

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

WASHINGTON LEGAL FOUNDATION,)
2009 Massachusetts Ave., NW)
Washington, DC 20016,)

Plaintiff,)

v.)

Civil Action No. _____

MICHAEL O. LEAVITT, in his official)
capacity as Secretary, U.S. Department)
of Health and Human Services,)
200 Independence Ave., S.W.)
Washington, DC 20201)

and)

MARK B. McCLELLAN, M.D., in his official)
capacity as Administrator, Centers)
for Medicaid and Medicare Services,)
7500 Security Blvd.)
Baltimore, MD 21244,)

Defendants.)

COMPLAINT

1. This is an action brought by the Washington Legal Foundation (WLF), a public interest law firm, to enjoin the U.S. Department of Health and Human Services (HHS) and its Centers for Medicaid and Medicare Services (CMS) from continuing to enforce a policy that violates the First Amendment rights of numerous WLF members, and to require HHS and CMS to adopt a new policy that will dissipate the chilling effect on First Amendment rights of those agencies' current policy.

2. The challenged policy prohibits numerous participants in the health care delivery system from providing truthful, nonmisleading information regarding insurance coverage

available to senior citizens and the disabled under Medicare Part D, the recently enacted Medicare program that offers insurance for the cost of prescription drugs. By blocking the access of WLF members to such information and advice, HHS and CMS are making it extremely difficult for WLF members to make informed choices regarding which insurance options best suit their individual needs. Among the groups restricted by HHS and CMS policy in most instances from providing timely, truthful information regarding Part D insurance options are physicians, hospitals, nursing homes, pharmacies, and pharmacists.

3. While as a theoretical matter, some Medicare beneficiaries could obtain some of the same information from other sources, doing so is not a realistic option for most beneficiaries, both because they often lack the ability to undertake the complex analyses necessary to compare available insurance options and because the groups whose provision of information HHS/CMS so tightly regulates are usually the very groups that have the most knowledge regarding the needs of Medicare recipients and the intricate details relating to the benefits provided by Part D plans. Consequently, such groups are uniquely positioned to provide relevant and accurate information regarding which insurance plan best meets the needs of their Medicare beneficiary patients.

4. By prohibiting the dissemination of truthful information about Part D insurance options by those best suited to provide accurate information, the HHS/CMS policy violates the First Amendment rights of WLF members who wish to receive such information and stands as an impediment to effective health care delivery.

Jurisdiction and Venue

5. The Court has jurisdiction over this action under 28 U.S.C. § 1331, in that the

action arises under the laws of the United States. Plaintiff's right to judicial review of the actions complained of is secured by the First Amendment to the U.S. Constitution, as well as by the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 and 704.

6. Venue for this action properly lies in this Court under 28 U.S.C. § 1391(e).

Parties

7. Plaintiff WASHINGTON LEGAL FOUNDATION (WLF) is a non-profit public interest law and policy center based in Washington, DC with members and supporters in all 50 States. It devotes a substantial portion of its resources to defending the rights of individuals and businesses to go about their affairs without undue interference from government regulators.

8. A principal focus of WLF's activities is litigation in support of the First Amendment rights of its members and supporters to receive truthful information regarding health care issues. For example, it recently won a lawsuit that permanently enjoined the Food and Drug Administration (FDA) from interfering with the First Amendment rights of its members and supporters to receive truthful information regarding safe and effective off-label uses of FDA-approved drugs and medical devices. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

9. WLF's members and supporters include many senior citizens who are Medicare beneficiaries entitled to enroll in a Medicare Part D prescription drug plan and seek access to truthful information and advice regarding the comparative benefits of competing prescription drug plans available to them under Part D.

10. Defendant MICHAEL O. LEAVITT is Secretary of the U.S. Department of Health

and Human Services, an agency of the federal government and an “agency” within the meaning of the APA. Defendant Leavitt is being sued in his official capacity.

11. Defendant MARK B. McCLELLAN is Administrator of the Centers for Medicaid and Medicare Services (CMS), a division of HHS and an “agency” within the meaning of the APA. Defendant McCLELLAN is being sued in his official capacity.

Statement of the Claim

A. CMS Statutory Authority

12. 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).

13. 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.

14. 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”).

15. 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).

B. CMS Implementation of Part D

16. On August 15, 2005, CMS issued its Medicare Marketing Guidelines for Medicare Advantage Plans (MAs), Medicare Advantage Prescription Drug Plans (MA-PDs), Prescription Drug Plans (PDPs), and 1876 Cost Plans (the “Marketing Guidelines”). The Marketing Guidelines were revised slightly on November 1, 2005 and revised further on July 25, 2006. Relevant pages of the Marketing Guidelines as amended are attached hereto as Exhibit A. The

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

17. 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 health-care delivery field.

