ORIGINAL

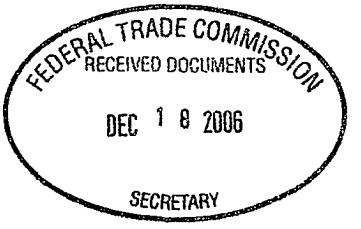
FULBRIGHT & JAWORSKI L.L.P.
A REGISTERED LIMITED LIABILITY PARTNERSHIP
801 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20004-2623
WWW.FULBRIGHT.COM

NAGIN@FULBRIGHT.COM
DIRECT DIAL: (202) 662-4723

TELEPHONE: (202) 662-0200
FACSIMILE: (202) 662-4643

December 18, 2006

CONFIDENTIAL



VIA HAND DELIVERY

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 Secretary Clark:

On behalf of our client Access Diabetic Supply, LLC ("Access"), we are enclosing two originals of Access' Comment in response to the Federal Trade Commission's Denial of Petition for Proposed Rulemaking; Revised Proposed Rule with Request for Public Comments; Revocation of Non-Enforcement Policy; and Proposed Rule, published in the Federal Register on October 4, 2006 in connection with the above-reference project.

Access also is enclosing two originals of a "Public Record" version of its Comment, which redacts from page two the number of outbound automated, interactive calls that Access has made to its customers. Access believes that release of this sensitive commercial information to Access' competitors would result in competitive harm to Access. Accordingly, Access respectfully requests confidential treatment for this redacted portion of its Comment.

Sincerely,

Neely B. Agin

Enclosures

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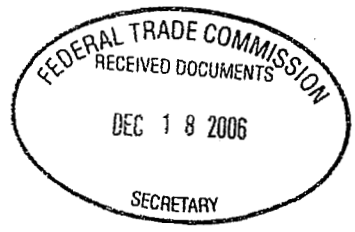

BEFORE THE
FEDERAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	)	
	)	
TSR Prerecorded Call Prohibition	)	16 C.F.R. Part 310
and Call Abandonment Standard	)	
Modification	)	Project No. R411001
	)	

COMMENTS OF ACCESS DIABETIC SUPPLY

PUBLIC RECORD VERSION

Neely B. Agin
FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Avenue, NW
Washington, DC 20004
202-662-4723

December 15, 2006

BEFORE THE
FEDERAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of	)	
	)	
TSR Prerecorded Call Prohibition	)	16 C.F.R. Part 310
and Call Abandonment Standard	)	
Modification	)	Project No. R411001
	)	

COMMENTS OF ACCESS DIABETIC SUPPLY

Access Diabetic Supply, LLC is pleased to submit these comments in response to the Federal Trade Commission's ("FTC" or "Commission") Denial of Petition for Proposed Rulemaking; Revised Proposed Rule with Request for Public Comments; Revocation of Non-Enforcement Policy; and Proposed Rule, published in the Federal Register on October 4, 2006 (the "Notice"). In its Notice, the Commission proposes an amendment to the Telemarketing Sales Rule ("TSR") that would add at 16 C.F.R. § 310.4(b)(1)(v) a prohibition of unsolicited prerecorded telemarketing calls without a consumer's express prior written agreement. In addition, the Commission announced its intention to revoke its current non-enforcement policy against unsolicited prerecorded telemarketing calls to consumers with whom a telemarketer has an "established business relationship."

I. Introduction and Background

Access Diabetic Supply, LLC ("Access") is a mail-order medical equipment and supply business that provides diabetic testing and respiratory supplies to thousands of people in the United States living with chronic illnesses, including diabetes and asthma. The vast majority of Access' patients are on Medicare, which covers most medically necessary durable medical equipment ("DME") and related supplies, including almost all of the products sold by Access. As a "participating supplier" in the Medicare program, Access is required to accept assignment

and to bill and collect from Medicare on the patient's behalf. This means that Access is required to handle the Medicare coverage, billing, and collection processes for its Medicare patients. These processes involve Access verifying each new patient's insurance benefits and obtaining a written order on a prescription from the patient's doctor. Then Access contacts the patient to explain the patient's benefits prior to shipping the patient's first order. Access then mails the patient's prescribed medical supplies to the patient's home, free of charge. Medicare rules limit Access to furnishing only ninety days of supplies at any time. Because its patients suffer from chronic and incurable illnesses, such as diabetes and asthma, they typically require new shipments about every ninety days to keep compliant with their prescription. To ensure that patients' reorder needs are met and that patients do not run out of necessary medical supplies, Access must regularly contact its patients.

