Outreach to Physicians: What They Want to Know and the Limits on What You Can Tell Them

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I. What Do Physicians Want to Know About Medicare Part D?

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I. What Do Physicians Want to Know About Medicare Part D?
“Dear Health Professional:
People with Medicare will need to make a decision soon about Medicare’s new, voluntary prescription drug coverage that will be available beginning in January 2006 … That’s why we want to make sure you know the basics about Medicare coverage, so you can help your patients prepare for this important decision.” (bold added)
What Do Physicians Want to Know?

- What are the best plans for their patients?
- Whether and how they can advise their patients on plan selection?
- How to address the volume of questions they are getting on Medicare Part D and plan selection.
What Do Physicians Want to Know, cont’d

- Fundamental questions about how Part D works
  1. Will access to drugs differ among plans?
  2. How will plans be structured?
  3. What about dual-eligibles and other low-income beneficiaries?
  4. Are payments available to physicians under Part D?
  5. What should providers understand about the coverage distinctions between Medicare Part B and Part D?
II. Barriers to Marketing Part D Plans to Physicians
Barriers to Marketing to Physicians: Overview

- Provider internal policies and procedures
- Medicare marketing guidelines
- Legal Considerations
- Ethical considerations
Physicians and physician organizations may be hesitant to make health plan recommendations to patients

- Liability concerns
- Business concerns
- Lack of information about plan distinctions
Medicare Marketing Guidelines: Providers

- CMS encourages providers to educate beneficiaries, but there are limits to what providers are permitted to do and say.

- Provider Promotional Activities:
  - Activities a provider may perform to educate potential enrollees or to assist potential enrollees in enrollment.

- CMS is concerned with Provider Promotional Activities because
  - Providers may not be fully aware of all Plan benefits and costs
  - Providers may confuse the beneficiary if the provider is perceived as acting as an agent of the Plan vs. acting as the beneficiary’s provider.
Plan Sponsors must ensure that any provider contracting with the Plan:

- Agree to the same restrictions and conditions that apply to the Plan Sponsor
- Is prohibited from steering, or attempting to steer an undecided potential enrollee toward a plan, or limited number of plans
- Comply with any applicable co-branding requirements

“Contracting with the Plan”
Medicare Marketing Guidelines: Providers, cont’d

- Providers are NOT permitted to:
  - Accept any enrollment applications
  - Rank order or highlight any of the plans they discuss
  - Advocate for any particular group or plan
Providers may:

- Distribute and/or make available plan marketing material
- Provide patients with information about different plans’ benefits
- Educate patients on what kind(s) of plan(s) would be best for them
Provider’s may (cont’d)

- Allow presentations by plan representatives in their places of business
  - Must ensure that the presentation is in a common area with open access to anyone who wants to attend
  - Must ensure the presentation does not take place anywhere health care services are provided
  - If access to the presentation is at all restricted in any way, the presentation may be improper
Provider’s may provide comparative and descriptive plan information, subject to the following:

- Materials may not “rank order” or highlight specific Plans
- Only include objective information
- Must have concurrence of all Plans involved in the comparison
- Must be approved by CMS prior to distribution
- Plans may NOT use providers to distribute comparative information UNLESS providers accept and display materials from all plans in the service area that contract with the provider.
Provider Marketing Guidelines, Cont’d

- Provider web sites
  - May provide links to Plan enrollment applications and/or provide downloadable enrollment applications
  - Site must provide the links/downloadable formats to enrollment applications for ALL plans with which the provider participates
  - May link to CMS Online Enrollment Center
Other Legal Considerations

- Legal Considerations
  - Anti-kickback Statute
  - False Claims Act
  - HIPAA
  - OIG Compliance Program Guidance

- Ethical Considerations
  - American Medical Association (AMA) Code of Ethics

- State Law
Federal Anti-Kickback Statute

- 42 U.S.C. §1320a-7b
- Felony
- Knowingly and Willfully
- Offer, Solicit, Give or Receive
- Remuneration in Exchange for
- Referral or Arranging or Recommending
- Item Payable by Federal Health Care Program
Anti-Kickback Statute, cont’d

- One purpose test
- Broad construction
- Safe harbors
- Effect if not in a safe harbor
- Special fraud alerts
Anti-Kickback Statute: Special Fraud Alert

- December 19, 1994

- If one purpose of any prescription drug marketing scheme is to induce the provision of a prescription drug item reimbursable by a federal health care program, the criminal anti-kickback statute is implicated

- A payment or gift may be considered improper if it is:
  - Made to a potential referral source
  - Related to the volume of business generated
  - More than nominal value and/or exceeds fair market value
31 U.S.C. §3729

- Imposes civil liability on any person or entity who submits a false or fraudulent claim for payment to the United States government.
- “Knowingly”
- Illegal marketing schemes can result in the submission of false claims
42 U.S.C. §1320d et seq.

MUST comply with HIPAA Privacy Rule and its specific rules regarding uses and disclosures of beneficiary information.

Marketing means: “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. . . .” 45 C.F.R. 164.501

Exceptions to authorization requirement

- Face to face communication
- Promotional gift of nominal value

Marketing restrictions will NOT apply if physician does not “encourage” the use of one Plan over another
OIG Compliance Program Guidance for Pharmaceutical Manufacturers

- Compliance with the Guidance is voluntary
- OIG outlines the elements it believes are necessary for an effective compliance program (e.g. compliance officer, training, policies and procedures, etc.)
- Expansive application of the anti-kickback statute to pharmaceutical marketing
To prevent business arrangements from being viewed as suspect, the Guidance suggests that manufacturers ask the following questions:

- Does the arrangement or practice have potential to interfere with or skew clinical decision-making? Is all provided information fully accurate?
- Does the arrangement or practice have the potential to increase costs to the federal healthcare program?
- Does the arrangement or practice have the potential to increase the risk of overutilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?
Opinion E-8.061: Gifts to Physicians from Industry

- Gifts should primarily entail a benefit to patients
- Should not be of substantial value
- Gifts of minimal value allowed if related to the physician’s work (e.g. pens and notepads)
- Textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function
III. How Can You Market Part D Plans to Physicians?
Marketing to Physicians, cont’d

- Many outreach opportunities
  - Provide plan materials to physicians
  - Educate physicians
  - Educational luncheons with office staff
  - Gifts of minimal value if related to physician’s work (e.g. pens, notepads)
Marketing to Physicians, cont’d

- Gifts for physicians that provide a benefit to beneficiaries
- Promotional activities for beneficiaries in common areas of physician offices
- Nominal gifts (less than $15) for beneficiaries who attend a marketing presentation at a physician’s office
IV. Compliance Tips
Compliance Tips

- Prepare a compliance plan (or adapt your current plan) to account for Part D issues
- Train key staff (e.g. management, sales force, marketing staff) and provide clear guidance regarding physician outreach
  - Appropriate methods of outreach, including $ limits on meals, types of permissible gifts, etc.
  - Types of plan materials available to physicians
  - How to educate physicians on plan features
  - Role playing
- Educate physicians on Part D marketing restrictions
Compliance Tips, cont’d

- Review receipts – is the sales force complying with the limits on $ and type of meals?
- Perform monitoring activities
- Follow-up with physicians
  - Does the physician have any concerns or questions about the plan?
  - Does the physician understand the marketing restrictions?
  - What type of interaction did the physician have with plan staff?
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