THE HENRY J. KAISER FAMILY FOUNDATION

MEDICARE

ISSUE BRIEF

THE FEDERAL GOVERNMENT'S AUTHORITY TO REGULATE ADVERTISING IN MEDICARE

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Congress has held several hearings concerning marketing and sales practices by private Medicare plans. Often the focus of these hearings has been on sales practices by plans, their agents and their brokers, and the extent to which more oversight of those practices is required.[1] A related question, and one not directly addressed at the Congressional hearings, is the extent to which the agency within the Department of Health and Human Services (HHS) that oversees the Medicare program, the Centers for Medicare & Medicaid Services (CMS), has the legal authority to regulate advertising by Medicare Advantage (MA) plans and prescription drug plans (PDPs)[2]. Further, if CMS has such authority, is the agency doing all that it can to ensure that Medicare beneficiaries get all of the information they need to make informed choices about delivery of their health care?

This policy brief explains the legal authority of CMS to regulate advertising and information issued by the private companies with which it contracts to provide a public benefit to Medicare beneficiaries. The policy brief contains an analysis of relevant statutory, regulatory, and case law. It also suggests additional steps CMS could take to protect consumers under its current authority.

STATUTORY AUTHORITY

Marketing Standards

In 1997, when Congress created Medicare Part C, then known as the Medicare+Choice program, Congress included provisions concerning marketing of the private plans offered under the newly created Medicare component.[3] Some of the provisions address marketing activities by health plans and their agents and so are not relevant to the authority to regulate the content of plan advertisements.[4] Other provisions, however, create a specific process for review by HHS of the content of all marketing materials and application forms. This review is conducted by CMS.

The statutory provisions prohibit health plans from distributing marketing materials and application forms until at least 45 days after submitting such materials to CMS for review. CMS is to review each material and form under guidelines it develops to determine whether the material or form is "materially inaccurate or misleading or otherwise makes a material misrepresentation."[5] Congress envisioned that CMS would develop standard language for such materials and accorded marketing materials that follow model CMS language special treatment. The statute provides that marketing materials that use model language created by CMS without any modification only need be submitted to CMS 10 days in advance of their use.[6] Materials approved for use in one area of the country are deemed approved for use in other areas without the need for additional review.

When Congress created Medicare Part D in 2003, it gave CMS the same authority as under Part C over marketing materials and application forms developed and used by Part D PDPs. The Part D statute says that the Part C statutory provisions apply to Part D marketing. Hence, Part D plans must submit their marketing materials and applications forms to CMS for review 45 days before distribution, with a shortened time frame for materials that use the model CMS language.[7]

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted in July 2008, added statutory provisions concerning marketing to include further restrictions on activities by plans, their agents, and brokers. MIPPA also requires that, for plan years beginning on or after January 1, 2010, the name of each MA plan and each PDP must include the plan type. The Secretary of HHS is authorized to develop standard terminology to be used by MA plans.[8]

Congressional delegation to HHS of authority to regulate marketing by private plans did not begin with Medicare Part C. Even before Part C was enacted, Congress had authorized HHS to regulate marketing for Medicare supplemental health insurance (Medigap) policies, which are offered by private companies. The relevant statutory provisions authorize HHS to oversee standards for the type of Medigap policies to be sold, when the policies may be sold, and to whom they may be sold. They include disclosure statements and notice requirements, and they establish both civil and criminal penalties for statutory violations.[9]

REGULATORY AUTHORITY

Authority to Issue Regulations

The Medicare statute contains an express delegation to HHS, and hence to CMS, to make and publish rules necessary to the efficient administration of the Medicare program.[10] This delegation of authority has been recognized and cited by various federal courts throughout the years,[11] including in cases involving complaints against health care plans and their agents for marketing fraud in the sale of MA plans.[12]

Additionally, Congress specifically authorized HHS to establish, through regulation, standards for Part C plans that are consistent with Part C and that are necessary to carry out the rest of the Part C statutory provisions. Congress authorized HHS to create, periodically review, and revise standards for Part D PDPs, with the caveat that regulations that impose new, significant regulatory requirements on a drug plan or its sponsor may only be implemented at the beginning of a calendar year.[13]