18. 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 a health-care provider that has entered into a contractual relationship with that PDP or its subcontractors, “including but not limited to: pharmacists, pharmacies, physicians, hospitals, and long-term care facilities.” Marketing Guidelines at 122. 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.

19. Physicians, hospitals, and nursing homes (which are included within CMS’s definition of “long term care facility” for Part D purposes, *see* 42 C.F.R. § 423.100), are also deemed “providers” for purposes of the Marketing Guidelines - even though they do not contract with PDPs.

20. The Marketing Guidelines state that providers “cannot direct, urge or attempt to persuade beneficiaries to enroll in a specific plan.” *Id.* at 123-124.

21. 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 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.

22. 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 PDP 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.*

23. 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.*

24. 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.

25. Some 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, “based on financial or any other interest of the provider....” *Id.* at 123, 128. However, other portions of the Marketing Guidelines contradict this statement with the admonition that a provider may not 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.

26. Separate and apart from the Marketing Guidelines, 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 as Exhibit B.

27. The S&C Memo 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.

C. Practical Consequences of the Marketing Guidelines and the S&C Memo

28. The above restrictions in the Marketing Guidelines and the S&C memo make it virtually impossible for providers to give meaningful information and advice to their patients, including WLF's members and supporters, 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 effectively mean that providers cannot even provide objective facts that could lead the beneficiary to conclude which plan is best for them. A provider's presentation of such facts about plan options might be construed as "steering" a beneficiary to choose a specific plan. Numerous other types of perfectly legitimate communications could run afoul of these 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.

29. 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.

30. 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 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 length of the “transition period” during which the PDP will pay 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).

31. 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.

32. 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; and
- PDPs vary significantly in terms of how cooperative or bureaucratic they are in resolving problems through their “help line” call centers.

33. 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 - including 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. Patients 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.

34. 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 deprive those patients, including WLF's members and supporters, of the benefits of that knowledge.

D. CMS's Rationale for Its Speech Restrictions

35. CMS has articulated several rationales for prohibiting patients' access to this information, regardless how truthful. CMS states in the Marketing Guidelines:

CMS is concerned with provider activities for the following reasons:

- Providers may not be fully aware of all plan benefits and costs; and
- 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.

Marketing Guidelines at 123. CMS further states, "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."

36. While it is true that in some cases providers may not be aware of all plan benefits and costs, 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. Indeed, a recent study in which the U.S. Government Accountability Office placed 900 calls to Part D plan call centers 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.” In reality, 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.

37. With respect to CMS’s second point, there is no reason to believe patients would think that a provider is acting as an agent of a particular PDP, if the provider is not purporting to do so. A patient discussing PDP alternatives with a physician or pharmacist is not likely to believe that the physician or pharmacist is acting on behalf of a particular PDP unless the provider is actually employed by the PDP sponsor (e.g., a physician employed by a staff-model health maintenance organization). In those circumstances, the provider would be subject to the Marketing Guidelines’ restrictions on activities of the PDP sponsor itself, and no separate restriction is necessary based upon his or her status as a provider.

38. 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 do not contract with PDPs or receive any payments from PDPs, so this is not a legitimate objection to their provision of advice as between competing PDPs.

39. The only providers that are paid by PDPs are pharmacies, and it is true that a pharmacy may receive higher rates from some PDPs on the drugs it dispenses than it receives

from other PDPs, as a result of the competitive model created by Congress. Additionally, a pharmacy which has not contracted with a given PDP to participate in its pharmacy network cannot receive any payment from that PDP. Further, with respect to pharmacies that service nursing homes, to the extent that PDPs deny coverage of prescriptions provided to nursing home residents by such pharmacies, they may suffer financially due to their inability to collect the cost of those prescriptions from PDP beneficiaries - particularly where the patients are dual eligibles, who make up a majority of the residents of many nursing homes and are, by definition, indigent.

40. However, these financial interests do not justify the type of gag rule that CMS has imposed on pharmacies via the Marketing Guidelines and the S&C Memo. The fact that a given PDP pays pharmacies more does not mean that it is not the best PDP for a given beneficiary, or group of beneficiaries. Indeed, many of the financial interests of pharmacies align with those of beneficiaries – both the patient and the pharmacy want to find the PDP that will cover the beneficiaries’ prescriptions to the greatest extent. The financial interests of pharmacies certainly do not justify a ban on providers distributing truthful, non-misleading comparisons between alternative PDPs.

41. Nursing homes may have financial liability for prescriptions that their residents require, but the resident’s PDP fails to cover - particularly prescriptions for dual eligibles, who generally do not have funds available to pay for non-covered prescription drugs. While this may create a “financial interest” as compared to physicians, once again it is a financial interest aligned with the interests of the patients - obtaining coverage of as many prescriptions as possible.

