December 18, 2006

Mr. Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room H–159 (Annex K)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

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

Dear Mr. Clark:

We submit these comments on behalf of medSage Technologies LLC ("medSage"), a Pittsburgh-based firm which helps home healthcare providers manage treatment for almost 250,000 patients through, *inter alia*, the use of prerecorded telephone calls. medSage has deep concerns regarding the pending proposal of the Federal Trade Commission ("FTC" or "Commission") to modify its current forbearance stance and begin enforcing the prerecorded call prohibition contained in the FTC's Telemarketing Sales Rule ("TSR"), even against sellers (and their telemarketers) who use prerecorded messages to contact consumers with whom those sellers have an "established business relationship."[1]

medSage believes that this proposal, if implemented with respect to at least a limited class of consumers who rely on medical and medically-related information they receive through such calls, could have serious consequences for patient care that would be not only undesirable, but also unintended by the Commission. For this reason, medSage respectfully requests that the FTC defer to Congress, and to a sister agency, the Department of Health and Human Services ("HHS"), and exclude from its proposal certain outbound calls, which have specifically been exempted by Congress from Medicare's broad proscription against unfettered telephone solicitations of patients and by HHS from its privacy rules regarding marketing, because such calls are so clearly in the best interest of patient care.

I. Background

Calls placed by medSage are designed to monitor a patient's compliance with prescribed medical therapies, involving both prescription medications and medical supplies, for conditions such as chronic obstructive pulmonary disease ("COPD") and sleep apnea. By ensuring consistent, proactive monitoring of patients and providing, in an affordable fashion, regular contact with them, medSage enables its home healthcare clients to improve markedly their patients' treatment compliance rates, resulting in superior clinical outcomes. Compliant patients are much less likely to develop costly chronic conditions such as heart disease and diabetes.

[1] 71 Fed. Reg. 58716 (October 4, 2006).

The medSage technology dynamically generates its calls based on prescribed therapy, order history, insurance coverage, and numerous other patient variables defined by the medSage home healthcare customer on whose behalf the calls are being made. The calls provide interactive messages pre-recorded in the voice of the patient's health care professional. During the course of the calls, a patient is asked a series of compliance questions and, if appropriate, a medication or supply-related question.

For example, medSage contacts COPD patients on a monthly basis to ensure compliance with prescribed medical therapy and to obtain approval from those patients to deliver their required supply of critically important medications. To further understand medSage's patient management approach, and the control it places in the hands of often elderly and/or housebound patients, it might be useful to listen to a sample call. The prerecorded message used for medSage home healthcare clients to manage their sleep apnea patients can be accessed by dialing (877) 621-7123. medSage would be happy also to provide additional examples.

Because these calls often include a question to patients regarding whether they need to replace equipment or replenish their stock of supplies or medications, such calls could, possibly, constitute "telemarketing" under the TSR and could qualify medSage as a "telemarketer."[2] Up until now, however, because of the Commission's policy of forbearing from enforcement of the TSR's provision relating to prerecorded calls when made to established customers, the FTC has not stood in the way of effective (and cost-efficient) patient care management. However, without a limited safe-harbor, under the Commission's current proposal, these patient care management calls would all have to stop, with potentially serious consequences for patient well-being.

To date, the FTC's enforcement of the TSR has basically been consistent with enforcement of related regulations by other agencies, namely the Federal Communications Commission ("FCC")

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[2] The TSR, 16 C.F.R., Part 310, defines a "telemarketer" as "any person who, in connection with telemarketing, initiates or receives telephone calls to or from a customer or donor." *Id.*, at § 310.2(bb). "Telemarketing" is defined as any "plan, program, or campaign which is conducted to induce the purchase of goods or services or a charitable contribution, by use of one or more telephones and which involves more than one interstate telephone call." *Id.*, at § 310.2(cc). By inquiring, during interstate calls, as to whether patients desire additional medicines or supplies, one could conclude that medSage is inducing the patients' purchase of goods and is, hence, making telemarketing calls.

