Legal Backgrounder

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# CMS INFORMATION POLICY UNDER MEDICARE "PART D" CREATES 1ST AMENDMENT PROBLEMS

By

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The United States has embarked on a new and historic undertaking: to provide extensive insurance coverage for drugs for senior citizens. The law, Medicare Part D, contemplates that new entities — called private *Prescription Drug Plans* or "PDPs" — will offer choices and compete for the patronage of each participant. Each senior citizen will decide which plan is best for him or her. The federal law assumes that, in making that choice, participants will have access to the information they need in order to choose the plan they want. The heart of the law is that private competition and the free market will keep costs down, offer more choices, and allow each participant to tailor the Part D insurance to meet their particular needs. Thus, if the participant does not like the choices of a PDP, the participant will simply pick a different PDP with a different plan that is better for that participant from among the many PDPs that the government has already approved.

The Center for Medicare and Medicaid Services ("CMS"), a part of the Department of Health and Human Services (HHS), implements Part D. Unfortunately, CMS has set up a series of significant limitations on the ability of *long-term-care pharmacies, consultant pharmacists and nursing homes* (the "Providers") to disseminate useful information to the Plan participants.

CMS restrictions are *unconstitutional violations of the providers' First Amendment commercial free speech guarantees*. This LEGAL BACKGROUNDER analyzes that issue and concludes that these restrictions are vulnerable to constitutional challenge. Congress decided that medical insurance needs more competition; the CMS rules undermine competition by forbidding truthful, nonmisleading speech.

Medicare Part D will empower senior citizens — the plan *participants* or beneficiaries — to make the choices that are best for each of them. There is no quick answer as to what choice is best, because that varies for each participant and the number and types of drugs that each participant will need. What may be the best PDP in one year may not be the best choice in the following year, when the participant's drug needs change. But that causes no real problem because Medicare Part D allows the participants to change PDPs just as the rest of us can change our medical insurance plans on a yearly basis.

The essence of the law is competition and the free market. Information is essential to the free market. Yet, CMS has decided to put sand in the gears of competition by prohibiting Providers from offering truthful, nondeceptive information to the participants. CMS has decreed that it will not allow the nursing homes and pharmacies to give truthful, non-misleading information about what different plans offer and why some plans may be better for participant #1 but other plans may be better for participant #2.

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Although the CMS restrictions on their face permit Providers to give patients written materials comparing PDPs, which may help the patients decide between Plans, the restrictions that the Guidelines impose effectively make it impossible for a Provider to do that. The Guidelines impose a prior restraint and then erect so many compliance hurdles that the Providers will not be able to publish any writing that is current. If the Providers (the nursing homes and pharmacies) must jump over all the hurdles, months will pass, and the written information will likely be out-of-date. Either way, it will be too late for the nursing home resident, who needs information now.

The following examples demonstrate the practical, and unusual, implications of these restrictions:

- Any person (or a pharmacy) can give information comparing PDPs to a newspaper reporter, and the reporter can publish an article comparing the PDPs based on this information. It appears, however, that under the Marketing Guidelines the pharmacy then could *not* give this newspaper article to nursing home residents. (In addition, the pharmacy cannot generate and give to residents its own document comparing the PDPs).
- For all practical purposes, Providers cannot engage in written comparisons of the benefits of the PDPs with whom they have contracts. While written comparisons are typical in today's market (*e.g.*, Progressive Auto Insurance routinely offers comparisons), the CMS Guidelines, by fiat, announce that no Provider can offer what Progressive offers on its web site. Although Providers can *orally* discuss some PDP-related options with nursing home residents, *writings* that detail the differences between the PDPs would be more useful to nursing home residents, and protect them more, because a misleading writing is easier to police than a misleading oral communication.
- Consider the case of two brothers: *Brother A*, is a 65-year-old dual eligible (Medicare/Medicaid) patient who is cognitively impaired, and *Brother B*, a 70-year-old ambulatory individual who possesses the means to pay for his own medication, and has the power of attorney over the health care decisions for *Brother A*. Under the Marketing Guidelines, a pharmacy effectively *cannot* give *Brother B* any written comparative PDP-related information that would enable him to make an informed choice regarding the health care needs for *Brother A*.