What the Regulations Say

The Part C and Part D marketing regulations contain virtually identical language. The regulations define marketing materials as materials targeted to Medicare beneficiaries. Marketing materials promote a Part C or Part D plan, inform beneficiaries that they may enroll or remain enrolled in a plan, explain the benefits of enrolling in the plan or the rules that apply to enrollees, and, most significantly, explain how services are covered, including any conditions that apply to such coverage.[14] According to the regulations:

> Examples of marketing materials include, but are not limited to: general audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet.[15]

As required by the Medicare statute, the regulations establish standards for CMS review of all marketing materials and enrollment forms and indicate that CMS may provide additional

standards in guidance. CMS review includes a determination that materials provide information "in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS…"[16] Among the information to be provided is an "adequate" written description of plan rules, including network limitations, and information necessary to help beneficiaries "make an informed decision" about whether to enroll in the plan. CMS must also determine that marketing materials "are not materially inaccurate or misleading or otherwise make material misrepresentations."[17]

CMS Guidelines

CMS issues Medicare Marketing Guidelines (Guidelines) for MA plans and PDPs, as well as for the other private Medicare health plans such as cost plans, to supplement and expand upon the regulations. The Guidelines are relied on heavily by plans and by CMS. However, the Guidelines and other such agency guidance manuals are not enacted pursuant to the same formal legal process as are regulations, which require publication in the Federal Register and an opportunity for public comment before they are adopted as final. As a result, they are not accorded the same legal deference as are regulations when a question arises about the agency's interpretation of the governing statute[18]. Nonetheless, as a practical matter, the Guidelines often drive day-to-day decisions by plans and their agents.

The Guidelines define marketing materials in more detail than the regulations and include a definition of advertising. Advertising materials include radio, television, and print ads.[19] They must include a statement that the organization contracts with the federal government. Radio and TV ads must include the plan's toll-free number. In addition, the Guidelines provide suggested language for Medicare sponsors to disclose information about plan and benefit restrictions and limitations. For example, CMS recommends marketing materials for HMOs include the statement, "enrollees must receive all routine care from plan providers; care provided by an out-of-network provider will not be covered by Medicare or the plan." CMS also recommends that private fee-for-service plans state that the "doctor or hospital must agree to accept the plans' terms and conditions prior to providing services, except emergencies."
In some areas, the Guidelines provide greater flexibility for plan advertisements than for other marketing materials. For example, advertisements are not expected to contain as much detailed information as other marketing materials. Additionally, while all pre-enrollment and post-enrollment materials must be printed in 12-point font size, the Guidelines allow plans to use smaller font sizes in advertisements, other than brochures and direct mail pieces, as long as the majority of the text and the footnotes are in the same font size.[20]

The Guidelines also establish an expedited review process for certain marketing materials and enrollment forms that is not found in the regulations. "File & Use" review is designed to streamline CMS review where organizations use model materials without modification or sponsoring organizations certify they have followed the Guidelines. Advertisements are among the marketing materials that are eligible for the streamlined File & Use review.[21]

The File & Use process has two separate components. Under File & Use Certification, the sponsoring organization submits the marketing materials to CMS five days before their distribution along with a certification by its chief executive officer or chief financial officer that

the materials are accurate, truthful, and not misleading. The model File & Use Certification contained in the Guidelines states that the organization agrees to retract and revise materials that CMS determines to be misleading or inaccurate, and that organizations may be accountable for beneficiary financial loss as a result of mistakes in marketing materials. Since 2006, the Guidelines have strongly encouraged all organizations to use File & Use Certification for all marketing materials that qualify for reduced review. [22]

In addition, CMS determines that some organizations qualify for less stringent review and they can submit certain marketing materials, including advertisements, five days in advance without a certification under File & Use Eligibility. Organizations that qualify for File & Use Eligibility have had contracts with CMS for at least eighteen months, or have submitted eighteen months worth of materials, and 90% of the materials reviewed for the previous six months must have been found to be acceptable by CMS. An organization can lose its eligibility by distributing materials that are not acceptable, i.e., that are misleading or inaccurate, or by failing to file two or more marketing materials five days in advance of distribution.[23]

CONTRACT PROVISIONS

Private entities that offer health plans under Medicare Part C and/or Part D do so pursuant to contracts with CMS.[24] CMS is authorized to include in its contracts with Part C plans any terms and conditions that the agency finds necessary and appropriate, so long as such provisions are not inconsistent with the Medicare statute.[25] Part D plan sponsors, as part of their contract, must agree to comply with the applicable requirements and standards and the terms and conditions of payment under Part D.[26]

