UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

REBECCA FOX, MARY SAMP, and **EDWARD SAMP**	)	
Plaintiffs,	)	
v.	)	CA No. 1:06cv01490 (RMC)
	)	Judge Collyer
MICHAEL O. LEAVITT, in his official capacity as Secretary, U.S. Department of Health and Human Services,	)	
and	)	
LESLIE V. NORWALK, in her official capacity as Acting Administrator, Centers for Medicare and Medicaid Services,	)	
Defendants.	)	

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Fed.R.Civ.P. 56, Plaintiffs Rebecca Fox, Mary Samp, and Edward Samp hereby move for summary judgment against the U.S. Department of Health and Human Services (HHS) and its Centers for Medicare and Medicaid Services (CMS), and entry of declaratory and injunctive relief to prevent them from continuing to enforce policies that violate Plaintiffs' First Amendment rights. Those policies prevent them from receiving truthful information regarding insurance coverage available to them under Medicare Part D, the newly enacted drug benefit program. There are no genuine issues of material fact, and Plaintiffs are entitled to judgment as a matter of law.

In support of their motion, Plaintiffs are filing a memorandum of points and authorities, a statement of material facts as to which there is no genuine issue, the Declaration of Jessie

England (Exhibit B), the Declaration of Margie White (Exhibit C), the Declaration of Ross W. Brickley (Exhibit D), the Declaration of Bill Donatelli (Exhibit E), the Declaration of Michael Scott Wood (Exhibit F), the Affidavit of Michael Flaherty (Exhibit G), the Declaration of Rebecca Fox (Exhibit H), the Declaration of Mary Samp (Exhibit I), and the Declaration of Richard Samp (Exhibit J). A proposed order is also attached.

WHEREFORE, Plaintiffs respectfully request that the Court grant its motion for summary judgment.

Respectfully submitted,

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Dated: October 15, 2007

Attorneys for Plaintiffs

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FOR THE DISTRICT OF COLUMBIA

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PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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Dated: October 15, 2007

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PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

INTRODUCTION AND SUMMARY OF ARGUMENT

Pursuant to Fed.R.Civ.P. 56, the Washington Legal Foundation (WLF) seeks summary judgment in its favor and entry of declaratory and injunctive against the U.S. Department of Health and Human Services (HHS) and its Centers for Medicare and Medicaid Services (CMS), to prevent them from continuing to enforce a policy that violates the First Amendment rights of Plaintiffs.[1] For so long as the policy remains in force, Plaintiffs continue to suffer irreparable harm by being deprived of their First Amendment rights to receive truthful information regarding insurance coverage available to them under Medicare Part D, the newly enacted drug benefit program.

By blocking Plaintiffs' access to such information, Defendants are depriving them and millions of other senior citizens of the opportunity to make informed choices regarding which benefit options best suit their individual needs. Part D was intended to provide senior citizens with many such options, yet Defendants' policy prevents Plaintiffs and other senior citizens from obtaining truthful information regarding those options from many of the individuals best situated

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[1] HHS's and CMS's policy is embodied in its Medicare Marketing Guidelines for Medicare Advantage Plans (MA), Medicare Advantage Prescription Drug Plans (MA-PDs), Prescription Drug Plans (PDPs), and 1876 Cost Plans (the "Marketing Guidelines"). Initially issued by CMS in August 2005, the Marketing Guidelines were most recently revised by CMS on July 25, 2006. CMS has posted the Marketing Guidelines as amended at www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf. Relevant excerpts from the Marketing Guidelines are attached to the Complaint as Exhibit A. The Marketing Guidelines impose strict limitations on the information that many health care providers may communicate to WLF's members and other Medicare beneficiaries, regardless how truthful the information. Other CMS documents, particularly its May 11, 2006 memorandum from the Director of CMS's Survey and Certification Group entitled "Nursing Homes and Medicare Part D," impose additional restrictions on the dissemination of truthful information by health care providers to Medicare beneficiaries. The May 11, 2006 memorandum, reference no. S&C-06-16 ("S&C Memo"), is attached hereto as Exhibit A.

to provide them with information tailored to their individual needs – their health care providers and professionals such as physicians, hospitals, nursing homes, pharmacies, and pharmacists.

Plaintiffs demonstrate herein that there are no genuine issues of material fact and that they are entitled to judgment as a matter of law. Plaintiffs are entitled to an injunction against continued enforcement of HHS/CMS policies that prevent them from obtaining truthful speech regarding the comparative benefits of the Part D plans (PDPs) available to them.

Defendants' efforts to bar truthful speech simply cannot withstand First Amendment scrutiny. The speech at issue – information regarding the relative merits of competing Medicare Part D plans – is noncommercial speech entitled to full First Amendment protection. When healthcare providers speak to Medicare beneficiaries about which Part D plan might be best for them, the providers are not proposing any sort of commercial transaction to which they could be a party. The speech at issues involves matters of public concern. Moreover, the speech restrictions imposed by Defendants are content-based; *i.e.*, Defendants are not merely trying to regulate the time, place, and manner of providers' speech but rather to regulate the content of what providers can say. Under those circumstances, content-based government speech restrictions of the type at issue here virtually never can withstand First Amendment scrutiny. CMS and HHS would be entitled to deprive Plaintiffs of such truthful information only by demonstrating both that the restrictions serve a compelling government interest and that they do so in the least restrictive manner possible. Discovery in the case has revealed that CMS and HHS cannot make such a demonstration; indeed, the evidence demonstrates that Defendants gave no thought whatsoever of the First Amendment ramification of their speech-suppression policies before putting them into effect.

Nor can the CMS and HHS speech restrictions withstand First Amendment scrutiny even if judged under the less demanding standards applicable to restrictions on commercial speech. Under those standards, the restrictions are impermissible unless the government can demonstrate that they directly advance a substantial government interest and are no more extensive than is necessary to serve that interest. None of the rationales advanced by Defendants in support of restrictions on providers' speech serve any substantial government interest. In general, the only motivation that a provider ever has to "steer" a Medicare beneficiary toward a specific Part D plan is a desire to have the beneficiary enroll in the plan that best serves his or her needs; providers rarely stand to directly profit from a beneficiary's choice of plans. Thus, there simply is no substantial government interest in preventing providers from disseminating truthful information to Medicare beneficiaries. To the extent that the government is concerned that a Part D plan may attempt to bribe health care providers to steer Medicare beneficiaries toward that plan, the most effective, and only narrowly tailored response to that concern, is to enforce the existing prohibition on such payments. *See* 42 U.S.C. § 1320a-7b(b) (prohibition against paying or receiving kickbacks in return for referring an individual to a service for which reimbursement may be available under a federal healthcare program, generally known as the "anti-kickback statute").

Indeed, the restrictions imposed on providers under this statute are widely known within the industry due to the severity of the penalties for violations and the many well-publicized enforcement cases, which frequently involve fines of tens of millions of dollars, extensive jail terms, and corporate bankruptcies. No rational provider would take actions that violate the anti-kickback statute, since the consequences of doing so can be absolutely ruinous. Consequently,

the blanket restrictions on provider speech contained in the Marketing Guidelines are not necessary to promote any governmental interest of preventing illegal payments to "steer" beneficiaries to Part D plans.

Plaintiffs will continue to suffer injury if declaratory and injunctive relief is not granted. For as long as the Marketing Guidelines remain in place, Plaintiffs' ability to receive truthful information regarding their Part D options from the providers and health care professionals most familiar with their medical requirements will be greatly restricted. Plaintiffs have an ongoing need for such information, because they cannot realistically make informed choices regarding Part D plans in the absence of such information. Every year they must decide whether to continue with their existing plan or to switch to one of the scores of competing plans, with the plans' respective premiums, formularies, prior authorization requirements, and other material features changing on at least an annual basis. Significantly, the best plan for a Medicare beneficiary may change when the beneficiary's circumstances change, such as changes in health status or admission to a nursing home. For example, due to an injury suffered in July 2007, Plaintiff Edward Samp has resided in nursing homes and rehabilitation facilities for the past several months. Depending on the course of his rehabilitation, he may be required to move into a nursing home on a long-term basis in the near future. Yet, he and his wife are being denied access to information that could assist them in choosing the Part D Plan that best serves his changing needs. Plaintiffs' injury – the deprivation of their First Amendment rights – is deemed irreparable injury as a matter of law and warrants the grant of declaratory and injunctive relief; no amount of money damages can ever compensate them for that loss.

No one disputes Defendants' right to provide seniors with whatever additional truthful

information they deems appropriate. An injunction would in no way affect Defendants' ability to provide such information or to prevent the dissemination of inaccurate information; all that is at issue is Defendants' efforts to restrict access to truthful information.

Plaintiffs Have Standing to Challenge Defendants' Policies. It is well settled that the First Amendment protects not only the right to speak, but also the right to receive information. Accordingly, Plaintiffs Rebecca Fox, Mary Samp, and Edward Samp, as consumers of Medicare Part D services who wish to receive information from entities whose speech is being suppressed by Defendants, have standing to challenge those speech suppression policies. They are suffering injury-in-fact (denial of their right to receive truthful information), the injury is directly traceable to Defendants, and their injury will be redressed if their requested relief is granted.

STATEMENT OF FACTS

The Medicare Part D Drug Benefit

Title 18 of the Social Security Act established the Medicare program to provide federally funded health insurance for the elderly and disabled. 42 U.S.C. §§ 1395 *et seq.* Coverage available under Medicare includes hospital inpatient and related care (Part A), supplemental coverage for outpatient services (Part B), and privately-administered managed-care alternatives for receiving Part A and/or B benefits (Part C).

Through its adoption of Title I of the Medicare Prescription Drug Modernization and Improvement Act of 2003 ("MMA"), Pub. L. 108-173, *codified at* 42 U.S.C. § 1395w-101 *et seq.,* Congress established a new Medicare prescription drug benefit program, known as Part D. CMS, which has been charged with administering the Part D program, issued final regulations for the program on January 28, 2005.

The Part D program provides that new entities, known as Prescription Drug Plans or "PDPs," are to offer choices in prescription drug insurance coverage to Medicare beneficiaries and compete for the patronage of each participant. Coverage under the PDPs took effect on January 1, 2006, with enrollment beginning on November 15, 2005. Medicare beneficiaries who receive their Part A/B benefits through a Part C "Medicare Advantage" plan instead of through "traditional Medicare" are entitled to receive their Part D prescription drug coverage from that Medicare Advantage plan (an "MA-PD").

Congress recognized that if participants were to make informed decisions regarding their choice of a plan in which to enroll, they would need access to detailed information regarding the services offered by the competing PDPs. Accordingly, the MMA mandates such access. For example, the MMA requires the Secretary of HHS to "conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under" Part D. 42 U.S.C. § 1395w-101(c)(1). It further requires PDPs to disseminate annually to all enrollees detailed information regarding their plans, including what drugs are covered, how the PDP's formulary functions, any beneficiary cost-sharing requirements, and the PDP's medication therapy management program (a required program that ensures that drugs are appropriately used to optimize therapeutic outcomes and reduce the risk of adverse events). 42 U.S.C. § 1395w-104(a)(1)(B). It further requires PDPs to furnish each enrollee in "easily understandable form" an explanation of benefits, including when benefits are provided. 42 U.S.C. § 1395w-104(a)(4).