Since medSage is not marketing on its own behalf, but rather as an agent for its home healthcare provider clients, medSage is not, however, a "seller," within the meaning of Section 310.2(z). The TSR's strictures generally apply both to "telemarketers" and "sellers." *See* §§ 310.3 (deceptive telemarketing acts or practices), 310.4 (abusive telemarketing acts or practices), and 310.5 (recordkeeping requirements). Both the seller and any telemarketer it uses are liable for any violations of the TSR. *See, e.g.,* FTC, *Report to Congress Pursuant to the Do Not Call Implementation Act on Regulatory Coordination in Federal Telemarketing Laws Submitted by The Federal Trade Commission,* at 22, 36 (September 2003) (available online at http://www.ftc.gov/os/2003/09/dnciareport.pdf, last visited December 17, 2006).

and HHS. In recent months, though, much attention has been devoted to the discrepancy that would, under the Commission's pending proposal, exist between the FTC's and FCC's respective rules regarding pre-recorded calls by sellers to customers with whom those sellers have existing business relationships. However, very little attention, if any, has been given to the potentially harmful consequences that could result from any precipitous action by the FTC undercutting the well-considered, highly targeted regulation by HHS of the marketing, by telephone or otherwise, of pharmaceuticals and supplies in the relatively unique world of home healthcare. medSage respectfully requests that the Commission do nothing to upset HHS'carefully balanced scheme, which has proven workable – efficient and effective – and upon which both patients and their home healthcare providers have come to rely.

II. Regulation of Telephone Solicitations Under Medicare

All of medSage's clients are durable medical equipment ("DME") providers.[3] Many of the patient customers of those providers rely on Medicare to pay for the equipment, supplies and medications they need in order to treat a wide array of medical conditions. Medicare heavily regulates DME providers. Of particular relevance here, Congress has specifically barred DME suppliers and their agents from unfettered telephone marketing to Medicare patients. *See* 42 U.S.C. § 1395m(a)(17).[4] This law permits telephone contact by DME suppliers or their agents in only three

[3] While DME suppliers are defined as retailers of durable medical equipment which, in turn, is defined as reusable equipment suitable for use in the home (42 C.F.R. § 414.202), many of medSage's clients offer access to pharmacy services, as well. Thus, medSage's calls on behalf of its clients might include inquiries about medications, or prescription refills, as well as about supplies or equipment, but all of medSage's clients are regulated as DME providers under the Medicare regulatory scheme.

[4] **PROHIBITION AGAINST UNSOLICITED TELEPHONE CONTACTS BY SUPPLIERS.**

(A) **IN GENERAL 1395m** A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) PROHIBITING PAYMENT FOR ITEMS FURNISHED SUBSEQUENT TO UNSOLICITED CONTACTS If a supplier knowingly contacts an individual in

specific circumstances: 1) when the patient has provided written permission for such contact; 2) when the supplier has furnished an item of DME to the patient and is contacting the patient regarding the furnishing of such item; and 3) when the supplier has furnished at least one item of DME to the patient during the prior 15 month period. 42 U.S.C. § 1395m(a)(17)(A).

These significant restrictions on telemarketing are already being enforced by the Office of Inspector General at HHS through Medicare non-payment, 42 U.S.C. § 1395m(a)(17)(B) and, in the case of a pattern of unlawful telephone solicitations, through Medicare program exclusion, 42 U.S.C. § 1395m(a)(17)(C) . . . a punishment that would be the death knell for many, perhaps most, DME suppliers. Further, Medicare regulations state that any supplier that "fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier" could be subjected to the payment of civil penalties. 42 C.F.R. §402.1(c)(5). A penalty of up to $10,000 can be imposed for such violation. *Id.*, at §402.105(d)(2)(iii).