Each year CMS issues a "Call Letter" that provides private health plan sponsors information needed to offer a health plan under Part C or Part D for the following year. The 2009 Call Letter, issued on March 17, 2008, for entities wishing to continue their contracts or to offer new contracts in 2009, contains an entire section devoted to marketing.[27] The Call Letter indicates that CMS will be moving towards standardized documents, rather than model documents, "to reduce variability and to ensure documents are more understandable and free of errors…"[28] The Call Letter also describes additional quality control measures that CMS will institute in response to the many inaccurate or incomplete marketing materials they have received.[29]

COURT CASES

There are no reported court decisions involving a challenge by a Part C or Part D plan sponsor to the authority of CMS to regulate marketing activities. On the other hand, several law suits have been filed in recent years by Medicare beneficiaries who allege that Part C or Part D organization marketing activities, including advertising, violate various state consumer protection and other state laws. In defending these law suits, health plan sponsors rely on CMS's authority to regulate health plans as part of their litigation strategy.[30] They allege that federal authority to oversee private health plans requires the cases to be litigated in federal court, not in state court, and/or preempts the state law claims. One court referred in its decision to the authority of CMS to regulate MA plans,[31] but none of the courts have addressed the authority of CMS to issue marketing regulations or guidance or the content of the regulations or guidance.

Courts also have not addressed specifically the issue of whether CMS can impose restrictions on the content of any marketing materials issued by Part C and/or Part D organizations. Based on other court rulings, however, it is unlikely that a challenge to CMS regulations would succeed. The Supreme Court has ruled that regulations issued by the Secretary of HHS, which prohibit recipients of funds under Title X of the Public Health Service Act from engaging in abortion counseling, did not violate the First Amendment. Applying the ruling in that case to Medicare marketing issues, a Part C or Part D sponsoring organization would have to show that the requirements imposed by CMS on plan advertising restrict speech outside the context of the Medicare program in order to be successful in its challenge. As the Supreme Court stated, ". . . when the Government appropriates public funds to establish a program it is entitled to define the limits of that program." [32]

OPPORTUNITIES FOR IMPROVED OVERSIGHT

The Part C and Part D programs are premised on beneficiaries having sufficient information to make an informed choice about how they receive their Medicare benefits.[33] Congress gave CMS broad authority to make sure that marketing materials, including advertisements, are clear, accurate, and not misleading. Using existing authority, CMS can take a number of additional steps to ensure that advertisements are used effectively to promote consumer choice.

Stronger Oversight of Plan Marketing Materials

First and foremost, CMS could use its existing statutory and regulatory authority to engage in greater oversight of plan materials. CMS has the authority to take corrective action against sponsoring organizations that misrepresent or falsify information to CMS or to individuals. CMS may impose civil money penalties against a plan, suspend marketing activities, suspend enrollment, and/or suspend payment. These sanctions are supposed to remain in place until CMS determines that the plan corrected the activity which gave rise to the sanction and until CMS is satisfied that the activity will not reoccur.[34]

In an ideal world, however, oversight would occur before advertisements reach the marketplace and not in response to complaints arising from inaccurate or misleading information. While the shear number of marketing materials may make review of every document difficult, Congress outlined in the Medicare statute a process for CMS to follow that takes into account the difficulty of the task. Plans can submit their advertisements and other marketing materials to CMS closer to distribution time if they use model language without modification. Ads approved for use in one region of the country can be used in all regions without re-submission.

CMS' File & Use review process helps health plans and CMS by providing for a shorter time frame for advance submission of advertisements than Congress authorized for materials that use model language (5 days in advance of distribution as opposed to 10 days). From a consumer perspective, however, the File & Use process does not provide a sufficient opportunity for agency oversight and review.[35] The very short time frame for submission before distribution makes it less likely that CMS will actually look at the materials or, if the agency does review them, will have sufficient time to catch misrepresentations and subtle marketing ploys. Virtually

any sponsoring organization can use the File & Use Certification process for submission of ads, even if the ads do not use CMS model language, and even if CMS has rejected the organization's marketing materials previously.