CMS, in connection with its implementation of Part D, issued the Marketing Guidelines on August 15, 2005. The Marketing Guidelines were revised slightly on November 1, 2005 and

revised further on July 25, 2006. The current, July 25, 2006 version of the Marketing Guidelines is used for all quotations and page citations set forth herein.

The Marketing Guidelines impose strict limitations on the dissemination of information regarding PDPs – not only by the PDPs themselves, but also by other organizations and individuals involved in the healthcare delivery field. Among the organizations upon which strict information dissemination limitations are imposed are entities referred to as "providers." The Marketing Guidelines define "provider" with respect to a PDP as "all providers contracted with the plan and their subcontractors, including but not limited to: pharmacists, pharmacies, physicians, hospitals, and long-term care facilities." Marketing Guidelines at 122. As Defendants concede, Answer ¶ 18, such a contractual relationship is a necessity for pharmacies that wish to obtain payment under Part D from a PDP for prescription drugs dispensed to individuals enrolled in that PDP, since a pharmacy generally must be in the contract "pharmacy network" of a PDP in order to receive payment for the drugs it dispenses.

Although the Marketing Guidelines are not altogether clear on this point, the language of the Marketing Guidelines suggests that all physicians, hospitals, and nursing homes (which are included within the definition of "long term care facility" for Part D purposes, *see* 42 C.F.R. § 423.100) are "providers" for purposes of the Marketing Guidelines - without regard to whether they contract with PDPs.[2] The Marketing Guidelines state that providers "cannot direct, urge or

[2] While Defendants' Answer states at ¶ 19 that "physicians, hospitals, and nursing homes are 'providers' within the meaning of the Marketing Guidelines only if they have a contract with a Medicare plan, including, but not limited to, a contract with a PDP," this is not self-evident from a reading of the Marketing Guidelines (quoted above); and before filing its Answer CMS never indicated any such limitation on when physicians or nursing homes, for example, would be subject to these restrictions. Indeed, nursing home personnel believe that the Marketing Guidelines apply to them, without any conditions. *See, e.g.*, the Declarations of

attempt to persuade beneficiaries to enroll in a specific plan." *Id*. at 123-124. The Marketing Guidelines acknowledge, however, that "[b]eneficiaries often look to their health care professionals to provide them with complete information regarding their health care choices (e.g., providing objective information regarding specific plans, such as covered benefits, cost sharing, drugs on formularies, utilization management tools, eligibility requirements for Special Needs Plans)." *Id*. at 123. For this reason, the Marketing Guidelines state that providers may "engage in discussions with beneficiaries when patients seek information or advice from their provider regarding Medicare options," but may only distribute CMS-approved marketing materials for "all" PDPs with which the provider participates - in each case, subject to the prohibition on attempting to persuade a beneficiary to enroll in any given plan. *Id.* at 123-124.

Consequently, while providers can provide answers to focused questions regarding particular plans, such as whether a given plan has a deductible, or can bury a beneficiary with marketing information from all of the PDPs with which they participate, they are prohibited from providing beneficiaries with bottom-line information about which plan best meets their needs and why. They cannot orally provide any information unless asked, even if it is obvious to them

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Jessie England ("England Decl.") and Margie White ("White Decl."), attached hereto as Exhibits B and C respectively. Consequently, it is clear that the effect of Defendants' actions has been to impose speech restrictions that such providers have understood to apply to them. While Plaintiffs would certainly welcome a revision of the Marketing Guidelines that clarifies that the speech restrictions do not apply to nursing homes, physicians, pharmacists, and hospitals unless they have contracted with a Medicare plan, that would not cure the First Amendment violation with respect to those providers who have contracted with a Medicare plan. Further, separate and apart from the Marketing Guidelines, CMS issued the S&C Memo (discussed below) which states that nursing homes may not steer beneficiaries to a given Part D plan for any reason, without limiting such restrictions to nursing homes that have contracted with a Part D plan. This reflects an overall policy on the part of Defendants of restricting provider speech without regard to the limitation suggested in their Answer.

that a beneficiary is enrolled in the wrong PDP for their situation (e.g., one which does not have any of the drugs prescribed for the patient on formulary, meaning they will not be covered), since doing so would be "attempting to persuade" the patient to switch to a different PDP which does have those drugs on formulary.

While the Marketing Guidelines allow providers to give objective answers to questions orally when asked, they prohibit providers from preparing and distributing any written materials "that describe plans in any way (e.g., benefits, formularies)" unless all of the PDPs with which the provider contracts are listed and these materials are approved by CMS in advance. *Id*. at 124-125. Incredibly, however, there is no mechanism for providers to submit such materials to CMS or obtain CMS approval; CMS permits materials to be submitted to it only by the PDPs themselves. If a provider is involved in developing such printed materials "comparing the benefits of different plans," the materials "must have the concurrence of all plans involved in the comparison and must be approved by CMS prior to distribution…." *Id.* at 125. In no event may the printed materials "rank order" the listed plans or "highlight specific plans." *Id.*

The Marketing Guidelines indicate that providers "may distribute printed information comparing the benefits of different plans (all or a subset) in a service area when the comparison is done by an objective third party" known as a "non-benefit/service-providing third party" ("NBPTP"). The Marketing Guidelines define a NBPTP as "an organization that neither administers the health care/prescription drug benefit nor provides health care services/Part D drugs to Medicare beneficiaries" and that "suppl[ies] information to [a PDP's] membership, which is paid for by [the PDP] or the non-service/benefit providing third part[y] entity." *Id*. at 114. "An example of [a NBPTP] could be a research firm that provides comparative data

relating to Medicare Advantage/Part D plans." *Id*.

Since the NBPTP's comparison must be paid for by a PDP or by the NBPTP itself (*i.e.*, provided for free), a provider could not even retain a third-party consulting firm to prepare a comparison of different PDPs for the provider to distribute. Even if it could, this requirement effectively precludes the provider itself from speaking through written materials, as it cannot distribute written materials prepared by it, but only those prepared by an "objective" third party.

Portions of the Marketing Guidelines state that a provider may not "[d]irect, urge, or attempt to persuade" a patient to enroll in any specific PDP, or "steer, or attempt to steer" a patient to any given PDP, when its actions are "based on financial or any other interest of the provider…." *Id*. at 123, 128. However, other provisions of the Marketing Guidelines contradict this statement and impose far tighter restrictions on providers; those provisions virtually admonish a provider not to direct, urge, or attempt to persuade a patient to enroll in a given PDP, period, without limiting the restriction to situations where the provider has a financial interest. *Id*. at 123-124.

Separate and apart from the Marketing Guidelines, but as part of its policy to chill the dissemination of truthful information, on May 11, 2006 CMS released a policy memorandum which states that nursing homes and pharmacies may not "coach" or "steer" nursing home residents to a PDP "for any purpose." Specifically, CMS stated:

> Under no circumstances should a nursing home require, request, coach or steer any resident to select or change a plan for any reason. Furthermore, a nursing home should not knowingly and/or willingly allow the pharmacy servicing the nursing home to require, request, coach, or steer any resident to select or change a plan….

Memorandum from Director, Survey and Certification Group, to State Survey Agency Directors,

dated May 11, 2006, reference no. S&C-06-16 ("S&C Memo"), at 3. A copy of the S&C Memo is attached hereto as Exhibit A.

The S&C Memo – which is essentially an enforcement initiative, with punitive consequences – was issued to the state regulatory agencies charged with on-site review of nursing homes (e.g., state departments of health), and instructs these agencies that they should issue a citation penalizing nursing homes if they violate this edict. *Id*. Such citations, if not corrected by the nursing home to the satisfaction of the regulatory authorities, can result in the imposition of severe sanctions, including civil monetary penalties, a ban on further admissions of Medicare and/or Medicaid residents, and termination from participation in the Medicare and Medicaid programs - which would put most nursing homes out of business. 42 U.S.C. §§ 1395i-3(h) and 1396r(h); 42 C.F.R. § 488.406. The S&C Memo has clearly had its intended effect of chilling nursing homes' speech regarding Part D plans. *See* England Decl. ¶ 7; White Decl. ¶ 7-8.[3]

Consequences of the Marketing Guidelines and the S&C Memo

The above restrictions imposed by the Marketing Guidelines and the S&C memo make it

[3] While the S&C Memo purports to base its content-based speech restrictions on existing CMS regulations, in fact those regulations provide no support for its restrictions on provider speech. The S&C Memo cites 42 C.F.R. § 483.12(d) as support for its prohibition on steering residents to a Part D plan for any reason. The provisions relied upon by CMS in that regulation read: "(d) Admissions Policy. (1) The [nursing] facility must – (i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and (ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits." This regulation simply does not provide any basis for CMS's restriction of speech pursuant to the S&C Memo. To the contrary, the S&C Memo reflects a continuation of the agency policy first reflected in the Marketing Guidelines, to prohibit any meaningful provider communications to beneficiaries regarding the comparative benefits of competing Part D plans.

virtually impossible for providers to give meaningful information and advice to their patients, including Plaintiffs, regarding which Part D plan best suits their needs. The prohibitions on communications that "attempt to persuade" a beneficiary that a given plan is the best for them clearly prevent a provider even from recommending a Part D plan to a Medicare beneficiary when the beneficiary asks for a recommendation. Indeed, its practical impact is that providers cannot even supply objective facts that could lead the beneficiary to conclude which plan is best for them. Under Defendants' policies, a provider's presentation of such facts about plan options could be construed as "steering" a beneficiary to choose a specific plan. Numerous other types of perfectly legitimate communications could run afoul of these broad restrictions on providers' communications. In addition to being contradictory and confusing, these restrictions purport to prohibit dissemination of truthful and nonmisleading information for which Medicare beneficiaries have considerable need.

Although health care providers have been abiding by CMS's speech restrictions, they have been frustrated by those broad restrictions because they realize that the result is that seniors often are not obtaining information necessary to make informed choices about which PDP best meets their needs, information which those practitioners could (and are willing to) provide if so permitted. For example, Jessie England, a registered nurse and licensed nursing home administrator in Ohio, receives constant requests from patients and their relatives regarding which PDP is best for them. England Decl. ¶ 7. Yet, the speech restrictions have prevented her from providing them the advice she believes they need. *Id.* Similarly, Margie White, an assistant administrator at a different Ohio nursing home, has been repeatedly forced by the speech restrictions to decline to provide patients with the PDP selection advice they need and

which she is equipped to provide. White Decl. ¶¶ 7-8.

Pharmacists have been similarly inhibited by the CMS speech restrictions from providing advice to patients regarding the choice of a PDP. Ross W. Brickley, the former President of the American Society of Consultant Pharmacists who has worked for many years as a consultant pharmacist, states that in the past year-and-a-half he has participated in over 40 "family night" events at various nursing homes designed to apprise patient family members of important information regarding the care of their loved ones. Declaration of Ross W. Brickley ("Brickley Decl.") ¶ 10. At those events, the most frequently asked question is, "Which [Part D] plan is best for my loved one?" *Id.* Although qualified to provide a well-informed response based on his experience as a consulting pharmacist and on his familiarity with available PDPs, Brickley has felt constrained by the CMS speech restrictions not to respond directly to such questions. *Id.*

The Part D benefit as established by Congress is extremely complex, and CMS has added to the complexity of choosing a plan by permitting PDPs to adopt widely varying plan benefit designs, policies, requirements, and restrictions. Medicare beneficiaries have numerous Part D plans to evaluate - generally more than 40, and in some areas more than 80.

