



December 18, 2006

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex K)
600 Pennsylvania Avenue, NW.
Washington, DC 20580

**Re: TSR Prerecorded Call Prohibition and Call Abandonment Standard
Modification, Project No. R411001**

Dear Chairman Majoras:

PolyMedica Corporation (including its subsidiaries, "PolyMedica") hereby submits comments on the proposed rulemaking regarding the TSR Prerecorded Call Prohibition and Call Abandonment Standard Modification, 71 Fed. Reg. 58716 (October 4, 2006) (the "Proposed Rule"). The Proposed Rule prohibits the use of outbound prerecorded calls without express signed written permission specific to the called person and called number, even where there is an existing business relationship. We understand the Federal Trade Commission's concerns in general, that purchases sufficient to establish an existing business relationship under the telephone sales rule ("TSR") not provide a basis for telephone solicitations for additional purchases using IVR or other prerecorded outbound call technology. Nevertheless, in view of the expansive definition of "telemarketing" in the TSR, the Proposed Rule would apply to and impede important health related communications by health care providers and health plans to their patients, to the detriment of those patients. *See*, 16 C.F.R. § 310.2(cc). In the case of communications by health care providers and plans, the Proposed Rule is not in the interest of consumers.

In addition, application of the Proposed Rule to health plans would be inconsistent with the comprehensive regulatory procedures established by the Centers for Medicare and Medicaid Services ("CMS") for enrollment and customer service in Medicare Part D plans and Medicare Advantage plans published by CMS on August 15, 2005 and most recently revised on July 25, 2006.

For these reasons, PolyMedica respectfully requests that health care providers and plans (which may be defined to be "covered entities" under 45 C.F.R. Part 160) be excepted from the Proposed Rule as adopted in final form. At the minimum, we urge that health care providers and plans be permitted to afford the recipients of outbound

prerecorded calls to opt out from receiving such calls from the provider or plan, where there is an existing relationship as defined in the TSR. This is presently done by PolyMedica and provides an efficient mechanism for those who do not desire to receive outbound prerecorded calls, including interactive voice response (“IVR”) calls, from PolyMedica.

PolyMedica is the nation’s largest provider of blood glucose testing supplies and related services to people with diabetes and today serves more than 913,000 active patients. In addition, PolyMedica is a full service mail order pharmacy and delivers a wide range of prescription medications to beneficiaries of Medicare Part D plans and others. PolyMedica employs more than 2,100 people in Massachusetts, Florida, Virginia and Maine.

TELEPHONE CALLS FROM PHARMACIES AND OTHER HEALTH CARE PROVIDERS TO PATIENTS SHOULD NOT BE SUBJECT TO THE PROPOSED RULEMAKING.

Pharmacies and suppliers utilize IVR systems for outbound calls to provide patients with efficient, user-friendly, and cost-effective systems to refill prescriptions and orders, and obtain permission to contact doctors for renewal orders of maintenance medications and supplies. Pharmacies and suppliers also use outbound IVR calls to provide reminder calls to obtain documentation needed for billing health plans and programs. In addition, physicians and other health care providers use outbound prerecorded reminder calls for appointments and for needed diagnostic, medical and surgical procedures. Home health agencies routinely conduct follow up calls for six months after discharge to assure the medical needs of patients are met, and the calls may be conducted by prerecorded IVR. These calls serve an important need for health care providers to efficiently reach out to patients to assure that the health care needs of patients are met.

PolyMedica has found that these communications are generally welcomed by patients. For example, last month PolyMedica processed over 25,000 prescription refills through the use of outbound IVR calls. This month PolyMedica expects to process approximately 29,000 prescription refills through the use of outbound IVR calls. Patients refilling their prescriptions with these calls do not object to the calls, as they use them to order refills. The Proposed Rule states that “comments ... have made it clear that consumers consider prerecorded calls more coercive and abusive than live telemarketing calls because they are powerless to interact with a recording.” 71 Fed. Reg. 58726. However, we respectfully submit that such comments and the evaluation of the comments do not appropriately distinguish health care calls of the kind described in this letter from calls by vendors of non-health care merchandise seeking sales of additional merchandise. Although the kinds of calls by health care providers described in this letter raise a technical issue under the Proposed Rule because of the expansive definition of “telemarketing,” they are far from what are traditionally considered telemarketing calls.

As applied to calls by health care providers and suppliers to existing patients, the Proposed Rule seeks to address a problem that does not exist. In so doing, the proposal would impair providers' ability to efficiently communicate with patients or impose prohibitive costs in doing so, at a time when health care cost control is an urgent need both in governmental and employer health plans, as well as for consumers.

If the rule is adopted in its present form, pharmacies and health care providers would find it cost prohibitive to adequately staff call centers, assuming people were available in the fill the needed positions. One of the key circumstances leading to the use of IVR technology is the lack of labor to staff call centers. PolyMedica, for example, estimates that that it would need to add approximately 40 to 50 full time employees to accommodate the outbound call volume at an annual cost of approximately \$1.8 million, plus costs of recruiting and training of approximately \$375,000. Obtaining written consent is not feasible because consent would need to be obtained by PolyMedica from approximately 1 million patients. PolyMedica is not unique, and similar costs would be imposed throughout the health care system. Providers will be forced to consider obtaining the service offshore or simply not providing the service, with the effect that patients would not receive the reminders that in many cases determine whether they timely receive their medications or procedures, or not.