Furthermore, it is unclear whether CMS even has the authority to implement File & Use review as the system provides for a shorter time frame for review than the Medicare statute. The Marketing Guidelines that delineate the process were not adopted pursuant to the more formal process for adopting regulations. As discussed below, courts have not given deference to agency interpretations of a statute that conflict with a clear statutory statement and that are agency guidance, not regulations.[36]

The Supreme Court established a hierarchy of authority when questions arise concerning a government agency's interpretation of a statute. Clear, unambiguous statutory language rules over an agency interpretation that conflicts with the statute. If the statute is unclear or silent, courts will defer to an agency's interpretation where Congress delegated to the agency the authority to issue rules, and the agency's interpretation was promulgated under that authority. [37] Not all agency interpretations qualify for deference, however, and courts look differently at regulations and agency policy manuals. The Supreme Court twice declared that deference was not due to agency interpretations contained in agency manuals. The fact that a contract between CMS and another entity requires the entity to comply with CMS guidance does not give CMS interpretation contained in its manual the same legal effect as the statute or regulations.[38] Since the Medicare statute is clear and unambiguous concerning the time frames for review of Part C and Part D marketing materials, an argument may be made that CMS lacks authority to shorten that time frame through its File & Use review.

Additionally, the Office of Inspector General (OIG) continues to report that CMS oversight of marketing materials has not been as thorough and consistent as it could be.[39] Most recently, the OIG reviewed Part D marketing materials, including advertisements. The OIG found, among other things, that CMS at the time of the report had not completed a retrospective review of materials approved under the File & Use process to determine whether the materials followed CMS standards; that review of marketing materials conducted under the standard review process were inconsistent; that CMS does not include elements pertaining to marketing materials in its performance audits of Part D plans; and that the CMS system for tracking marketing materials could not identify all of the materials filed. Seventy-three percent (73%) of advertisements reviewed did not adhere to at least one element of the Guidelines. The OIG reiterated its recommendation from its 2000 report that CMS develop standard review instruments for marketing materials, and suggested that the protocols be included in the Marketing Guidelines. The OIG also recommended that CMS increase its monitoring of File & Use materials by conducting more frequent and more complete retrospective reviews, and that CMS enforce use of the current tracking system for materials.[40]

If CMS continues the File & Use processes, it could also restrict File & Use Certification review to materials that use language and/or a format it developed. Where CMS determines that an ad is misleading or inaccurate, CMS could hold the sponsoring organization financially responsible to an aggrieved beneficiary for his/her resulting losses, as the model File & Use Certification states, so that beneficiaries do not have to pay for health care costs that otherwise would have been paid

for by Medicare.[41] Currently, beneficiaries may be allowed to disenroll from a plan based on misleading or inaccurate advertisements or other marketing activities. They are not compensated, however, for out-of-pocket expenses for the health services that would otherwise have been covered by Medicare or a Medicare supplemental insurance (Medigap) policy had they not changed health coverage based on misleading promises in advertisements.[42]

CMS could also tighten the criteria it uses to determine File & Use Eligibility, limiting its use to organizations that have had contracts with CMS for three or more years and requiring that all reviewed marketing materials within the past year have been accurate. Additionally, CMS could perform spot checks of advertisements to ensure that organizations continue to comply with all of the requirements.

CMS has used its enforcement powers to suspend marketing activities by sponsoring organizations where the organizations and their agents have engaged in activities such as door-to-door sales and misleading sales presentations that violate the Medicare statute, regulations, and Marketing Guidelines. CMS could apply similar sanctions against sponsoring organizations that consistently use radio, television, and print advertisements that misrepresent or misinform the public about plans offered by the organizations.

Standardized Forms and Language

CMS could ease its oversight burdens by requiring greater use of standardized forms or standardized language. The use of more standardized forms and language would also help consumers by reducing inaccurate and misleading materials, including advertisements.

Standardized forms and language are different from model language and documents. Unlike model documents, standardized documents and standardized language are not created by CMS in isolation. CMS is required by federal law to solicit input from all interested parties when it proposes to require the use of standardized documents. Pursuant to the Paperwork Reduction Act (PRA) of 1995, all federal agencies must post a notice in the Federal Register and provide the public with an opportunity to comment on the proposed documents to be used, both as to content and as to the burden of having to comply with the agency requirement.[43] While CMS sometimes uses its various electronic mailing lists to solicit comments from stakeholders on its draft model documents,[44] there is no official publication of these documents in the Federal Register as there is with publication of standardized documents subject to the PRA. Thus, standardized documents that go through the PRA process may be compared to regulations which go through a similar notice and comment process. Model documents may be compared to the more informal agency guidance such as the Marketing Guidelines. Plans are bound to use standardized documents while they may not be bound to use model documents.