For example, Part D plans vary based upon, among other things:

- The monthly premium that the beneficiary must pay for coverage under the plan;
- The annual deductible of prescription drug costs which must be paid by the beneficiary before the plan will provide coverage for the beneficiary's drugs;
- What drugs, if any, the plan covers in the Part D "coverage gap" (a/k/a the "doughnut hole") – the benefit feature under which a beneficiary may receive no coverage for prescription drugs after the beneficiary's prescriptions during a year exceed an initial coverage limit ($2,250 in 2006) and until the beneficiary has incurred sufficient drug costs out-of-pocket ($3,600 in 2006) to qualify for coverage to resume, under the Part D "catastrophic" benefit;

- The drugs for which coverage is available (i.e., which drugs are on the plan's "formulary");

- The copayment amount that the beneficiary must pay for each drug that is on formulary (which may vary by drug), after any deductible has been satisfied (if the plan has a deductible);

- The drugs that are "on formulary" for a given plan, but for which coverage still will not be granted unless the plan grants "prior authorization";

- The specific criteria that must be satisfied in order for prior authorization to be granted for a specific drug, which for a given drug may be easy to satisfy under one PDP's policies but extremely difficult to satisfy under another PDP's policies;

- Whether the drug is subject to a "quantity limit" on the number of pills that the plan will pay for;

- The "transition policy" of the PDP with respect to payment for non-formulary drugs while the beneficiary is switched to drugs on the plan's formulary; and

- The pharmacies with which the PDP has contracted for inclusion in the plan's pharmacy network (coverage is generally available only for drugs dispensed by a network pharmacy).

In addition to these issues, an individual's entitlement to certain low-income subsidies available under the program and status as a nursing home resident can dramatically affect which PDP is best. For example, individuals who are eligible for both Medicare and Medicaid ("dual eligibles") do not need to pay a premium to enroll in a PDP, so long as the PDP they select has a premium at or below the "benchmark" (weighted average) premium for the given PDP region. Also, dual eligibles who are nursing home residents pay no deductibles and no copays, and have full coverage through the "coverage gap" - but only with respect to drugs which are on the plan's formulary and for which any utilization management requirements (such as prior authorization) have been satisfied. Accordingly, for these types of beneficiaries, a high copay level (e.g., $80 per prescription) is irrelevant, but the formulary status of the drug and the existence of any

utilization management requirements are highly important. Further complicating matters is the fact that a beneficiary's status may change, often quickly – *e.g.*, when a beneficiary not covered by Medicaid is admitted to a nursing home and "spends down" his or her assets, becoming Medicaid eligible (and therefore dual eligible).[4]

There are numerous other differences between PDPs which are important in determining the best PDP for a given individual. Much of this information is not available on the Medicare website or from 1-800-Medicare, and realistically can only be learned from providers. For example:

- PDPs may deny coverage of prescriptions based on a "refill too soon" policy which denies coverage when the previous refill was for a 30 day supply, and only 25 days have passed. For a nursing home resident who has difficulty swallowing and may spit some pills out onto the floor, these policies are inappropriate, and the beneficiary should choose a PDP with a policy of covering those refills;

- One PDP may pay for delivery of prescriptions to assisted living facilities, whereas another PDP may require a relative of the patient to pick up the prescription and bring it to the facility. This creates the potential for medication errors, particularly in light of the numerous prescription medications which many seniors must take; and

- PDPs vary significantly in terms of how cooperative or bureaucratic they are in resolving problems through their "help line" call centers.

Not surprisingly, the vast majority of seniors are unable on their own, or even with the assistance of relatives, to make an informed choice among competing PDPs. England Decl. ¶¶ 4, 6; White Decl. ¶ 7; Brickley Decl. ¶¶ 4-6; Declaration of Bill Donatelli ("Donatelli Decl.") ¶ 7, attached hereto as Exhibit E.

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[4] For a good overview of the many differences among PDPs and the complex issues seniors must address when choosing a plan, *see* Christopher J. Gearon, *Press 'D' for Details: Before Enrolling in Medicare's New Drug Plan, Study the Options; You Can Start Now*, Washington Post, at HE1 (November 15, 2005).

The individuals and groups who are most likely to understand the relative merits of competing PDPs for particular Medicare beneficiaries are the health care providers who regularly interact with these PDPs, such as physicians, pharmacies, pharmacists, and nursing homes. These providers are most familiar with the requirements adopted by various PDPs and how they impact patients with given characteristics. Indeed, in many cases determining the best PDP for a Medicare beneficiary goes beyond a mechanistic comparison between the drugs which the beneficiary is currently taking and the formularies of competing PDPs, which is what the computer program on the Medicare website does, since elderly patients will frequently be receiving additional prescriptions as their health condition changes. Beneficiaries can clearly benefit from receiving advice from providers who have had experience in dealing with different PDPs and their policies as they relate to the providers' other patients in similar circumstances.[5]

Despite the fact that these health care providers are the very groups and individuals who are frequently best situated to give their patients relevant information and sound advice in the choice of a PDP, the Marketing Guidelines act to deprive those beneficiaries, including Plaintiffs, of the benefits of that knowledge.

The experiences of Rebecca Fox, Edward Samp, and Mary Samp well illustrate the

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[5] As Michael Wood, a licensed pharmacist from Utah explains:

> Only pharmacists have sufficient institutional knowledge to assess both the formularies and the Part D plan administration and to make a recommendation as to which Part D plans would work the best with the particularities of a given patient. Pharmacists have years of experience dealing extensively with Pharmacy Benefit Managers and are best able to match the particularities of a plan with each patient's condition.

Declaration of Michael Scott Wood ("Wood Decl.") ¶ 8, attached hereto as Exhibit F. *See also* Donatelli Decl. ¶ 10.

adverse impacts that the Marketing Guidelines have had on Medicare beneficiaries.

Plaintiff Rebecca Fox

Rebecca Fox is an 88-year-old widow living by herself in Coraopolis, Pennsylvania. Ms. Fox has been a Medicare beneficiary since she turned 65. Exhibit H, Declaration of Rebecca E. Fox ("Fox Decl.") ¶ 3. Before the establishment of Medicare Part D, Ms. Fox was enrolled in the "Lilly Answers" program, which allowed her to purchase prescription drugs at a discount price. *Id.* ¶ 4. Although she was "pleased" with the program, it was terminated effective May 15, 2006 because of the implementation of the Medicare Part D drug benefit program. *Id.* ¶ 4, 6.

In June 2005, the Pennsylvania Department of Aging contacted Ms. Fox and informed her that she was eligible to enroll in its PACE/PACE NET program, a program designed to reduce prescription drug costs for elderly Pennsylvania residents. *Id.* ¶ 5. In response to that solicitation, Ms. Fox enrolled in the program, at no cost. *Id.*

In January 2006, Governor Edward Rendell wrote to Ms. Fox, advising her that she was eligible to participate in the new Medicare Part D drug benefit program. *Id.* ¶ 7. The letter stated that he knew that the enrollment process was "confusing" for many Pennsylvania seniors. *Id.* The letter stated that because Ms. Fox was already enrolled in PACE or PACE NET, she already had a drug benefit; that the PACE program would review her records, the drugs she used, and the pharmacies where she bought those medications; and that they would then arrange for her to be enrolled in both PACE and the federally approved pharmaceutical assistance plan "that best met [her] needs." *Id.* Governor Rendell advised that she should "just stay enrolled in PACE or PACE NET and wait for PACE program mailings that would help [her] sort through all the options." *Id.*

Ms. Fox subsequently received a letter from the Director of the PACE program, informing her of her right, through May 15, 2006, to enroll in the Medicare Part D program of her choice. *Id.* ¶ 8. The letter said, however, that coverage she was receiving under the PACE/PACE NET program "was as good as the coverage" offered under the new Part D program. *Id.* Ms. Fox also received voluminous information from various Medicare Part D plans; she attempted to determine which plan would best suit her needs, but quickly became confused by the printed materials she reviewed. *Id.* ¶¶ 9-10. She sought assistance from her pharmacist (with whom she had been a customer for many years) regarding which plan to choose, but was told that he could not advise her and that the choice of plans would have to be up to her. *Id.* ¶ 11-12.

Ms. Fox realized that she should probably be making some sort of decision regarding enrollment in Part D, but she did not know where to turn for assistance. Because the letters she had received from Pennsylvania suggested to her that they would be providing her with specific advice regarding which Part D plan, if any, she should enroll in, she decided to defer any action until she received that advice. *Id.* ¶ 13. That decision turned out to be a mistake, because Pennsylvania did not (as promised) ever provide her with the promised advice. In September 2006, her pharmacist informed her that her share of the bill for her prescription drugs for the previous summer had gone up considerably as a result of cancellation of the "Lilly Answers" program and her failure to enroll in a Part D plan. *Id.* ¶ 14.

Ms. Fox then contacted a PACE NET representative, who admitted that she had never been enrolled in a Part D plan and that she would have to choose among available plans. *Id.* ¶ 16. The representative recommended that Ms. Fox choose from among two plans: Humana or

AARP. *Id.* Ms. Fox's pharmacist declined her request to recommend one plan or the other, so she attempted to make the choice on her own. *Id.* ¶ 17. She submitted an application to AARP (because she found the sales pitch from the Humana representative to be too high-pressure). *Id.* ¶ 18. But when did not hear back from AARP, she sent an additional application in to Humana (on the advice of the PACE NET representative). *Id.*

The result was that she ended up being enrolled in two different Part D plans. *Id.* ¶ 19. She became very confused regarding what to do at that point; finally, with the help of her pharmacist, she was able to cancel her Humana enrollment without financial penalty. *Id.* She was quite upset by the whole enrollment process. The only information sent to her was too detailed for her to understand; and the one person within the health care field with whom she regularly interacts – her pharmacist – told her that he was not in a position to provide her with specific advice on choice of a plan. *Id.* ¶ 21. She is still enrolled in AARP; but she wishes that her pharmacist were in a position to provide her with information on an on-going basis regarding whether plans other than AARP would better serve her needs, particularly if her health care needs were to change. *Id.* ¶¶ 20, 24. Friends to whom Ms. Fox expressed her outrage over this incident told her that they had similar difficulty in receiving accurate, understandable information about Part D options. *Id.* ¶ 22.

Plaintiffs Edward and Mary Samp

Plaintiffs Edward and Mary Samp have had a similarly frustrating experience in attempting to receive accurate information regarding their Medicare Part D options. Edward Samp, age 89, and Mary Samp, age 87, are residents of Youville House, an assisted living facility for senior citizens located in Cambridge, Massachusetts. Edward and Mary have been

married since 1946 and have been Medicare beneficiaries since they turned 65. Exhibit I, Declaration of Mary A. Samp ("Samp Decl.") ¶ 2. Before the establishment of Medicare Part D, they were enrolled in prescription drug plans offered by their former employers – the City of Cambridge (Edward) and Harvard University (Mary). *Id.* ¶ 5. They were generally pleased with the discounted drug prices they received under those plans. *Id.*

Mary has taken charge for arranging medical coverage both for herself and for Edward. Once Medicare Part D coverage became available, she began investigating whether they should enroll in a Part D plan. Based on advice Mary received from the Harvard University Retirees Association, she decided she was better off continuing to obtain her prescription drug coverage from Harvard rather than signing up for a Part D plan. *Id.* ¶ 6.