Finally, to be eligible for Medicare reimbursement, a DME supplier must submit, and receive approval of, an application to the Centers for Medicare and Medicaid Services ("CMS"). Among the certifications that a supplier must make are the following: the supplier operates its business in compliance with all federal and state license requirements; has not made a false statement or misrepresentation of a material fact on its application for billing privileges; has documentation for all reimbursable transactions; honors all warranties; operates from a physical facility, which can be inspected by the CMS, and not a mere post office box; has a primary business telephone and advises customers how they may contact the supplier; maintains liability insurance; agrees in writing not to make any telephone contacts with patients except as authorized by law and described above; meets specified customer service standards; and operates a customer complaint process. *Id.*, at §424.57(c).[5]

This entire regulatory scheme is, obviously, very detailed and protective, likely to screen scofflaws and sufficient to protect patients from, *inter alia*, abusive telemarketing. Given the potential penalties (civil fines and, even, debarment), a DME supplier is not going to make, or permit its associate to make, unsolicited contacts in violation of the rules.

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violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) EXCLUSION FROM PROGRAM FOR SUPPLIERS ENGAGING IN PATTERN OF UNSOLICITED CONTACTS If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier's conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this Act, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1128.

[5] The Department of Health & Human Services ("HHS") takes regulatory action against suppliers who have violated their certification. *E.g., Medisource Corp. v. CMS*, Docket No. A-05-112 (HHS Department Appeals Board, January 31, 2006).

Moreover, the use of telephone calls and other communications technology can provide measurable benefits in the treatment of patients. This finding was documented by the General Accounting Office, *Information Technology Benefits Realized for Selected Health Care Functions*, GAO 04-224 (October 2003).

For example, this report noted that the use of speech recognition technology that permits patients to talk with a computer "using applications that are developed to anticipate the topic of conversation and possible responses" (*i.e.*, prerecorded calls) resulted in patients' diabetic retinal exams increasing from 71% to 93% and the rate of adolescents receiving full vaccinations increasing from 29% to 43%. *Id.*, at 104. Further, this technology produced substantial cost savings. Per-call costs were only 10-30% of total vendor service costs. Also, these prerecorded calls were completed more quickly "with up to 500 calls per hour; completing call campaigns in 1-2 days that previously took 2-6 weeks." *Id.*, at 103. Thus, a very strong case can be made that the use of prerecorded calls serves the public interest.

.III. HIPAA Regulation of Marketing

Moreover, medSage, like its home healthcare clients, is governed by the federal government's Health Insurance Portability and Accountability Act ("HIPAA") regulations protecting patient privacy, 45 CFR §§ 160 and 164.100, *et seq*. ("Privacy Rule"). Therefore, all of medSage's prerecorded calls to patient customers on behalf of medSage's home healthcare clients must be HIPAA compliant. As is the case with respect to Medicare, the "cost" of violating HIPAA can be enormous. Violations of HIPAA are subject to both criminal and civil penalties.[6]

The privacy regulations issued under HIPAA set strict standards on how patient/customer health information may be used, and whether, or under what circumstances, covered entities[7] may communicate that information to others. The HIPAA Privacy Rule prohibits covered entities from using or disclosing "protected health information" ("PHI") – information relating to an individual's medical condition or treatment – for, *inter alia*, purposes of marketing without specific, written authorization from the individual. This prohibition relates to written, as well as to *any* form of telephonic communication, whether through a live caller or a prerecorded message, regardless of whether there is a pre-existing business relationship, unless the communication falls within one of the specifically delineated exceptions. In this regard, the Privacy Rule is far broader than the relevant provision in the TSR, limited as it is to prerecorded messages. Thus, the HIPAA scheme of, among other things, regulating marketing calls to protect patient privacy, is far more "stringent," certainly more inclusive, than the FTC's rules.

However, and it is this that is most important for present purposes, HHS specifically excluded from the definition of "marketing" contained in the Privacy Rule certain types of health-

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[6] 45 C.F.R. § 160.500, *et seq*. Privacy provisions of HIPAA are enforced by HHS' Office of Civil Rights.