CMS acknowledges that plans do not use suggested or model language. Hence, the announcement in the 2009 Call Letter of the move towards standardized materials, starting with the standardized combined annual notice of change (ANOC) and evidence of coverage (EOC) for the 2009 plan year. Because the ANOC/EOC is now a standard document, rather than a model document, CMS published a notice in the Federal Register announcing use of the standard ANOC/EOC and giving the public the opportunity to comment on its use.[45]

The ANOC/EOC is not the first time that CMS has exercised its statutory and regulatory authority to require the use of standardized materials developed by the agency, however. CMS has required MA plans and PDPs to use a standardized summary of benefits (SB), which provides current and potential enrollees with information about the benefits offered by the plan, for many years.[46] CMS requires plans to use other standardized documents such as notices of appeal rights at certain levels of the Part C and Part D appeal processes.[47]

Moreover, CMS' explanation for the use of the standardized ANOC/EOC – "to reduce variability and to ensure documents are more understandable and free of errors…"[48] – and its explanation for use of the standardized SB – "to allow beneficiaries to more easily compare the benefits offered by different organizations"[49] – are equally applicable to the advertisements developed by health and drug plans. Television, radio, and print ads can be misleading, particularly if they do not contain pertinent information. And, without common elements, it can be difficult to compare the products in the different ads. CMS has the same authority over these marketing materials as over the ANOC/EOC and SB. Thus, CMS could require, for example, that all television, radio, and print ads contain standard elements, such as plan name and type, premium amount, and network and other restrictions.

CMS also has the authority to require plans to use the language concerning plan networks and other requirements that it has already developed. Congress implicitly assumed that CMS would develop standardized language when it authorized CMS to expedite review of materials that do not deviate from the language developed. CMS will need to develop standardized plan names and descriptions pursuant to the new provisions in MIPPA, and the new language will need to be in place before marketing begins for the 2010 plan year. CMS could issue a PRA notice that allows the public to comment on the current language concerning networks as well as the language concerning standardized plan names.

CMS will need to be vigilant in both developing standardized documents and in overseeing their use. The recent report by the OIG on marketing materials for prescription drug plans found that both model and standardized documents for PDP sponsors were inconsistent with the Marketing Guidelines and failed to include specific language the Guidelines require to be included in the documents. The OIG also found problems with language developed by plan sponsors. The OIG recommended that CMS continue its efforts to revise model and standardized documents so that they include all of the required information.[50]

Font Size

CMS could eliminate the distinction in its Marketing Guidelines concerning font size for print ads and font size for other materials. Unlike pre- and post-enrollment marketing materials, ads satisfy the Guidelines if they use a font size that is smaller than 12 points, and the "majority" of the text and footnotes are in the same, undefined font size. Although these other materials convey more detailed information about plans and benefit structure, the reasons to establish a minimum font size are the same for all marketing materials. As the Guidelines state with regard to font size for plan member materials, "[r]eadability of written materials is crucial to informed choice…"[51]

Additionally, the Guidelines do not define the term "majority." This leaves open the possibility for 49% of a print advertisement to be in a font that is difficult to read for people with visual impairments. There are no restrictions on the information that could be in the smaller print size. Advertisements could be required to use 12-point font. If they contain different font sizes, CMS should require, at a minimum, that all CMS-required standardized language be in the larger, 12-point font.