However, she was confused regarding how to proceed with Edward's coverage, and remains confused to this day. *Id.* ¶ 7. He received a letter from the City of Cambridge in November 2005, advising him that the City of Cambridge was arranging for Part D coverage for its retirees and that he should not sign up for Part D coverage on his own. *Id.* In January 2006, the City of Cambridge wrote again, advising Edward that he was to be provided Part D coverage by Blue MedicareRx through Blue Cross Blue Shield of Massachusetts. *Id.* ¶ 8. Edward received voluminous information regarding the scope of benefits, both from the City of Cambridge / Blue MedicareRx and from other Part D plans, all of which Mary and Edward found very confusing. *Id.* To complicate Edward's situation further, he is retired from the U.S. Navy on 100% disability, a retirement that qualifies him for benefits under the TRICARE prescription drug benefit. *Id.* ¶ 9. In January 2006, Edward received a letter from the U.S. Department of Defense, informing him that "[t]here will almost always be no advantage to

enrolling in a Medicare prescription drug plan for most TRICARE beneficiaries." *Id.* The letter also stated that should Edward enroll in a Medicare prescription drug plan, TRICARE would be reduced to a secondary payer. *Id.*

Despite their confusion regarding how to proceed, Mary and Edward found it very difficult to get anyone to provide advice. Medical personnel at Youville House and at the rehabilitation center that is attached to Youville House told Edward and Mary that they were not in a position to provide such advice. Pharmacists at the pharmacy with which they had done business for a number of years also said that they could not provide any advice that could be deemed "steering" Edward and Mary to a particular prescription benefit plan. *Id.* ¶ 10. Finally, Mary located an attorney at a local organization that provides legal services to the elderly to review materials that Edward and Mary had received and to advise them on how to proceed. That volunteer attorney recommended that Edward enroll in Blue MedicareRx, with the caveat that she had no particular expertise on medical benefit issues. *Id.* ¶ 11. Based on that advice, Edward and Mary decided in early 2006 to enroll Edward in the Part D plan offered by Blue MedicareRx, and he continues to be enrolled in that plan. *Id.* ¶ 12. However, Edward purchases a large number of prescription medications on a regular basis, and his monthly bill is substantial. *Id.* ¶ 13. Edward and Mary continue to be concerned that Edward may not be enrolled in the plan that best meets his needs, and they wish they could receive additional information – particularly from their pharmacist – regarding whether other plans would be better for him. *Id.* ¶ 14.

That concern increased in July 2007 when Edward Samp fell and seriously injured his ankle. Since that time, he has resided in a series of hospitals, rehabilitation centers, and nursing

homes. *Id.* 4. One such facility, the Lexington Health Care Center (LHCC) in Lexington, Massachusetts, is a skilled nursing facility. *Id.*; Affidavit of Michael Flaherty, Exhibit G. As such, LHCC officials are subject to the speech restrictions imposed by the S&C Memo. Edward has resided in a series of nursing homes and rehabilitation centers in the past decade. Samp Decl. ¶ 3. He is currently undergoing rehabilitation services at the Youville Rehabilitation Center; but the maximum time for such stays is quite limited under Medicare, and he will be required to leave there within the next several weeks, very likely to another nursing home. *Id.* ¶ 4. Obviously, his medication needs (and thus his Part D needs) are likely to change as his recovery continues and his physical condition changes.

Plaintiffs' Lawsuit

The Washington Legal Foundation (WLF) filed suit on behalf of its members (including Rebecca Fox, Mary Samp, and Edward Samp) on August 24, 2006, alleging a violation of the First Amendment rights of its members to receive truthful information about their Part D options. The Complaint alleged that the CMS/HHS speech-suppression policies, evidenced by the Marketing Guidelines and the S&C Memo, injured WLF's members by making it impossible for them to make fully informed decisions regarding a choice of a PDP. Complaint ¶¶ 44, 49. The Complaint alleged that were the offending policies enjoined, providers would provide WLF's members with truthful information regarding the comparative merits of available PDPs. *Id.* ¶ 50. The two defendants – HHS Secretary Michael O. Leavitt and the Administrator of CMS (a position currently held by Leslie V. Norwalk in an acting capacity) – were sued in their official capacities only.[6] The suit sought both injunctive and declaratory relief.

[6] The defendants are referred to collectively hereinafter as "CMS."

On March 19, 2007, the Court denied WLF's motion for a preliminary injunction, on the grounds that WLF lacked standing to sue on behalf of its members. In light of that ruling, WLF thereafter filed a motion for leave to amend the complaint, to add WLF's members (Rebecca Fox, Edward Samp, and Mary Samp) as plaintiffs and to dismiss WLF as a plaintiff. The Court granted the motion for leave to amend on May 4, 2007.

ARGUMENT

The Federal Rules of Civil Procedure provide that when a party moves for summary judgment, "[t]he judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). Plaintiffs submit that they have demonstrated that they are entitled to an award of declaratory relief (a declaration that current CMS policies violate their First Amendment rights) and injunctive relief (an injunction against further CMS efforts to restrict what health care providers can say to Plaintiffs regarding their Part D options).

I. CMS's Content-based Restrictions on Noncommercial Speech Are Subject to Strict Constitutional Scrutiny, a Scrutiny CMS Cannot Withstand

The federal courts have long recognized that the First Amendment, subject only to narrow and well-understood exceptions, does not countenance governmental control over the content of messages conveyed by private individuals. *See, e.g., Texas v. Johnson*, 491 U.S. 397, 414 (1989). "As a general matter, 'state action to punish the publication of truthful information seldom can satisfy constitutional standards.'" *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) (quoting *Smith v. Daily Mail Publishing Co.*, 443 U.S. 97, 102 (1979)). While the courts have very occasionally upheld content-based speech restrictions, they have always imposed on the

government a heavy burden of demonstrating the necessity of such restrictions. *See, e.g., Ashcroft v. ACLU*, 542 U.S. 656, 666 (2005) (affirming grant of a preliminary injunction where the federal government had failed to show that it was likely to prevail on merits and holding that "[a]s the Government bears the burden of proof on the ultimate question of [the challenged Act's] constitutionality, respondents [the movants] must be deemed likely to prevail unless the Government has shown that respondents' proposed less restrictive alternatives are less effective than [enforcing the Act]"); *R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992) ("Content-based regulations are presumptively invalid," and the government bears the burden to rebut that presumption.); *Burson v. Freeman*, 504 U.S. 191, 198 (1992). In the procedural context of this motion for a preliminary injunction, the burden rests on CMS to demonstrate the compelling interest that justifies its speech restrictions.

Plaintiffs do not expect CMS to contend that the speech restrictions imposed by the Marketing Guidelines and the S&C Memo are not, in fact, content-based. Those documents quite clearly target speech based solely on its content. *See, e.g.*, Marketing Guidelines at 123-24 ("Providers . . . cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific plan."). The Supreme Court has made clear that any such speech restrictions should be deemed content-based. *See, e.g., Turner Broadcasting System, Inc. v. Federal Communications Comm'n*, 512 U.S. 622, 643 (1994) ("As a general rule, laws that by their terms distinguish favored speech from disfavored speech on the basis of the ideas expressed are content-based.").[7] Because they

[7] For purposes of determining whether a speech restriction should be deemed content-based, it makes no difference whether the restriction seeks to silence particular viewpoints or simply silences all speech on a given topic; both types of restrictions are deemed content-based. A speech restriction qualifies as content-based even when it applies equally to all speech on the prohibited topic, without regard to the viewpoint expressed. *See, e.g., Simon &*

are content-based, the CMS speech restrictions are subject to an exacting scrutiny that very few such restrictions can even hope to survive. *See, e.g., Burson*, 504 U.S. at 198 (content-based restrictions on noncommercial speech are subjected to "exacting scrutiny," and will be upheld only if the government can show that the restrictions are necessary to serve a "compelling state interest" and are "narrowly drawn to achieve that end.").

A. Providers' Recommendations Regarding Which Part D Plans Best Serve Their Patients' Needs Do Not Qualify As Commercial Speech

There is no merit to any argument that the speech being restricted should be deemed commercial speech, a designation that would subject the CMS speech restrictions to a less exacting level of First Amendment scrutiny.

The Supreme Court has made clear that "commercial speech," while entitled to a substantial degree of constitutional protection, is afforded a somewhat lower level of First Amendment protection than is speech that is noncommercial in nature. *See, e.g., Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557, 562-63 (1980). In general, "commercial speech" is defined as "speech which does no more than propose a commercial transaction." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976). Indeed, the Supreme Court has "characteriz[ed] the proposal of a commercial transaction as '*the test* for identifying commercial speech.'" *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 416 (1993) (emphasis in original) (quoting

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Schuster, Inc. v. Members of New York State Crimes Victims Board, 502 U.S. 105, 117 (1991) (in determining whether a regulation of speech is content-based, "it is irrelevant whether the state is trying to suppress particular ideas."). Thus, the Marketing Guidelines do not escape a "content-based" classification simply because they do not play favorites among PDPs (*e.g.*, by permitting providers to steer their patients toward some PDPs but not others).

Bd. of Trustees of State University of New York v. Fox, 492 U.S. 469, 473-74 (1989)). Fully protected speech is not transformed into commercial speech merely because the speaker is drawing a salary (or otherwise making a profit) while speaking. *Id*. at 482 ("Some of our most valued forms of fully protected speech are uttered for a profit. *See, e.g., New York Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Buckley v. Valeo*, 424 U.S. 1 (1976) (per curiam).").

The activities at issue here – *e.g.*, recommending a specific PDP to a patient – do not propose a commercial transaction between the speaker and the listener. Rather, CMS prohibits speech that does no more than recommend that the patient enter into a commercial transaction with a third party, even when (as is virtually always true) the provider receives no remuneration for making that recommendation. Thus, under the governing standard, the speech here is not commercial speech.

In addition, the speech here does not reflect any of the related characteristics that the Supreme Court has on occasion used in identifying commercial speech. For example, none of the three guideposts for classifying speech as commercial set out in *Bolger v. Youngs Drug Products Corp.* 463 U.S. 60, 66-67 (1983), are applicable here. First, advice provided to patients regarding which PDPs to select is not an "advertisement" under the common understanding of that term. *Id.* at 66. Second, the speech in question makes no reference to any product and service being offered by the speaker for a fee. *Id.*; *see also Securities & Exchange Comm'n v. Wall Street Publishing Institute, Inc.*, 851 F.2d 365, 372 (D.C. Cir. 1988). Third, most providers have virtually no economic motivation for their speech. *Id.* at 67. Physicians, hospitals, and nursing homes rarely have financial dealings with PDPs or receive payments from them, so those providers are largely indifferent from an economic standpoint regarding which PDPs are selected

by their patients. While pharmacists occasionally stand to gain financially to a small degree if their patients choose one PDP rather than another, those gains are sufficiently small that it is not fair to characterize Part D recommendations given to their customers as "economically motivated." *Id.*[8] *Bolger* classified the brochure at issue in that case as "commercial speech" only after concluding that the brochure possessed all three characteristics – writing in a form commonly understood to constitute advertising; frequent references to a product or service being offered by the speaker for a fee; and an economic motivation to recommend a particular course of action to the listener. Given that the providers subject to CMS's speech restrictions rarely possess any of the three characteristics of commercial speakers discussed in *Bolger* – and never more than one – the speech at issue here cannot plausibly be deemed commercial.