As these examples demonstrate, these restrictions on truthful, non-misleading speech are not the culmination of a carefully-tailored and thoughtful analysis. Rather, the CMS Guidelines are an overbroad and unnecessary restraint on the rights of nursing homes and pharmacies to communicate with nursing home residents and on their rights to receive those communications. Less restrictive alternatives are available to ensure that nursing home residents receive accurate information and that providers do not improperly "steer" residents to a particular plan or set of plans for their own financial needs to the detriment of beneficiaries' clinical needs, but CMS has failed to use them.

Medicare Part D gives Medicare beneficiaries, and more particularly nursing home residents, an array of options that become overwhelming without the proper contextual information needed to make a choice. They need to choose the one Plan, from among as many as 80 available Plans, that is best for them given their medical and financial circumstances. The Plans all have different premiums, and other differences, such as — which drugs are covered under each Plan's formulary (*i.e.*, the list of drugs that each plan covers); whether the Plan requires prior authorization for its drugs; how prior authorization works under each Plan; which Plans require step therapy; and which Plans limit the quantity of a particular drug that may be prescribed.

To parse through such details is a substantial challenge. To do it without the assistance of comparative charts or other visual aids is daunting, particularly in a nursing home environment where residents do not usually have access to computers and may be too frail to interact with an operator on a 1-800-Medicare line. Those in the best position to assist nursing home residents in making sense of these issues are their pharmacists and nursing home personnel. But, the Marketing Guidelines (not the Part D authorizing statute or its regulations) *preclude* pharmacists and nursing home personnel from assisting in any meaningful way because they only can provide information, if at all, only *orally*, not in writing.

If the information were written, the beneficiaries could study it; if they cannot understand it, they could

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give it to a loved one or relative to advise them. A beneficiary who has given a power of attorney to a family member or other individual could show the writing to that person for assistance in selecting and enrolling in a plan. It serves to bring home to the beneficiary exactly what is going on. A writing also provides a written record so that the beneficiary does not have to rely on her memory.

On August 15, 2005, CMS issued its *Marketing Guidelines for Medicare Advantage and Prescription Drug Plans* (the "Marketing Guidelines").[1] The term, "Guidelines," is a bit of a misnomer because the "Guidelines" are not merely recommendations. They are CMS's interpretation of what marketing practices are permitted under the statute and under CMS's own regulations. All PDPs, nursing homes, and pharmacies are bound by contract to comply with these Marketing Guidelines, and nursing homes must comply because the CMS Guidelines classify them as "non-benefit providing third parties."

The "Marketing Guidelines" severely limit the ability of both *long-term-care pharmacies* and *nursing homes* to enroll nursing home residents into the new Part D Medicare Prescription Drug benefit, which began on January 1, 2006. For ease of reference, both *long-term-care pharmacies (and their consulting pharmacists) and nursing homes* can be considered "Providers;" *Long-term-care pharmacies* are "LTCPs;" and *nursing homes* are simply "nursing homes."

Nursing homes, as care providers, obviously have a close relationship with their nursing home residents and family members. The LTCPs also have a close relationship with these individuals. It is quite common for the LTCPs to send representatives to the nursing homes monthly to make sure that they give the proper drugs to the right people without unhealthy side effects. These services save between $3.4 billion and $5.5 billion (1997 dollars) in additional drug related problems, thanks to the special efforts of the nursing homes and the LTCPs.[2]

In spite of that enviable track record, the Marketing Guidelines restrict what "Providers" may and may not say about the new Prescription Drug Benefit program, even if what they say is truthful, non-misleading and in writing. The Marketing Guidelines include very specific limitations on the types of statements that pharmacies, including LTCPs and their consultant pharmacists, may make concerning PDPs in which the LTCPs participate or do not participate [*i.e.*, are in-network or out-of-network]. The Marketing Guidelines, among other things, prohibit both pharmacies and nursing homes from accepting any completed enrollment applications for submission to PDPs from a Medicare beneficiary.

CMS not only restricts competition, it violates free speech. The Supreme Court has long viewed with suspicion restrictions like those here that seek to keep vital, truthful, non-misleading information from health care consumers. These restrictions are particularly onerous because they impose a *prior restraint on vital, truthful, non-misleading* information.

Let us be clear: CMS may and should prohibit false or misleading speech, but CMS may not prohibit truthful, non-misleading speech simply because some people might utter misleading speech. To do that, the Supreme Court announced a long time ago, is to allow the Government to "burn the house to roast the pig."[3] Government laws restricting free speech must be more narrowly tailored than that.