Other Suggestions Concerning the Content of Advertisements

Types of plans: Consumers experience confusion when ads contain generic statements about plans offered by a specific sponsor without identifying the type of plan. The new statutory requirement that plan names also include their plan type will help in ads that use a plan name. For example, a sponsor will have to refer to its plan as "Gold Plan HMO," rather than just "Gold Plan." The requirement does not address the confusion that arises when ads refer only to the sponsoring organization and do not indicate that that organization may offer multiple MA plans as well as multiple PDPs. CMS could limit advertisements from a plan sponsor to one type of plan, for example, HMOs or PPOs, rather than allowing ads to appear as if all of the offerings from the sponsor are for the same type of plan. Where CMS allows marketing materials to promote more than one type of plan, the materials could list benefits separately so as to distinguish among the plans offered.[52]

Ads directed towards the larger Medicare population: Enrollment in a Part C or a Part D plan is generally open to all Medicare beneficiaries, regardless of age and health status, who live in the plan's service area and who have the requisite parts of Medicare.[53] Other than Special Needs Plans (SNPs), which can limit enrollment to certain populations, Part C plans are prohibited from discriminating in enrollment and coverage, including discrimination based on health status.[54] Part D plans must have sufficient access to pharmacies in their network, including pharmacies that serve residents of long-term care facilities.[55] Thus, Part C and Part D plans in their advertising campaigns need to make sure that they reach out to all populations of Medicare beneficiaries who live in their service areas, regardless of age, health status, race, or ethnicity. CMS could review ads more carefully to ensure that they are directed to the larger Medicare population.

Endorsements: Many advertisements contain endorsements by individuals who are purported to be enrolled in the plan being advertised. Some contain endorsements by celebrities such as sports and television stars. CMS could incorporate into its Guidelines and its plan contracts a reminder that plan sponsors are required to comply with the standards developed by the Federal Trade Commission (FTC) for endorsements and testimonials in advertisements.[56] Under FTC rules, endorsements do not have to use the exact words of the endorser, but they must reflect the endorser's opinions or experiences. They cannot contain representations that are deceptive or that cannot be substantiated. If the endorser is a celebrity, then the advertiser must continue to make sure that the endorsement remains the view of the celebrity. If the advertisement says that an endorser used a product, the endorser must be a true user.[57] Unless an advertisement uses actual consumers, ads that appear to present an endorsement from consumers must disclose that the endorsers are not actual consumers.[58] It is unclear whether endorsements and testimonials in

advertisements that do not differentiate among the plans offered by a particular sponsor meet the FTC standards, given that the endorser may only have knowledge about one particular plan. CMS could reject any advertisement that is questionable and refer the advertisement to the FTC for review.

Other Opportunities to Reduce Confusion in Advertising

Not all of the problems generated by advertising by Part C and Part D plan sponsors can be addressed by changes to marketing standards or review of marketing materials. Some of the confusion results from the nature of the program itself. Part C and Part D provide for a wide array of plan types with different benefit structures and other variables concerning access to care. The large number of plans approved by CMS means that beneficiaries may be overwhelmed by advertisements. Even where the number of plan sponsors is limited, each plan sponsor may be approved by CMS to offer so many plans that advertising for those plans becomes difficult to understand. CMS could use its contract process to limit the number of plans each organization can offer in an effort towards reducing confusion. Congress could take steps to standardize benefit packages, making comparisons easier for beneficiaries.

Plan names can be an advertisement in and of themselves. Plans may have words like "value" or "gold" or "reward" as part of their name. Some sponsors offer several different plan types with the same or similar name. An advertisement for Organization X's "Silver Plan" may in fact be an advertisement for several different MA plans and several different PDPs all of which have the word "Silver" in their name.[59] CMS could correct this through the plan bid process by requiring that plans use more relevant terms in their titles, and by rejecting multiple plan offerings from a plan sponsor where each has the same or a similar name.

CONCLUSIONS

CMS oversight of Part C and Part D plan television, radio, and print advertisements stems from statutory, regulatory, and sub-regulatory authority. Many of the mechanisms are already in place to ensure that ads convey accurate and complete information to beneficiaries about the plans that are available to them. CMS could provide additional protections and ensure dissemination of more effective information by enforcing current standards for advertisements and by utilizing its existing authority to toughen requirements on the content and format of advertisements.