B. Even if Providers' Speech Were Commercial in Nature, It Would Still Be Entitled to Full First Amendment Protection

A second, independent reason that the CMS speech restrictions must be subjected to strict scrutiny is that they prohibit the dissemination of truthful information that is of public concern.

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[8] As consulting pharmacist Ross Brickley explains:

> There is no realistic financial incentive for a consulting pharmacist such as myself to encourage a patient or his/her financially responsible party to enroll in a particular Part D prescription drug plan. . . . The only real financial interest which the pharmacy has in selection of Part D plans is finding the plan that will cover the patient's medications, rather than imposing that cost on the patient.

Brickley Decl. ¶¶ 12-13. Abby Block, the CMS official in charge of drafting the Marketing Guidelines, testified that she is unaware of any CMS study suggesting that pharmacists have a financial incentive to steer beneficiaries to a particular plan. Block Deposition at 32-33, 54 (attached to Declaration of Richard Samp, Exhibit J). Of course, the government has little basis for seeking to "protect" Part D beneficiaries from "unscrupulous" pharmacists acting in their own financial interests where, as here, those interests coincide with the interests of the patient – both seek PDPs that will cover the costs of the patient's medications.

There can be little doubt that information regarding Part D options available to Medicare-eligible individuals is of considerable public concern; given the high costs of prescription drugs, such information has a significant effect on the ability of seniors to balance their household budgets. The First Amendment bars government officials from prohibiting the publication of "truthful information about a matter of public significance" "absent a need . . . of the highest order." *Smith*, 433 U.S. at 103. The rationale for protecting speech on matters of public interest applies regardless whether the speech at issue is deemed commercial or noncommercial.

The Supreme Court has explained that government is granted greater leeway in regulating speech directly related to commercial transactions because of its interest in "preservation of a fair bargaining process," an interest that often cannot be vindicated without some regulation of speech. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (plurality). Direct government regulation may be the only mechanism to ensure that vendors provide potential customers with accurate information about the products and services they wish to sell. It is thus "the State's interest in regulating the underlying transaction" that "give[s] it a concomitant interest in the underlying expression itself," *Edenfield v. Fane*, 507 U.S. 761, 767 (1993), and the power to "deal effectively with false, deceptive, or misleading sales techniques." *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 69 (1983).

But the government's interest in regulating the speech of a commercial entity (or in regulating the speech of its employees) diminishes as that speech becomes further removed from an underlying sales transactions between a vendor and its potential customers. Speech of the type the Marketing Guidelines seek to regulate – *e.g.*, recommendations to enroll in a specific PDP – may lead seniors to enter into transactions with third parties, but it has absolutely no

relationship to the government's interest in preserving a fair bargaining process between a commercial speaker and its customers. The absence of such a relationship suggests that the government's interests in regulating providers' speech are significantly diminished.

Moreover, as noted above, society's First Amendment interest in promoting uninhibited speech on an issue increases when, as here, the issue is one acknowledged to be of significant public interest.[9] For example, when those seeking to disseminate information have been challenged by those asserting an interest in nondissemination, the Supreme Court has consistently resolved such disputes by reference to whether the information involved a matter of public interest. *See, e.g., Smith*, 443 U.S. at 103; *New York Times Co. v. United States*, 403 U.S. 713 (1971) (*per curiam*) (publication of Pentagon Papers over objections of federal government justified in part by fact that papers included information of great public concern). Most recently, in *Bartnicki v. Vopper*, 532 U.S. 514 (2001), the Court held that the First Amendment prevented individuals whose illegally intercepted telephone conversations had been broadcast on a radio station from suing the radio station, in large measure because the conversations involved "information of public concern." 532 U.S. at 534. Similarly, the First Amendment right of government employees to speak freely (without fear of discipline by their employers) hinges largely on the public importance of the issues addressed. *See Pickering v. Bd. of Education*, 391 U.S. 563, 566 (1968).

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[9] There is no reason to conclude that providers' views regarding selection of a PDP are any less valuable than the views of others whose speech is not restricted. The fact that many providers are for-profit corporations is immaterial, for "[t]he inherent worth of the speech in terms of its capacity for informing the public does not depend upon the identity of its sources, whether corporation, association, union, or individual." *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765, 777 (1978).

In *Thornhill v. Thompson*, 310 U.S. 88 (1940), the Supreme Court rejected an effort to prevent speech by an entity that wished to speak out on an issue of public importance. The case involved labor picketing that sought "to advise customers and prospective customers" regarding labor conditions "and thereby to induce such customers" to change their purchase decisions. *Thornhill*, 310 U.S. at 99. Despite Alabama's claim that information being conveyed by picketers was false, the Court overturned an injunction against picketing because the First Amendment bars the government from "impair[ing] the effective exercise of the right to discuss freely industrial relations which are *matters of public concern*." *Id.* (emphasis added). The Court reasoned, "Free discussion concerning the conditions in industry and the causes of labor disputes [is] indispensable to the effective and intelligent uses of the process of popular government to shape the destiny of modern industrial society." *Id.* at 103. Similarly, free discussion concerning an issue of life-changing importance to America's seniors is in jeopardy if the federal government is permitted to prevent truthful speech by companies and individuals wishing to discuss the issue.

Indeed, because of the importance of open discussion on matters of public concern, some members of the Supreme Court would grant full First Amendment protection even to *false* speech on issues of public concern and even when uttered in a commercial setting. For example, Justice Breyer opined, without contradiction by his colleagues in a case arising in a commercial context, that "speech on matters of public concern needs 'breathing space' – potentially incorporating certain false or misleading speech – in order to survive." *Nike, Inc. v. Kasky*, 539 U.S. 654, 676 (2003) (Breyer, J., dissenting from dismissal of writ of certiorari). This Court need not embrace that view in order to rule that the *truthful* speech at issue here – regardless

whether it is deemed commercial or noncommercial – is entitled to full First Amendment protection. Such a ruling requires no more than an understanding that the First Amendment "embraces at least the liberty to discuss publicly and truthfully all matters of public concern." *Consolidated Edison Co. of New York v. Public Serv. Comm'n*, 447 U.S. 530, 534 (1980).

C. CMS Cannot Meet Its Burden of Demonstrating that Its Speech Restrictions Serve a Compelling Interest by the Least Burdensome Means

When a regulation is subject to strict scrutiny, it may be upheld only where the government shows that the statute serves a compelling interest and that the statute is the least restrictive means of achieving that interest. None of CMS's reasons for adopting its speech restrictions are compelling; and the interests do not, in any event, outweigh the harm they inflict on a beneficiary's ability to make an informed choice of a Part D plan.

There can be no serious dispute that the Marketing Guidelines do, in fact, impose speech restrictions on health care providers. *See, e.g.*, Marketing Guidelines at 123-25. Many such providers (including all pharmacists), because they are intimately involved in the administration of drugs to their patients, of necessity have contractual relationships with most or all available PDPs. *See, e.g.*, Brickley Decl. ¶ 12 (Brickley's pharmacy contracted with all of the PDPs in the area serviced by his pharmacy). The Marketing Guidelines explicitly state that providers that have entered into such contractual relationships are subject to severe speech restrictions. Marketing Guidelines at 122. Moreover, CMS has made clear through other documents that providers are subject to those speech restrictions regardless whether they have contracted directly with any PDPs. For example, the S&C Memo states:

> Under no circumstances should a nursing home require, request, *coach, or steer* any resident to select or change a plan for any reason. Furthermore, a nursing home should not knowingly and/or willingly allow the pharmacy servicing the nursing home to

> require, request, *coach, or steer* any resident to select or change a plan [42 C.F.R. § 483.12(d)].

S&C Memo at 3. Moreover, providers are well aware of the CMS speech restrictions and, as a result, have curtailed their speech regarding PDPs – even though they realize that their patients could benefit greatly from their advice regarding choice of plans. *See, e.g.*, England Decl. ¶ 7; White Decl. ¶¶ 7-8; Brickley Decl. ¶ 10. Plaintiffs Rebecca Fox and Mary Samp have been unable to obtain advice regarding PDP choices from their health care providers precisely because of the CMS speech restrictions. Fox Decl. ¶¶ 12, 17; Samp Decl. ¶¶ 10, 14.

Absence of a Compelling Interest. Before examining CMS's articulated justifications for its speech restrictions, it should be kept in mind that few interests have been characterized as sufficiently compelling to justify content-based restrictions on speech. "It is basic that no showing merely of a rational relationship to some colorable state interest" suffices as a compelling interest. *Sherbert v. Verner*, 374 U.S. 398, 406 (1963). "Only the gravest abuses, endangering paramount interests," *Thomas v. Collins*, 323 U.S. 516, 530 (1945), are compelling. The Court must "searchingly examine the interests that the State seeks to promote . . . and the impediment to those objectives that would flow if its statute is not enforced." *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 126 S. Ct. 1211, 1220 (2006).[10]

[10] Plaintiffs are aware of only one case in recent decades in which the Supreme Court upheld, in the face of a First Amendment challenge, a content-based restriction on fully protected speech. In *Burson*, the Court upheld a law that prohibited electioneering activity in support of a candidate for public office within 100 feet of a polling place on election day. In doing so, the Court emphasized the extremely limited temporal and geographic scope of the prohibition, and the State's extremely strong interests both in maintaining the integrity of elections and in protecting voters from harassment that could interfere with the constitutionally protected right to vote. *Burson*, 504 U.S. 191, 210-11 (1992). The CMS speech restrictions contain no similar limitations, and are not intended to protect any competing constitutional rights.

The Marketing Guidelines list several justifications for the CMS speech restrictions. First, CMS speculates that health care providers may not be fully aware of all plan benefits and costs. Marketing Guidelines at 123. Second, CMS states that a provider may confuse the beneficiary if the provider is perceived as acting as an agent of the recommended PDP vs. acting as the beneficiary's provider. *Id.* Third, CMS points to potential conflicts of interest:

> Providers may face conflicting incentives when acting as a plan representative. For example, some providers may gain financially from a beneficiary's selection of one plan over another plan. Additionally, providers generally know their patients' health status. The potential for financial gain by the provider steering a beneficiary's selection of a plan could result in recommendations that do not address all of the concerns or needs of a potential plan enrollee.

Id.