[7] Covered entities are: (1) payors (*e.g.*, insurers); (2) home healthcare providers that bill electronically; and (3) data clearinghouses, meaning entities that convert home healthcare data into standard formats (*e.g.*, billing services). 45 C.F.R. § 160.103.

related activities, to enable covered entities to communicate with patients *without an authorization*. After several rounds of notice and comment rulemaking, HHS modified its definitional regulations to provide that a covered entity will not be engaged in marketing when it communicates with an individual about: (1) a health-related product or service provided by, or included in a plan of benefits of, the covered entity (including communications about entities participating in a network, replacement of or enhancements to a health plan and value-added items or services); (2) the individual's treatment; or (3) case management or care coordination for the individual, or directions or recommendations for alternative treatments, therapies, providers or settings of care for the individual.[8]

HHS noted on numerous occasions that these exceptions were intended to make it easier for health care providers and payors to communicate information to patients about their care. "The Department believes that certain health care communications, such as refill reminders or informing patients about existing or new health care products or services, are appropriate . . ."[9]

These exceptions were initially published in a notice and comment rulemaking that culminated in a final rule published on December 28, 2000. At that time, the rule permitted such communications without authorization, but noted that if the communication was in writing and the covered entity received payment from a third party to make the communication, additional disclosures were necessary, as well as an opt-out mechanism. After receiving numerous comments asserting that the framework was too confusing (covered entities would have difficulty determining which communications were subject to the additional requirements) and the disclosures and opt-out mechanisms not helpful to consumers, HHS reopened the final rule (on this and other topics) and proposed the simpler framework described above.[10] All communications from a covered entity related to an individual's treatment, case management/coordination (including with respect to the reordering of medications or medical supplies), or recommendations for alternative treatment are exempt from the authorization requirement.

HHS examined this matter in depth, running through two full notice and comment rulemaking processes, and adjusting its position each time.[11] After due deliberation, HHS determined that use of carefully protected PHI for purposes of communicating treatment information, such as refill reminders, was of sufficient value that it would not require individual authorization.

The FTC should certainly not act hastily to upset HIPAA's carefully constructed scheme, balancing as it does a consumer's right to, and need for, privacy against a limited intrusion, if it can

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[8] 45 C.F.R. § 164.501.

[9] 67 Fed. Reg. 53181, 53188 (Aug. 14, 2002). *See also*, 65 Fed. Reg. 82462, 82493 (Dec. 28, 2000).

[10] *See*, 67 Fed. Reg. 14775 (March 27, 2002); 67 Fed. Reg. 53181 (Aug. 14, 2002).

[11] The Commission's Order today is fully consistent with this suggestion. *See*, *e.g.*, 67 Fed. Reg. 53184-53190; 65 Fed. Reg. 82493, 82717-18; and 67 Fed. Reg. 14775, 14789-90.

even be called that, in the best interest of patient care. If the FTC does not now feel comfortable creating an enforcement exception for HIPAA-regulated entities without more study, at a minimum it should refrain from taking any action with respect to entities covered by Medicare's telephone solicitation provision and/or HIPAA's Privacy Rule until it has had the opportunity to confer with HHS and/or has heard more on this point from affected home healthcare providers and their patient customers.[12]

There is ample precedent for one federal agency to consult with one or more of its sister agencies in order to obtain the benefit of their special expertise as part of the first agency's rulemaking process. Indeed, in some cases, Congress specifically directs one federal entity to consult with other federal and, even, state agencies. *E.g.,* Children's Health Act of 2000, Pub. L. 106-310, 114 Stat. 1101, 1122 (2000). In that law, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the National Institutes of Health were directed to collaborate and consult with, *inter alia*, other federal agencies and state and local agencies with appropriate expertise.