[1] See, e.g., Senate Finance Committee Hearing, Selling to Seniors: The Need for Accountability and Oversight of Marketing and Sales by Medicare Private Plans, Feb. 7, 13, 2008; http://finance.senate.gov/sitepages/hearings.htm; Senate Select Committee on Aging, Field Hearing: What Seniors Don't Know Before They Enroll - Aggressive Sales of MA Plans in Missouri , June 30, 2008 http://aging.senate.gov/hearing_detail.cfm?id=300238&

[2] For a discussion of advertising by Medicare private plans, see, I. Cai., G. Kreps, J. McAuley, X. Zhao, M. Kitchman Strollo, T. Neuman, K. Boortz, *Pitching Private Medicare Plans: An Analysis of Medicare Advantage and Prescription Drug Plan Advertising* (September 2008). See, also, Subcommittee on Health, House Committee on Ways & Means, Hearing on Medicare Advantage, March 21, 2007, statement for the record by the Center for Medicare Advocacy. http://waysandmeans.house.gov/hearings.asp?formmode=view&id=5845

[3] The name of the Part C program was changed to Medicare Advantage as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108-73 (December 8, 2003).

[4] 42 U.S.C. § 1395w-21(h)(4).

[5] 42 U.S.C. § 1395w-21(h)(1), (2).

[6] 42 U.S.C. § 1395w-21(h)(5).

[7] 42 U.S.C. § 1395w-101(b)(1)(B)(vi).

[8] The Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275 (July 15, 2008), Section 103, amending 42 U.S.C. §§ 1395w-21(h), 1395w-104(l).

[9] 42 U.S.C. § 1395ss.

[10] 42 U.S.C. § 1302(a).

[11] *See*, e.g., Crestview Parke Care Center v. Thompson, 373 F.3d 743 (6th Cir. 2004);
Transitional Hospitals Corp. of Louisiana, Inc. v. Shalala, 222 F.3d 1019 (D.C. Cir. 2000);
State of N.Y. v. Sullivan, 802 F.Supp. 752 (N.D.N.Y.,1992), aff'd sub.nom. State of N.Y. v. Health and Human Services, 992 F.2d 321 (2d Cir. 1993).

[12] Harris v. Pacificare Life & Health Ins. Co, 514 F.Supp.2d 1280 (M.D. Al. 2007).

[13] 42 U.S.C. §§ 1395w-26(b)(1), 1395w-112(f).

[14] 42 C.F.R. §§ 422.80(b)(1)–(4); 423.50.

[15] 42 C.F.R. §§ 422.80(b)(5); 423.50(c). The Part C and Part D regulations differ in the capitalization, or lack thereof, of "internet."

[16] 42 C.F.R. §§ 422.80(c)(1); 423.50(d)(1).

[17] 42 C.F.R. §§ 422.80(c); 423.50(d).

[18] *Barnhart v. Walton*, 535 U.S. 212 (2002); *U.S. v. Mead Corp.*, 533 U.S. 218 (2001); *Public Citizen v. H.H.S.*, 332 F.3d 654 (2003) (holding that the pronouncements in the Medicare PRO manual were inconsistent with the Medicare statute).

[19] Medicare Marketing Guidelines, (Guidelines) Section 2, Definitions, at pg. 5.
http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf.

[20] Guidelines, pgs. 22, 31, 48.

[21] Guidelines, pgs. 89, 99.

[22] Guidelines, pgs. 99-102.

[23] Guidelines, pgs. 102-105.

[24] 42 U.S.C. §§ 1395w-27 (a); 1395w -112(b).

[25] 42 U.S.C. § 1395w-27(e)(1).

[26] 42 U.S.C. § 1395w-112(b)(1).

[27] 2009 Call Letter, http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf.

[28] 2009 Call Letter, pg 84. The first standardized document is a combined Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) sent to current plan enrollees in advance of the annual coordinated enrollment period that begins on November 15.

[29] 2009 Call Letter, pg 85. Note that the Call Letter uses the general term "marketing materials" without indicating whether the inaccurate materials included advertisements.

[30] *See*, e.g., *Harris v. Pacificare Life & Health Ins. Co.*, 514 F.Supp.2d 1280 (M.D. Al.2007); *Dial v. HealthSpring*, 501 F.Supp.2d 1348, (S.D. Ala. 2007); *Williams v. Viva Health, Inc.*, 2008 WL 220799 (M.D. Ala. Jan. 25, 2008). *Bolden of HealthSpring of Ala.* 2007 WL 4403588 (S.D. Ala. 2007), *Uhm v. Humana*, 2006 WL 1587443 (W.D.Wash. 2006). Plaintiffs in the *Uhm* case alleged that they chose the defendant prescription drug plan based on its advertising materials.

[31] *Harris v. Pacificare Life & Health Ins. Col*, 514 F.Supp.2d at 1290.