Those justifications self-evidently do not constitute the sort of "compelling interest" that can warrant extreme measures such as content-based speech restrictions. Any CMS attempt to argue that it can meet the "compelling interest" standard would be rejected forthwith. For that reason, Plainitffs provide a more detailed discussion of CMS's likely justifications in Section II, wherein Plaintiffs will show why those justifications are without merit and thus insufficient to withstand even intermediate First Amendment scrutiny. Suffice to say that the failure of recent congressional efforts to craft anti-pornography statutes that could withstand strict First Amendment scrutiny – despite a very compelling government interest in protecting children from obscene and/or indecent speech – suggests that CMS could come nowhere close to meeting its burden of demonstrating a "compelling interest" in regulating truthful speech by health care providers regarding Part D options. *See Ashcroft v. ACLU,* 542 U.S. 656, 666 (2004); *Reno v. ACLU,* 521 U.S. 844, 874 (1997). "It is rare that a regulation restricting speech because of its content will ever be permissible." *United States v. Playboy Entertainment Group,* 529 U.S. 803,

817 (2000).

II. The CMS Speech Restrictions Cannot Survive Intermediate First Amendment Scrutiny

As demonstrated above, the CMS speech restrictions are content-based restrictions on fully protected non-commercial speech and thus are subject to strict First Amendment scrutiny. But even if the restrictions were judged under the intermediate scrutiny applicable to commercial speech, they still could not withstand First Amendment scrutiny.

Although the government has greater leeway to regulate commercial speech, putative regulators of such speech still face a significant burden. At a minimum, the Supreme Court requires that the government prove that the restriction "directly advances" a "substantial government interest" and is "narrowly tailored" to achieve a reasonable "fit" between CMS's stated goals and the agency's means of achieving them. *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980).[11] For the *Central Hudson* test to be satisfied, the Court must be persuaded that the cost of the regulation has been "carefully calculated." *Discovery Network*, 507 U.S. at 416 n.12. As with fully protected speech, the burden of justifying its restrictions rests squarely with CMS. *Bolger*, 463 U.S. at 71 n.20 ("party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *Thompson v.*

[11] Under the four-part *Central Hudson* test, courts consider as a threshold matter whether the commercial speech concerns unlawful activity or is inherently misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, then the challenged speech regulation violates the First Amendment unless government regulators can establish that: (1) they have identified a substantial government interest; (2) the regulation "directly advances" the asserted interest; and (3) the regulation "is no more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566.

Western States Medical Center, 535 U.S. 357, 373 (2002).[12]

A. The Speech at Issue Concerns Lawful Activity and Is Not Misleading

To qualify for constitutional protection, commercial speech first "must concern lawful activity and not be misleading." *Central Hudson*, 447 U.S. at 566. CMS does not, of course, contend that it is unlawful for PDPs to sign up Medicare-eligible individuals for their plans. So even assuming that providers' speech could somehow be tied in to those contractual arrangements, there can be no doubt that the speech "concern[s] lawful activity."[13]

Moreover, the only speech at issue here is truthful, non-misleading speech: Plaintiffs object to CMS policies that prevent providers from supplying them with truthful information regarding which Part D plan best suits their needs. CMS may not impose a blanket ban on all speech on a topic simply because it fears that some of that speech may be misleading. The Supreme Court has made clear that the "free flow of commercial information is valuable enough to justify imposing on would-be regulators the cost of distinguishing the truthful from the false,

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[12] The evidentiary burden is not light; for example, the government's burden of showing that a commercial speech regulation advances a substantial government interest "in a direct and material way . . . 'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.'" *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

[13] The federal anti-kickback statute does, of course, make it a crime to pay or receive a kickback in return for referring an individual to a service for which reimbursement may be available under a federal healthcare program. 42 U.S.C. § 1320a-7b(b). But the CMS speech restrictions are not limited to speech for the purpose of facilitating receipt of a kickback; rather, they apply to *all* speech that recommends a specific PDP. Given their breadth, the speech restrictions cannot be justified as a measure designed to regulate speech that proposes an illegal transaction. Accordingly, a CMS assertion that it adopted the speech restrictions with the anti-kickback statute in mind would not affect the *Central Hudson* analysis.

the helpful from the misleading, and the harmless from the harmful." *Ibanez v. Florida Dep't of Bus. & Prof. Regulation*, 512 U.S. 136, 146 (1994). Accordingly, because the speech at issue here is truthful, the burden shifts to CMS to demonstrate that its speech restrictions are permissible under the remaining *Central Hudson* factors.

B. There Is No Government Interest in "Protecting" Seniors from Truthful Speech

As with fully protected speech, CMS must articulate legitimate governmental goals to justify restrictions on commercial speech. The only variation between the two analyses is one of degree: restrictions on non-commercial speech must serve a "compelling" state interest, while commercial speech restrictions can be justified if they serve a "substantial" interest. *Sable Communications of Calif. v. FCC,* 492 U.S. 115, 126 (1989) ("Government may . . . regulate the content of constitutionally protected speech in order to promote a compelling interest if it chooses the least restrictive means to further the articulated interest."); *Central Hudson*, 447 U.S. at 564 ("State must assert a substantial interest to be achieved by restrictions on commercial speech.").

CMS undoubtedly has an interest in protecting seniors from false or misleading speech that might cause them to sign up with an inappropriate Part D plan. But CMS cannot possibly have *any* sort of interest (*i.e.*, either compelling or substantial) in "protecting" seniors from the only type of speech at issue in this case: truthful information regarding which Part D plan best serves their needs. The Supreme Court has categorically rejected all arguments that there can be a government interest in depriving consumers of truthful commercial information, even when the government fears that consumers might somehow misuse the information:

> We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information. In *Virginia Bd. of Pharmacy* [*v. Virginia*

> *Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)], the State feared that if people received price advertising from pharmacists, they would "choose the low-cost, low-quality service and drive the 'professional' pharmacist out of business" and would "destroy the pharmacist-customer relationship" by going from one pharmacist to another. We found these fears insufficient to justify a ban on such advertising. 425 U.S. at 769.

Western States, 535 U.S. at 374-75.

Western States went on to quote *Virginia Bd. of Pharmacy* at length, to emphasize the inappropriateness of ever restricting speech for the purpose of suppressing truthful information:

> "There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. . . . But the choice among these alternative approaches is not ours to make or the Virginia General Assembly's. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. Virginia is free to require whatever professional standards it wishes of its pharmacists; it may subsidize them or protect them from competition in other ways. But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering."

Id. at 375 (quoting *Virginia Bd. of Pharmacy*, 425 U.S. at 770).

Plaintiffs find it ironic that the Marketing Guidelines permit a PDP to convey to seniors reasons why they should sign up for that Part D plan above all others, but that providers – who have little or no financial stake in the decision – may not make similar a similar recommendation, no matter how truthful. *Western States* makes crystal clear that CMS's desire to shield seniors from those truthful views does not constitute a "substantial" government interest under the *Central Hudson* test.

C. The CMS Speech Restrictions Do Not Directly Advance an Important Government Interest

Under the third prong of the test, "The limitation on expression must be designed carefully to achieve the State's goal." *Central Hudson*, 447 U.S. at 564. Toward this end, "the

restriction must *directly* advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Id.* (emphasis added). In order to satisfy these requirements, "a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. "[M]ere speculation or conjecture" is insufficient to fulfill the requirements. *Id*. at 770. The government's burden is not met when a "[s]tate offer[s] no evidence or anecdotes in support of its restrictions." *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995) (quoting *Burson*, 504 U.S. at 211).

The Marketing Guidelines set forth several rationales for restricting patients' access to information from providers regarding choice of Part D plans. None of those rationales even begins to explain how the restrictions directly and materially advance CMS's interest in protecting seniors from false or misleading speech that might cause them to sign up with an inappropriate Part D plan.

First, CMS opines that "[p]roviders may not be fully aware of all plan benefits and costs." Marketing Guidelines at 123. Second, CMS states that "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." *Id.* Third, CMS raises the possibility that providers may have interests that conflict with those of the beneficiary:

> Providers may face conflicting incentives when acting as a plan representative. For example, some providers may gain financially from a beneficiary's selection of one plan over another plan. Additionally, providers generally know their patients' health status. The potential for financial gain by the provider steering a beneficiary's selection of a plan could result in recommendations that do not address all of the concerns or needs of a potential plan enrollee.

Id.

CMS has put forward no evidence in the public record to support any of these concerns, and WLF is not aware of any. While CMS is undoubtedly correct that not *all* providers are fully aware of *all* benefits and costs of *all* the plans available to their patients, the reality is that *nobody* (including CMS itself) can provide a beneficiary with all of the permutations of possible benefits and costs which they may apply under all of the beneficiary's PDP options in every different circumstance - there are simply too many variables at issue. Compelling evidence on that point is a recent study in which the U.S. Government Accountability Office placed 900 calls to Part D plan call centers and found that only 34% of the answers it received to the 5 questions posed were "accurate and complete"; 22% of the answers provided were "inaccurate." GAO, *Prescription Drug Plan Sponsor Call Centers Were Prompt, But Not Consistently Accurate and Complete* (hereinafter, "GAO Report"), at 6 (June 2006), available at http://www.gao.gov/new.items/d06710.pdf. Providers will frequently have more accurate information on the relevant issues than beneficiaries can obtain from other sources, and will be in a position to provide truthful and non-misleading information. *See, e.g.*, Wood Decl. ¶ 8. Accordingly, despite CMS's claim that not all providers know all there is to know about all plan benefits and costs, the evidence overwhelmingly shows that restricting provider speech does not directly and materially advance CMS's interest in protecting seniors from being misled regarding a choice of Part D plans.

Second, the CMS speech restrictions do not directly and materially advance its alleged interest in avoiding confusion among seniors who might think that a provider is acting as an agent of a particular PDP sponsor. There is no reason to believe that a senior would mistakenly

think that a provider is acting as an agent if it does not claim to be doing so; if there were any doubt on that issue, CMS could simply require providers to state that they are not acting as agents for recommended PDPs. Moreover, if a senior is operating under that mistaken impression, he or she is likely to be *more* skeptical of what the provider has recommended, thereby *decreasing* the possibility that the provider's speech could lead the senior to sign up with an inappropriate PDP. Of course, if the provider is, in fact, an agent in the employ of a PDP, then it would be subject to the Marketing Guidelines' restrictions on activities of the PDP sponsor itself, and no separate speech restriction based on its status as a provider would be necessary.

CMS's third rationale, regarding providers potentially gaining financially based upon one plan being selected over another, also fails to justify the severe restrictions on speech set forth in the Marketing Guidelines and the S&C Memo. First, many providers will not benefit or suffer financially based upon a patient's choice of PDP. Physicians, hospitals and nursing homes generally do not contract with PDPs or receive any payments from PDP sponsors, so this is not a legitimate objection to their provision of advice as between competing PDPs.

The only providers that are paid by PDPs are pharmacies, which receive payment for the drugs that they dispense to Part D beneficiaries. However, those payments do not create a conflict of interest between the pharmacist and the beneficiary. As consulting pharmacist Ross Brickley explains:

> There is no realistic financial incentive for a consulting pharmacist such as myself to encourage a patient or his/her financially responsible party to enroll in a particular Part D prescription drug plan. There are negligible differences in the ingredient charges and dispensing fees (the compensation my employer, the pharmacy, receives from a Part D plan for dispensing a particular prescription drug) payable by the different Part D plans with which my pharmacy has contracted. My pharmacy contracted with all Part D plans

> in each area where it provides services. The only real financial interest which the pharmacy has in selection of Part D plans is finding the plan that will cover the patient's medications, rather than imposing that cost on the patient.