A good example of deference and/or collaboration can be found with the National Park Service's ("NPS") rules for using personal watercraft within NPS-managed areas. In 2000, the NPS adopted rules that prohibit the use of personal watercraft in any portion of the National Park System unless the NPS determines that such use is appropriate for the specific park facility. *Personal Watercraft Use Within the NPS System*, Final Rule, 65 Fed. Reg. 15077 (March 21, 2000). In that decision, the NPS recognized the value of other federal agencies' special expertise in making determinations of the appropriateness, if any, of the use of personal watercraft in a specific park facility. The NPS stated its policy as follows:

> It is the policy of the National Park Service to regulate motorized recreational activity in park areas to mitigate resource degradation. It is our intention to utilize the expertise of the Environmental Protection Agency, Occupational Safety and Health Administration and other cooperating agencies as a way of maintaining the environmental integrity of park areas. *Id.*¸ 65 Fed. Reg., at 15078

This has not been a hollow policy of the NPS. Rather, it has affirmatively sought out the expertise of other agencies when determining the appropriateness of the use of personal watercraft. *See, e.g., Curecanti National Recreation Area, Personal Watercraft Use*, Final Rule, 71 Fed. Reg. 55111 (September 21, 2006); *Lake Meredith National Recreation Area, Personal Watercraft Use,* Final Rule, 69 Fed. Reg. 30216 (May 27, 2004); *Amistad National Recreation Area, Personal Watercraft Use,* Final Rule, 69 Fed. Reg. 3020 (May 27, 2004). The FTC should similarly collaborate here.

IV. Existing Written Authorization

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[12] *Telephone Sales Rule,* Extension beyond January 2, 2007, of the previously announced forbearance policy in enforcement of the prohibition of prerecorded calls in the Telemarketing Sales Rule ("TSR") (FTC, December 18, 2006).

As illustrated in the foregoing sections, both under Medicare regulations regarding telephone solicitations by DME suppliers, and under HIPAA regulations regarding the use of private patient information in marketing, calls such as those placed by medSage on behalf of its home healthcare clients do not require the written authorization of the patient customers being contacted. Nonetheless, out of an abundance of caution, and because, from time to time, DME suppliers and/or "covered entities" or their "business associates" (agents) under HIPAA might make telephone solicitations and/or use protected health information in ways that fall outside the safe-harbors of the Medicare and/or HIPAA regulations, to the best of medSage's knowledge, the patient customers medSage contacts *have* generally already provided written and signed authorization to their home healthcare provider permitting that provider (or its associate) to contact the patient via mail or phone with respect to his/her medical condition and treatment of that condition. Thus, these patient customers have not only authorized, but expect to receive, such calls from time to time.

V. Conclusion

medSage complies with all applicable government regulations, such as HIPAA and the many requirements of the CMS and takes its responsibilities in this regard very seriously. However, inconsistent regulations resulting from well intentioned, but separate rulemaking processes by sister agencies are not only confusing to those covered entities attempting to comply, but often result in noble efforts by one agency "to get it right," being undercut by another equally well-intentioned agency trying to do the same thing. medSage respectfully suggests that is precisely what is happening here.

For all the foregoing reasons, medSage respectfully requests that the FTC create a narrow exception for the home healthcare industry with respect to the Commission's expressed intention to begin enforcement of the prohibition of prerecorded calls that is contained in the TSR's call abandonment provision, so as to provide consistency between the FTC's regulation of telemarketing under the TSR, Medicare's regulation of telephone solicitations and HHS' regulation of marketing under HIPAA. medSage fully supports the purpose behind the FTC's proposed revocation of its previously announced policy of forbearance. It understands the FTC's desire to propel its efforts to eliminate abusive telemarketing practices, which – if unrestrained – threaten further to bombard consumers with nuisance calls. However, the Commission should not overreact by eliminating a certain very narrow subset of home healthcare-related communications, such as the medical monitoring calls provided through medSage, that are of critical importance to quality and cost-effective patient care.

Sincerely,

Judith L. Harris
Robert H. Jackson

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