[32] *See Rust v. Sullivan*, 500 U.S. 173, 197 (1991).

[33] For example, the Medicare statute authorizes CMS to provide for broad dissemination of information about Part C plans "to promote an active, informed selection" among plan options. 42 U.S.C. § 1395w-21(d)(1).
[34] 42 C.F.R. §§ 422.750; 422.752(a)(5); 423.750; 423.752(a)(5).
[35] It is unclear whether CMS even has the authority to implement File & Use review as the system provides for a shorter time frame for review than the Medicare statute. Furthermore, the Marketing Guidelines that delineate the process was not adopted pursuant to the more formal process for adopting regulations.
[36] Endnote 16, *supra*.
[37] *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842-843 (1984); *U.S. v. Mead Corp*, 533 U.S. 218, 226-227 (2001); *Christiansen v. Harris County*, 529 U.S. 576, 587 (2000).
[38] *Public Citizen v. U.S. Department of Health and Human Services*, 332 F.3d 654, 660-661 (2003).
[39] See, e.g., OIG, "Medicare Managed Care – 1998 Marketing Materials," OEI-03-98-00271 (Feb. 2000); OIG, "Assessment of Sponsors' Materials Under the Temporary Medicare Approved Drug Discount Card Program," OEI-05-04-00190 (Oct. 2005); OIG, "Medicare Advantage Marketing materials for Calendar Year 2005," OEI-01-05-00130 (Aug. 2006).
[40] OIG, "Marketing Materials for Medicare Prescription Drug Plans," OEI-01-06-00050 (Sept. 2008), http://www.oig.hhs.gov/oei/reports/oei-01-06-00050.pdf.
[41] Marketing Guidelines, pg 102.
[42] Draft White Paper Addressing Marketing by Medicare Private Plans, Medicare Private Plans Subgroup, Senior Issues Task Force, National Association of Insurance Commissioners (August 6, 2008) (Draft White Paper) pgs 9-10, http://www.naic.org/documents/committees_b_senior_issues_medpp_080806_whitepaper_draft.doc.
[43] 44 U.S.C. § 3506(c)(2)(A).
[44] *See*, for example, the July 31, 2008, memorandum soliciting comments to a draft Chapter 13 of the Prescription Drug Manual, which includes notices to beneficiaries eligible for the Part D low-income subsidy. http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/DraftPDBMChap13_LIS_07.31.08_wAppendices.pdf
[45] 73 Fed. Reg. 47953 (Aug. 15, 2008), http://edocket.access.gpo.gov/2008/pdf/E8-18957.pdf.
[46] Marketing Guidelines, pg. 35.
[47] *See*, CMS Pub. 100-16, Medicare Managed Care Manual, Chapter 13: Grievances, Organization Determinations, and Appeals, http://www.cms.hhs.gov/manuals/downloads/mc86c13.pdf; Prescription Drug Manual, Chapter 18: Part D Enrollee Grievances, Coverage Determinations, and Appeals, http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/PartDManualChapter18.pdf.
[48] 2009 Call Letter, pg 84.
[49] Marketing Guidelines, pg. 35.
[50] OIG, "Marketing Materials for Medicare Prescription Drug Plans," OEI-01-06-00050 (Sept. 2008). Note that, while CMS has not developed model advertisements, CMS does include recommended language for marketing materials concerning such issues as plan networks.
[51] Guidelines, pg. 48.
[52] Recommendation from the Draft White Paper pgs. 37-38. Note that this is one of the few recommendations agreed upon by state insurance commissioners, health plan representatives, and consumer representatives.
[53] 42 C.F.R. §§ 422.50; 423.30. There are exceptions for people with end stage renal disease (ESRD), 42 C.F.R. § 422.50(a)(2), and for people eligible to enroll in Medicare Advantage Special Needs Plans (SNPs), 42 C.F.R. § 422.52.
[54] 42 C.F.R. §§ 422.110; 422.504(a)(2).
[55] 42 C.F.R. §423.120(a).
[56] 16 C.F.R. Part 255.
[57] 16 C.F.R. § 255.1
[58] 16 C.F.R. § 255.2.
[59] State insurance commissioners and consumer groups recommended that the use of such nomenclature be discouraged. NAIC Draft White Paper at pg. 23.

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