Brickley Decl. ¶¶ 12-13. Seniors, of course, have precisely the same interest: to ensure that the plans they choose best cover the costs of their medications. In the absence of substantial evidence of conflicting financial interests between seniors and their health care providers and professional, CMS has failed to demonstrate that its speech restrictions will directly and materially advance its interests in protecting seniors from misleading speech arising out of such conflicts.

In sum, CMS cannot satisfy the third prong of the *Central Hudson* test: it cannot show that its speech restrictions have been carefully designed to protect seniors from signing up for inappropriate Part D plans.

C. The Speech Restrictions Are Broader Than Necessary to Serve an Important Government Interest

Finally, CMS's speech restrictions are considerably more extensive than necessary to serve – indeed, they are at odds with – the only justifiable governmental interest here: protecting seniors from false or misleading speech that might cause them to sign up with an inappropriate Part D plan.[14] While commercial speech jurisprudence does not require CMS to employ the least restrictive means of advancing an interest, CMS must make an effort reasonably to fit its means to its ends. *Western States,* 535 U.S. at 371-72; *Discovery Network,* 507 U.S. at 769; *Fox,* 492

[14] The breadth of the CMS speech restrictions is extraordinary. Providers are barred not only from providing their views regarding the most appropriate PDP, but also from providing their patients with the views of independent third parties. *See generally* Marketing Guidelines at 114, discussed *supra* at 10 (providers may not retain NBPTPs – independent third parties – to compile comparative Part D plan information for use by their patients).

U.S. at 480. Several facts demonstrate that CMS has failed to do so here.

First, CMS imposes a blanket ban on all speech that recommends the choice of a specific PDP. Marketing Guidelines at 123-24 (providers "cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific plan"); S&C Memo at 3 ("Under no circumstances should a nursing home require, request, coach, or steer any resident to select or change a plan for any reason."). Such blanket bans are particularly disfavored under the First Amendment. *See, e.g.*, *Edenfield*, 507 U.S. at 777 ("Broad prophylactic rules in the area of free expression are suspect."); *Pearson v. Shalala*, 164 F.3d 650, 657-58 (D.C. Cir. 1999). CMS has not explained why its interest in preventing seniors from being misled regarding their choice of a Part D plan could not be fully satisfied by imposing disclaimer requirements on providers. For example, if there is a financial benefit to a pharmacy from the patient's selection of a recommended PDP over other alternatives, the pharmacy could be required to disclose that financial benefit to the patient when the recommendation is made.[15] Another possible disclaimer: a requirement that providers advise their patients regarding other sources of relevant information. Indeed, the Marketing Guidelines already state that providers should advise their patients regarding other sources of relevant information (such as 1-800-Medicare and the Medicare.gov web site) when

[15] Plaintiffs do not mean to concede that such a disclaimer requirement would be constitutionally permissible, or that a similar disclaimer would be permissible with respect to other providers and other professionals that have entered into contracts with recommended plans -- *e.g.*, hospitals, physicians, and nursing homes that have entered into contracts with Medicare Advantage plans that cover both Part A/B benefits and prescription drug benefits. Rather, the point is that blanket speech bans cannot possibly be constitutionally permissible, even when judged under the *Central Hudson* test, given that disclaimers would fully satisfy CMS's interest in protecting seniors from potentially misleading speech and would do so in a manner that intrudes far less on First Amendment rights.

discussing plan alternatives. Marketing Guidelines at 124.[16] In those instances in which CMS may have reason to conclude that patients might mistakenly believe that the provider is acting as an agent for a recommended plan, a requirement that the provider advise its patients that it is not, in fact, acting as an agent of the recommended plan would fully satisfy CMS's concerns while intruding far less on First Amendment rights than do the Marketing Guidelines. The Supreme Court has repeatedly held that blanket speech bans run afoul of the fourth *Central Hudson* prong when the government could satisfy its important interests by imposing disclaimer requirements on would-be speakers. *See, e.g., Western States*, 535 U.S. at 376; *44 Liquormart*, 517 U.S. at 507; *In re R.J.M.*, 455 U.S. 191, 203 (1982).[17]

Second, if CMS's principal concern is that PDP sponsors might start bribing providers to steer patients to their plan, there are numerous non-speech methods of satisfying that concern. Plaintiffs note that such payments are prohibited by federal law and subject both payer and recipient to severe civil and criminal penalties. *See* 42 U.S.C. § 1320a-7b(b) (prohibition against paying or receiving kickbacks in return for referring an individual to a service for which reimbursement may be available under a federal health care program). CMS has presented no reason to suggest, nor could it, that the threat of criminal enforcement of the anti-kickback

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[16] There is considerable evidence however, that the information provided by the government itself is not accurate. For example, a September 25, 2007 letter from U.S. Rep. Pete Stark to the GAO stated that Stark "continue[d] to be concerned with the completeness and accuracy of information provided to beneficiaries who contact [Medicare] call centers." *See* Declaration of Richard Samp, Exhibit J.

[17] Nor can CMS's speech restrictions be justified by an assertion that patients might be able to get the same information from other sources. Restrictions on the free flow of truthful, non-misleading information cannot stand simply because there is the possibility that the same message might be received by other means. *See, e.g., Ladue v. Gilleo*, 512 U.S. 43, 56 (1994); *Bolger*, 463 U.S. at 69.

statute would be insufficient to deter PDP sponsors from offering such payments to providers, even without the imposition of the CMS speech restrictions.[18]

In sum, even when analyzed under the intermediate level of First Amendment scrutiny applicable in commercial speech cases, the CMS speech restrictions are constitutionally impermissible.

III. PLAINTIFFS HAVE STANDING TO PURSUE THIS CLAIM

Plaintiffs possess First Amendment rights to hear speech from willing speakers. It is well settled that the First Amendment protects not only the right to speak, but also the right to receive information. *Virginia State Bd. of Pharmacy*, 425 U.S. at 756-57 (First Amendment protection is afforded "to the communication, to its source and to its recipients both"); *Smith v.*

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[18] Health care providers are well aware of the severe sanctions that regularly are imposed on entities that violate the anti-kickback statute. The most recent report from HHS's Office of Inspector General, which is charged with ensuring compliance with the anti-kickback statute, details the extent of those sanctions. During the six month period ending September 30, 2006, 3,425 individuals and entities were officially excluded from further participation in federal health care programs as a result of having been found to have violated the federal anti-kickback statute (or for other forms of fraud/abuse involving those health care programs), and 472 criminal actions were initiated, based on similar misconduct. *See* HHS Office of Inspector General, *Semi-Annual Report to Congress* (April 1, 2006 - September 30, 2006), available at http://oig.hhs.gov/publications/docs/semiannual/2006/Semiannual%20Final%20FY%202006.pdf.

On the other hand, CMS officials appear not even to have considered the deterrent effect of the anti-kickback statute before deciding that it was necessary to impose speech restrictions on providers. *See* Deposition of Abby Block at 36-38. Nor did they give any consideration whatsoever to First Amendment considerations before imposing the restrictions. *Id.* at 14; Deposition of Thomas Hamilton at 34-35. (Hamilton was the CMS official in charge of drafting the S&C Memo. *Id.* at 17.) Indeed, Block does not even consider the ban on "steering" to constitute a speech restriction at all. Block Dep. at 12. Excerpts from the depositions are attached to the Declaration of Richard Samp. Under those circumstances, CMS cannot reasonably assert that its speech restrictions are not any broader than necessary to serve its regulatory concerns.

United States, 431 U.S. 291, 318 (1976) ("The First Amendment necessarily protects the right to receive information and ideas."); *Kleindeinst v. Mandel*, 408 U.S. 753, 762 (1972); *Washington Legal Found. v. Henney*, 202 F.3d 331, 333-34 (D.C. Cir. 2000) ("First Amendment protections extend both to distribution and receipt of commercial speech."). Accordingly, Plaintiffs possess a First Amendment interest in ensuring that the federal government does not impose constitutionally impermissible restrictions on the speech of those willing and able to provide them with information.

Plaintiffs Rebecca Fox, Mary Samp, and Edward Samp have demonstrated that the CMS speech restrictions are preventing their health care providers from advising them regarding which Part D plans best suit their needs. When Ms. Fox sought such advice from her pharmacist, she was told that he was not permitted to provide such advice and that she would have to make the choice on her own. Fox Decl. ¶ 12, 17. Edward and Mary Samp encountered similar unwillingness among their health care providers, based on the CMS speech restrictions, to recommend a Part D plan. Samp Decl. ¶ 10. All three continue to desire to obtain such recommendations from their health care providers and professionals, but are being obstructed by the CMS speech restrictions. Fox Decl. ¶¶ 21-24; Samp Decl. ¶ 14-15. Their providers are not the only ones who are declining to recommend Part D plans due to the CMS speech restrictions; health care providers across the country are declining to provide that information, despite being well-positioned to do so and despite the fact that they are constantly being asked for such information by their patients. England Decl. ¶ 7; White Decl. ¶ 7-8; Brickley Decl. ¶ 10.

Edward and Mary Samp are being adversely affected not only by the Marketing Guidelines but also by the S&C Memo, which imposes speech restrictions on nursing homes.

Edward Samp has been in and out of nursing homes for the past decade. Most recently, he resided in the Lexington Health Care Center throughout August 2007. He currently resides in the Youville Rehabilitation Center (YRC), awaiting recovery from a severely broken ankle. Samp Decl. 4.[19] His remaining time at YRC is quite limited; unless he is deemed mobile within the next two weeks, he is likely to return to a nursing home to complete his recovery. *Id.* Accordingly, it is vital to the Samps that nursing home officials be in a position to provide them advice regarding which Part D plan best serves Edward Samp's needs. However, those officials are prohibited by the S&C Memo from providing the Samps with such advice.

In light of the above, Plaintiffs Rebecca Fox, Mary Samp, and Edward Samp have standing to challenge the CMS speech restrictions on First Amendment grounds. The Supreme Court has explained that the:

> [I]rreducible constitutional minimum of standing contains three requirements. . . . First, and foremost, there must be alleged (and ultimately proven) an "injury in fact" – a harm suffered by the plaintiff that is "concrete" and "actual and imminent, not 'conjectural' or 'hypothetical.'" . . . Second, there must be causation – a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant. . . . And third, there must be redressability – a likelihood that the requested relief will redress the alleged injury.

Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 102-103 (1998) (citations omitted).

The evidence indicates that Rebecca Fox, Mary Samp, and Edward Samp have met all three requirements. They have suffered a concrete injury: they have been denied access to information that their health care providers are willing to provide. The injury is fairly traceable to the complained-of conduct: the health care providers declined to provide assistance because

[19] Plaintiffs are not sure whether officials at YRC are bound by the S&C Memo, or whether only the Marketing Guidelines restrict the speech of those officials.

CMS had directed them not to do so.[20] Finally, they have demonstrated redressability: health care providers would be willing to provide the requested advice if the CMS speech restrictions were lifted.