Again, health care calls of the kind described in this letter are different than non-health care telemarketing calls. Department of Health and Human Services Privacy regulations under the Health Insurance Portability and Accountability Act ("HIPAA") state that marketing communications relate to "a product or service a purpose of which is to encourage recipients ... to purchase or use the product or service." 45 C.F.R. § 164.501. The regulations further state that "marketing does not include communications ... that are tailored to the circumstances of a particular individual and ... [are] made by a healthcare provider to an individual as a part of the treatment of the individual." *Id.* More specifically, communications "for the purpose of ... recommending to that individual alternative treatments [and] therapies" are not marketing. *Id.* This includes refill reminders. *See* Standards for Privacy of Individually Identifiable Health Information, Guidance issued July 6, 2001, at 31. Indeed, "many services, such as a refill reminder communication or nursing assistance provided through a telephone service, are considered treatment activities if performed by or on behalf of a health care provider, such as a pharmacist . . ." Standards for Privacy of Individually Identifiable Health Information; Final Rule, 65 Fed. Reg. 82461, 82498 (Dec. 28, 2000). Here, a service specifically approved by the Department of Health and Human Services would be proscribed by the Proposed Regulation.

We submit that the considered judgment of the Department of Health and Human Services regarding health-related communications should be followed by the FTC. The Department of Health and Human Services, and CMS as discussed below, have effectively occupied the field of regulating communications between health care

providers and plans, and patients. Where these agencies in the exercise of their expertise see a need, they do not hesitate to regulate that communication. The best way to accomplish this is to exempt entities that are subject to the HIPAA privacy regulations from the Proposed Rule, by exempting “covered entities” under 45 C.F.R. Part 160 from the Proposed Rule.

MEDICARE HEALTH PLANS SHOULD SIMILARLY BE EXCEPTED FROM THE PROPOSED RULEMAKING.

The Modernization Act of 2003 (“MMA”), P.L. 108-173, created a prescription drug benefit for Medicare beneficiaries and established a new Medicare managed care system. Insurance companies and others under contracts with CMS offer prescription drug plans (“PDPs” or “MA-PDs”). In addition, insurance companies under contracts with CMS offer Medicare Advantage managed care plans (“MA Plans”).

The MMA charges the Secretary of Health and Human Services (the “Secretary”) to establish regulations related to the marketing materials of PDPs, MA-PDs and MA Plans. 42 U.S.C. § 1395w-104(b). The law allows for sanction or revocation of the endorsement of a program offered by a sponsor if the Secretary determines that the sponsor engaged in false or misleading marketing practices. The Secretary may also impose a civil monetary penalty for conduct that a party knows or should know is a violation. 42 U.S.C. § 1395w-141(i)(3).

CMS comprehensively regulates all marketing activity by PDPs, MA-PDs and MA Plans. Marketing materials and scripts, including IVR scripts, are subject to review and scrutiny. To the extent this communication involves a solicitation for a product or service, its form and content are regulated by CMS. *See* 42 U.S.C. 1395mm. For example, federal regulations prohibit some marketing practices. MA Plans must not discriminate against recruiting beneficiaries from low-income areas, mislead or confuse beneficiaries, misrepresent the health plan or CMS, or provide monetary rebates for enrollment. 42 C.F.R. § 422.80(e)(1).

Unlike the FTC’s Proposed Rule, Medicare law does not prohibit outbound telemarketing by prerecorded calls as a form of information dissemination or customer service for PDPs, MA-PDs or MA Plans. 42 U.S.C. §§ 1395w-104(a); 1395w-21(h). In fact, CMS stated that “by allowing plans to utilize different methods for marketing, greater numbers of beneficiaries will be reached and thus enrolled.” Medicare Marketing Guidelines For: MAs, MA-PDs, PDPs and 1876 Cost Plans, at 132 (July 25, 2006). The Medicare Marketing Guidelines promulgated by CMS require compliance with the National Do Not Call Registry provisions of the TSR (which when adopted, *did not* prohibit outbound prerecorded calls to existing customers). As noted, the regulations and guidelines also specifically require approval of telephone scripts, including IVR and prerecorded scripts. The Proposed Rule goes beyond the regulations and guidance established by CMS for PDPs, MA-PDs and MA Plans. It therefore upsets the balance

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struck by CMS for enrollment and customer service between efficiency and accuracy, and on the other hand intrusiveness.

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For the above reasons, we submit that health care providers, which again can be defined as “covered entities” under 45 C.F.R. Part 160, should be excepted from the Proposed Rule.

Thank you for your time in considering these comments and suggestions. PolyMedica appreciates and supports CMS’ efforts to expand access to the regulatory process to suppliers for the improvement of delivery of quality healthcare to the beneficiaries of the Medicare Program. We welcome the opportunity to work with CMS in resolving the issues contained in this document. Please feel free to contact me directly at the following phone number (781) 486-8111 with any questions that you may have.

Sincerely,

David Kreiss
Chief of Government Affairs