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[1] http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1535. The Guidelines are at: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/.

[2] J. Lyle Bootman, et al., *The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities*, 157 ARCH. INTERN. MED. 2089, 2093 (Oct. 13, 1997).

[3] *Butler v. Michigan*, 352 U.S. 380, 383 (1957). See discussion in, 4 RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE § 20.61 (3d ed. 1999). In this case, the state argued that by "quarantining the general reading public against books not too rugged for grown men and women in order to shield juvenile innocence, it is exercising its power to promote the general welfare." The unanimous Court disagreed, because the law was not carefully tailored, a point discussed below.

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Just four years ago, the Court struck down federal restrictions on pharmacies' commercial speech — by holding unconstitutional a statute prohibiting pharmacies from advertising compounded drugs.[4] The Court held that the pharmacies have a First Amendment right of free speech, so long as the speech was accurate and honest. The Court's rationale in that case is directly applicable to the restrictions that the Marketing Guidelines impose, because those Guidelines are overbroad, not narrowly tailored, and prohibit speech that is both truthful and not misleading. Indeed, CMS's articulated and explicit rationale for the Marketing Guidelines' restrictions is precisely the type of paternalistic considerations that courts routinely reject in commercial free speech cases.[5]

The Guidelines state that if a Provider wants to draft materials that simply compare the various Plans, the Provider must first obtain the prior approval of all the PDPs it is comparing. Then, the Provider must persuade one of the PDPs to submit the materials to CMS for review because the CMS Guidelines do not permit the Provider to submit the material directly to the agency. Historically, the case law has always been hostile to prior restraint and censorship because it places enormous power in the hands of Government. The CMS Guidelines are even worse, for they place censorship powers in the agency itself and with private groups, the PDPs. The Guidelines do not even permit the Providers to seek CMS approval directly.

If the PDP submits marketing materials to CMS, it must respond within 45 days or the regulations deem the materials approved; not so for the Provider. If the Provider has made it this far, it must then submit the materials to CMS for approval and then . . . wait. There is no time limit. As a practical matter, the bureaucracy of working with multiple PDPs as well as CMS presents a nearly insurmountable hurdle: the Guidelines impose no time limit for the PDPs to respond to the Provider and they offer no incentive for any PDP to take on responsibility for seeking CMS approval.

If the Provider's materials eventually do reach CMS, that is not the end of the matter, for CMS, like the private PDPs, also have the power to censor. If CMS disapproves any part of the written materials, it will transmit its objections to the PDP, which (one hopes) will *eventually* pass them on to the Provider; then the Provider apparently must go through the entire process again after making the required revisions.

It is unlikely that every PDP compared in the materials would assent to such a comparison if the comparison would reveal that other Plans were more advantageous to the patients. As a result, by making it virtually impossible to provide truthful, comparative, and written materials to patients, CMS effectively preclude Providers from assisting their own patients in choosing a plan.

The CMS restrictions create constitutional problems, impede competition, prevent consumers from getting truthful information, and undermine the free market principles that animate this new law. CMS should seriously consider withdrawing them.

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[4] *Thompson v. Western States Medical Center*, 535 U.S. 357, 367-68 (2002). Licensed pharmacies challenged provisions of the Food and Drug Administration Modernization Act (FDAMA) that prohibited advertising and promotion of particular compounded drugs. Justice O'Connor, for the Supreme Court, held that FDAMA provisions were unconstitutional restrictions of commercial speech.

[5] *See, e.g.*, Blackmun, J. joined by Brennan, J., concurring in the judgment in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 574-75 (1980):

> "I seriously doubt whether suppression of information concerning the availability and price of a legally offered product is ever a permissible way for the State to 'dampen' demand for or use of the product. Even though 'commercial' speech is involved, *such a regulatory measure strikes at the heart of the First Amendment.* This is because it is a covert attempt by the State to manipulate the choices of its citizens, not by persuasion or direct regulation, but by *depriving the public of the information needed to make a free choice*. As the Court recognizes, the . . . the conduct of citizens is molded by the information that government chooses to give them. Ante, at n. 9 ('We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy. In those circumstances, a ban on speech could screen from public view the underlying governmental policy'). *See* Rotunda, *The Commercial Speech Doctrine in the Supreme Court*, 1976 U. ILL. LAW FORUM 1080, 1080-1083." (emphasis added).

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