CMS should not be heard to suggest that an injunction is unnecessary because the speech restrictions are not as severe as Plaintiffs suggests and that providers are still permitted to provide a wide range of information. First of all, that has not been the experience of Plaintiffs and many other seniors: they are being denied information because their providers understand that they are subject to severe CMS speech restrictions. Samp Decl. ¶ 10; Fox Decl. ¶¶ 12, 17. Evidence from nursing home officials and pharmacists indicates that, based on the CMS speech restrictions, they repeatedly decline requests from patients and their relatives to identify the PDP that bests meets the patients' needs. England Decl. ¶ 7; White Decl. ¶¶ 7-8; Brickley Decl. ¶ 10. The harm being suffered by Plaintiffs cannot be deemed too speculative where the evidence demonstrates that providers would be willing to speak to patients but for the CMS speech restrictions. *Wisconsin Gas Co. v. FERC,* 758 F.2d 669, 674 (D.C. Cir. 1985). Nor has CMS given any indication that it intends to back off its blanket prohibition against anything that might be deemed to constitute "steering" of a patient by a provider to a particular Part D plan.[21]

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[20] To establish the requisite causation, one need not demonstrate that the defendant's injury-inflicting activity is being applied to one *directly*. It is sufficient to demonstrate that it is more likely than not that the defendant is the source of one's injury; if that standard is met, it is irrelevant that the only relationship between the plaintiff and the defendant is (as here) indirect. *Friends of Earth, Inc. v. Laidlaw Envtl. Servs (TOC), Inc.*, 528 U.S. 167, 180-81 (2000); *Warth v. Seldin*, 422 U.S. 490, 515 (1975); *Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986).

[21] Indeed, in a June 15, 2006 response to the GAO Report discussed above – in which the GAO criticized Part D plan call centers for failing to provide "accurate and complete" responses to questions posed by GAO callers – CMS stated that the call centers were prohibited from providing answers that GAO would have deemed "accurate and complete"

Nor could there be merit to any CMS argument that Plaintiffs and other seniors do not have a significant need of assistance in understanding their Part D options. Indeed, in recognition of the inherent complexity of the issues facing seniors in choosing among Part D plans, Congress has mandated that seniors be provided access to massive amounts of information regarding plan benefits. *See, e.g.*, 42 U.S.C. §§ 1395w-104(a)(1)(B) and (a)(4). It is widely recognized by health care professionals that the vast majority of seniors are unable on their own, or even with the assistance of relatives, to make an informed choice among competing PDPs. England Decl. ¶¶ 4, 6; White Decl. ¶ 7; Brickley Decl. ¶¶ 4-6; Donatelli Decl. ¶ 7. In the absence of an injunction, Plaintiffs will continue to be denied access to speech from the very group of individuals – their health care providers – best equipped to provide them with informed advice regarding an extremely complex issue of great importance to them.

Courts unfailingly deem denial of First Amendment rights to constitute irreparable harm sufficient to warrant injunctive. *See Elrod v. Burns*, 427 U.S. 347, 373-74 (1976) ("the loss of First Amendment freedoms for even minimal periods of time constitutes irreparable injury"); *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 301 (D.C. Cir. 2006) (denial of First Amendment speech rights constitutes irreparable injury where First Amendment interests are either threatened or in fact being impaired at the time relief is sought) (citing *Elrod* and *National Treasury Employees Union v. United States*, 927 F.2d 1253, 1254-55 (D.C. Cir. 1991)).

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because those answers would have constituted prohibited "steering" of seniors to a particular plan, a practice "prohibited under Medicare's marketing guidance." June 15, 2006 Memorandum from CMS Administrator Mark B. McClellan to GAO's Leslie G. Aronovitz, attached to the GAO Report as Appendix I. In other words, CMS broadly construes its speech restrictions to prohibit providing information that the GAO deemed a necessary part of "accurate and complete" answers to commonly asked questions.

Because Plaintiffs' First Amendment rights are being impaired at this very moment and will continue to be impaired in the absence of an injunction, irreparable harm exists as a matter of law.

Moreover, the injury being inflicted on Plainitffs is not capable of being remedied by money damages. Plaintiffs have not included in the complaint a claim for money damages, nor could they. The federal government enjoys sovereign immunity from such claims unless explicitly waived, and the Federal Tort Claims Act, 28 U.S.C. §§ 2671 *et seq.*, does not extend its waiver of sovereign immunity to constitutional tort claims. *FDIC v. Meyer,* 510 U.S. 471, 478 (1994). Thus, even if there were a means by which one could measure the damages being suffered by Plaintiffs (and there is not), those damages would still be "irreparable" because they could not be recovered in this or any other lawsuit. *See CSX Transportation, Inc. v. Williams,* 406 F.3d 667, 673 (D.C. Cir. 2005) ("irreparable injury is suffered where monetary damages are difficult to ascertain or inadequate"); *Chaplaincy of Full Gospel Churches*, 454 F.3d at 298.

Plaintiffs have an ongoing need for information regarding their Part D options, because they cannot hope to make informed choices regarding Part D insurance plans in the absence of such information. Every year they must decide whether to continue with their existing plan or to switch to one of the scores of competing plans, with the plans' respective premiums, formularies, prior authorization requirements, and other material features changing on at least an annual basis. Furthermore, the best plan for a Medicare beneficiary may change when the beneficiary's circumstances change, such as changes in health status or admission to a nursing home. In the absence of an injunction, Plaintiffs will continue to suffer injury by being denied access to crucial information about their Part D options.

The federal government has a substantial interest in ensuring that seniors receive accurate information that will assist them in selecting an appropriate Part D plan. However, the preferred method for government regulators seeking to ensure a well-informed citizenry is to correct any potential inaccuracies in the public record by supplying accurate speech of its own, not by censoring the initial speaker. *Virginia State Bd. of Pharmacy*, 425 U.S. at 756. An injunction would not prevent CMS from continuing to provide seniors with its own comparative information regarding Part D plans, or from encouraging seniors to consult as many sources of information as possible before selecting a PDP.

CONCLUSION

Plaintiffs respectfully requests that the Court grant its motion for summary judgment. They request that the Court declare that CMS's speech-suppression policies violate the First Amendment. They further request that the Court conduct a hearing at which the precise scope of injunctive relief can be determined.

Respectfully submitted,

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Dated: October 15, 2007

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of October, 2007, a copy of the foregoing motion for preliminary injunction, along with the accompanying memorandum of points and authorities, the statement of material facts as to which there is no genuine issue, and all exhibits, was served on the following counsel of record via the court's electronic filing system:

Brian G. Kennedy, Esq.
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave., NW
Room 7204
Washington, DC 20530

and by email to Brian G. Kennedy at brian.kennedy@usdoj.gov.

/s/ Richard A. Samp
Richard A. Samp

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

REBECCA FOX, MARY SAMP, and **EDWARD SAMP**	)	
Plaintiffs,	)	
v.	)	CA No. 1:06cv01490 (RMC)
	)	Judge Collyer
MICHAEL O. LEAVITT, in his official capacity as Secretary, U.S. Department of Health and Human Services,	)	
and	)	
LESLIE V. NORWALK, in her official capacity as Acting Administrator, Centers for Medicare and Medicaid Services,	)	
Defendants.	)	

STATEMENT OF MATERIAL FACTS AS TO WHICH PLAINTIFFS CONTEND THERE IS NO GENUINE ISSUE

Plaintiffs Rebecca Fox, Mary Samp, and Edward Samp contend that there is no genuine issue regarding the following material facts.

1. The Medical Marketing Guidelines for Medicare Advantage Plans (MA), Medicare Advantage Prescription Drug Plans (MA-PDs), Prescription Drug Plans (PDPs), and 1876 Cost Plans [hereinafter, the "Marketing Guidelines"] impose restrictions on the speech of health care providers who are contracted with a Plan. In particular, the Marketing Guidelines prohibit such providers from recommending to their patients any specific Part D Plan. Marketing Guidelines at 121-128.

2. A May 11, 2006 memorandum from the Director of CMS's Survey and Certification Group, reference no, S&C-06-16 [hereinafter, the "S&C Memo"] imposes restrictions on the

speech of nursing homes. In particular, the S&C Memo provides that under no circumstances should a nursing home require, request, coach, or steer any resident of the nursing home to select or change a plan for any reason. S&C Memo at 3.

3. In response to the Marketing Guidelines and the S&C Memo, many health care providers have declined to provide their patients with advice regarding choice of Part D plans that they otherwise would have been willing to provide. Declarations of Jessie England, Margie White, Ross Brickley.

4. Because of the complexity of issues raised in attempting to compare Part D Plans with one another, the great majority of seniors are unable on their own, or even with the assistance of relatives, to make informed choices among competing PDPs. Declarations of Jessie England, Margie White, Ross Brickley, and Bill Donatelli.

5. Often times health care providers will be the individuals best situated to provide informed advice to their patients regarding appropriate choices of PDPs. Declarations of Michael Scott Wood, Bill Donatelli.

6. Plaintiff Rebecca Fox is 88 years old. She has been extremely confused regarding which of the available Part D Plans best suits her needs. She would like to receive more guidance on that issue. The one health care provider with whom she has any regular contact is her pharmacist, and so she has requested that he recommend which Part D Plan is best for her. Her pharmacist has declined to provide such a recommendation, in light of the Marketing Guidelines. Declaration of Rebecca Fox.

7. Plaintiffs Edward and Mary Samp are 89 and 87 years old, respectively. They have been extremely confused regarding which of the available Part D Plans best suits their needs.

They would like to receive more guidance on that issue. Their pharmacist, who they have used for many years, declines to recommend a specific Part D Plan, in light of the Marketing Guidelines. Declaration of Mary Samp.

8. Plaintiff Edward Samp has been in declining health for the past decade; during that period, he has been in and out of nursing homes and rehabilitation centers for a variety of ailments. He is currently in a rehabilitation center and, due to lack of mobility, may well be forced to return to a nursing home in the next several weeks. Edward and Mary Samp are concerned that should Edward Samp be confined to a nursing home, health care providers will be unwilling, in light of the S&C Memo, to recommend the Part D Plan that best suits his needs. Declaration of Mary Samp.

9. Because financial terms offered to pharmacists by the various Part D Plans are all roughly similar, pharmacists have virtually no financial incentive to encourage patients to enroll in a particular Part D plan. Declaration of Ross Brickley. Deposition of Abby Block, 32-33, 54.

10. The only real financial incentive that a pharmacy has in selection of Part D plans is finding the plan that will cover the patient's medications, rather than imposing that cost on the patient. Declaration of Ross Brickley.

11. Before promulgating the Marketing Guidelines and the S&C Memo, the CMS officials responsible for approving those documents gave no consideration to whether those documents might infringe on the First Amendment rights of health care providers and patients. Deposition of Abbey Block, 12, 14; Deposition of Thomas Hamilton, 34-35.

12. Before promulgating the Marketing Guidelines, the CMS officials responsible for approving that document gave no consideration to whether enforcement of the federal anti-

kickback statute would be sufficient – without the need for any speech restrictions – to serve CMS's interests in preventing inappropriate steering of patients to a particular Part D Plan based on a health care provider's financial self-interests. Deposition of Abby Block, 36-38.

Respectfully submitted,

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