42. CMS's last rationale for its restrictions on provider speech, namely the fact that providers know the health status of their patients, is puzzling. Part D's design includes a sophisticated risk-adjustment system which pays PDPs more for patients who are older and in poorer health, so that PDPs should be indifferent to the health status of the beneficiaries they enroll - beneficiaries in poorer health will cost the plan more for drug coverage, but the plan receives more from CMS to compensate for this. Even if some individuals were more valuable to PDPs as enrollees than others, however, at most this would warrant a restriction on PDPs paying providers to recommend patients to (or away from) that PDP based upon the patients' health status. It would not justify a blanket ban on any provider advice regarding alternative PDPs. Indeed, any PDP payment to a provider in exchange for recommending a given PDP to a beneficiary, for whatever reason, would violate existing law (the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b)).

E. Effects of CMS Policy

43. As a result of the CMS and HHS speech-suppression policies outlined above, numerous health-care providers have refrained from providing information and advice to their patients regarding the PDP in which they should enroll.

44. The unwillingness of providers to provide such information and advice to their patients has deprived WLF's members and supporters, as well as other Part D beneficiaries, of valuable information that would assist them in making an informed choice of PDP. If CMS and HHS were to relax their speech suppression policies to permit the free flow of truthful information, providers would be willing to provide WLF's members and supporters with desperately needed information and advice that would assist them in making an informed

choice of PDPs. HHS's and CMS's chilling of communications regarding the relative merits of PDPs has resulted in many Medicare beneficiaries enrolling (or acquiescing in being randomly auto-enrolled by CMS) into PDPs which do not cover many of the drugs which their physicians have prescribed for them, when other PDPs would have provided such coverage.

F. WLF Efforts to Change CMS Policies

45. On April 4, 2006, WLF wrote to Defendant McClellan to express its view that numerous aspects of the Marketing Guidelines were unauthorized by statute and violated First Amendment rights. The letter asked CMS to revise the Marketing Guidelines to eliminate its restrictions on truthful, non-misleading speech. A copy of the letter is attached as Exhibit C.

46. Despite these objections and the objections raised by numerous other advocacy groups, on July 25, 2006 CMS issued a new version of the Marketing Guidelines which continues to include all of the restrictions described herein.

COUNT I

47. WLF incorporates by reference the allegations of Paragraphs 1 through 46.

48. CMS's and HHS's policy of suppressing truthful, non-misleading speech by providers regarding the comparative merits of PDPs available to their patients interferes with the ability of WLF patient-members to receive such materials, in violation of rights secured to those individuals by the First Amendment to the United States Constitution.

49. WLF's patient-members have been injured by this CMS/HHS policy, in that it has deprived them of information and advice that they deem vital to making informed choices regarding Part D enrollment.

50. If this CMS/HHS policy were withdrawn, it is likely that providers would provide

WLF's patient-members with truthful and non-misleading information regarding the comparative merits of available PDPs.

COUNT II

51. WLF incorporates by reference the allegations of Paragraphs 1 through 50.

52. Even if CMS/HHS were today to abandon the policies complained of herein, those policies would continue for the foreseeable future to have a chilling effect on the exercise of First Amendment rights.

53. Accordingly, CMS and HHS are under a continuing constitutional obligation to remedy the effects of their past First Amendment violations by implementing a policy designed to overcome the continuing effects of their past violations.

54. CMS's and HHS's failure to adopt policies designed to remedy the effects of their past First Amendment violations is itself a violation of the First Amendment rights of WLF's patient-members, because those effects dissuade providers from conveying their knowledge regarding the comparative merits of PDPs and thereby interfere with the ability of those patient-members to receive truthful information that they deem vital to making informed choices regarding Part D enrollment.

WHEREFORE, Plaintiff Washington Legal Foundation respectfully requests the following relief:

(1) that the Court enter a declaratory judgment that the CMS/HHS policies described herein – which effectively prevent physicians, nursing homes, pharmacies, and pharmacists from providing their patients with timely, nonmisleading information regarding the

comparative merits of PDPs – violate the rights of WLF’s members under the First Amendment to the Constitution;

(2) that the Court enter preliminary and permanent injunctions against Defendants, preventing them from enforcing, relying on, or otherwise giving effect to the above-described policies;

(3) that the Court enter a mandatory injunction against Defendants, requiring them to adopt policies designed to counteract the continuing effects of their past First Amendment violations;

(4) that the Court award WLF the costs of this action and attorney fees; and

(5) that the Court award such other relief as it determines to be just.

Respectfully submitted,

/s/ Richard A. Samp
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