pharmacy Information
- Out-of-Network coverage
- Grievance and Appeals Procedure
- Drug Utilization Management
- Medication Therapy Management Programs
- Quality Assurance
- Disenrollment rights and responsibilities

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Anti-Duplication Notices

- **Plans will not have to provide anti-duplication notices to Medicare beneficiaries.**
- **If Part D Plans choose to market to their enrollees other health insurance products that are not part of their contract under Part D, these other products will have to include an anti-duplication notice as required by Section 17 of the NAIC model regulation.**

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Post-Enrollment: Studies and Statistical Data

Plans may refer to results of studies or statistical data in relation to the following:

- Customer satisfaction
- Quality
- Cost, etc.



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Post-Enrollment Materials: Prohibited Use of Study Data

Plans *may not* use study or statistical data to directly compare their Plan to another Part D Plan.



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Use of Superlatives

Qualified superlatives *may* be used:

- “One of the best”
- “Among the highest”
- “Among the highest rank”



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Use of Superlatives

Absolute superlatives ***may not*** be used, ***unless*** substantiated with supporting data:

- “The best”
- “Highest ranked”
- “Rated number one”



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Availability of Alternative Formats

Plans must provide a disclosure on all Pre- and Post-Enrollment materials that alternative formats are available.

- Alternative formats include: Braille, foreign languages, audio tapes, large print, etc.



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Contracting Statement

The following Post-Enrollment marketing materials ***must*** include a statement either in the text of the material or as a footnote that the Plan contracts with the Federal government:

- Summary of benefits
- Member handbook
- Evidence of coverage

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True or False?

Part D Plans must distribute an Annual Notice of Change to new enrollees at the time of enrollment?

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Key Takeaways

- **There are required Post-Enrollment marketing materials that Part D Plans must distribute to beneficiaries at the time of enrollment and annually thereafter.**
- **The Summary of Benefits, Member Handbook, and Evidence of Coverage marketing materials must contain a contracting statement.**

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Thank You!

For further questions, contact:

- **For PDPs:**
 - **PDP Marketing Resource Line**
 - **1-866-770-PLAN (7526). Activation date will be announced through HPMS.**
- **For MA-PDs:**
 - **Regional Office Contacts**

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Medicare Part D Plan Training

Closing Remarks



Babette Edgar, PharmD, MBA
Director of the Division of Finance and
Operations Medicare Drug Benefit Group
CMS






Conference Takeaways

- **HPMS is the password protected Internet tool that is used to upload new or revised marketing materials and provides information on the status of materials undergoing review, including review due dates.**
- **Plans must refer to applicable sections of CMS marketing guidelines for specific content requirements.**
- **Using Model Language without modification, when available, will accelerate marketing material approval and distribution of materials into the marketplace.**

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Conference Takeaways

- **Categories of Pre-Enrollment, Advertising, and Post-Enrollment materials often overlap.**
- **Approved materials will be assigned a Material ID, which MUST be included on each piece of marketing material along with the date of approval.**
- **Any gratuity offered by a Part D Plan as a drawing/prize/giveaway, must be offered to all participants regardless of enrollment.**

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Conference Takeaways

- We want to help you meet your objectives!
- Plans can obtain help on a variety of issues related to materials development, guidelines interpretation, and material dispositions:
 - PDP Marketing Resource Line
 - 1-866-770-PLAN (7526). Activation date will be announced through HPMS.
 - MA-PD
 - Regional Office Contacts

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Your Feedback is Important!

- Post-test
- Satisfaction Survey



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Thank you!

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