As part of this reorder process, Access began delivering automated, interactive calls to its patients in June 2006. Since that time, Access has placed [REDACTED] automated, interactive calls to patients for a variety of purposes, including: (1) diabetic testing supply reorders, in which Access contacts established customers who according to Access' records are nearing the end of their testing supplies and offers to have replacement supplies shipped to their home; and (2) respiratory supply reorders in which Access offers patients who have placed a prescription drug refill to include with the order a replacement of prescribed respiratory supplies. These calls begin with an automated message that through a series of prompts tells the patient that records indicate the patient is due for a shipment of diabetic or respiratory supplies and asks the patient to confirm the need for the reorder. If the patient indicates that he or she needs the additional supplies to be shipped, the patient is then given an option to speak with a sales representative or to simply confirm the patient's current shipping address.

These automated, interactive calls are essential because Medicare coverage rules generally prohibit DME suppliers from automatically shipping replacement supplies, and particularly diabetic testing supplies, on a predetermined regular basis even if the patient has "authorized" the shipment in advance. Under these rules, a patient covered by Medicare must specifically request from the supplier his or her necessary diabetic testing supply refills before they may be shipped to the patient. In addition, Medicare coverage rules specify that refills of diabetic supplies are covered under Medicare only if the patient has nearly exhausted the patient's existing supply. Consequently, these calls help Access ensure that its patients' supplies will be covered by Medicare by verifying that the patient has, in fact, nearly exhausted his or her current supply.

If Access is no longer able to make these calls without first obtaining a patient's express written consent, it will be forced to develop and implement an alternative method for communicating with its patients to replace their medical supplies. This would be a significant expense for Access, not to mention all of the time of its employees that otherwise would be dedicated to providing services that improve the health of its patients. Because the majority of Access' products are paid for by Medicare, Access operates on very small profit margins. Any additional operating costs, and in particular, a significant expense such as would be required to develop and implement a new communication system, would put a significant strain on Access' ability to serve its patients.

In addition, the elimination of these calls would significantly impact the lives of Access' patients. Most of Access' patients are elderly and suffer from at least one chronic illness. These patients and their physicians rely on Access to remind them that they need to comply with their physician's prescribed plan of care by using the prescribed supplies as directed and promptly

refilling their supply order to prevent them from running out of needed supplies. Although Medicare only permits the dispensing of diabetic supplies every one to three months (depending on the patient's situation), physicians generally prescribe these supplies for a minimum of a year and often for a lifetime. Instead of repeatedly contacting each of their patients to make sure they are complying with their home treatment regiment, physicians can rely on companies like Access to follow up with their patients to order their refills every few months and help the patients keep compliant with physician's orders. In the case of patients with diabetes or asthma, the failure of a patient to be compliant with the plan of care prescribed by the patient's physician may result in many common complications of these diseases, such as hypertension, respiratory failure, renal failure, blindness, circulation problems, and even death. These complications not only endanger the patient's health, but result in millions of dollars in federal healthcare expenditures every year. As a result, these calls are extremely valuable in driving healthcare outcomes and improving the lives of the American public.

II. The Commission Should Continue its Non-Enforcement Policy Permitting the Use of Prerecorded "Health-Related" Calls by HIPAA-Regulated Entities and Amend the TSR to Allow For Such Calls

Access Diabetic Supply strongly supports the November 30, 2006 petition of Silverlink Communications, Inc. and Eliza Corporation requesting that the Commission maintain its current enforcement policy permitting the use of prerecorded "health-related" calls by entities subject to regulation under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Pub. L. 104-191. These calls, which provide information essential to the public health, such as reminders for prescription drug refills, clearly are not the type of unwanted prerecorded telemarketing messages that consumers might reasonably consider "abusive" and an invasion of privacy. Continuing the FTC's current non-enforcement policy for these calls will prevent

significant disruption in the provision of healthcare services by HIPAA-regulated entities and prevent disruption in calls that are extremely beneficial for the health of millions of Americans.

The Commission's October 4, 2006 Federal Register Notice represents a significant departure from the Commission's previously-stated policy that permitted prerecorded calls to patients with whom a supplier has an "established business relationship." Denial of Petition for Proposed Rulemaking; Revised Proposed Rule With Request for Public Comments; Revocation of Non-enforcement Policy; Proposed Rule, 71 Fed. Reg. 48,716 (October 4, 2006) (the "Notice"). By announcing that the Commission will cease its current non-enforcement policy beginning January 2, 2007, the Commission left companies with less than three months in which to replace their existing systems for communication with established customers. This simply is not a sufficient amount of time for HIPAA-regulated entities to develop an alternative method for delivering "health-related" calls on which their customers have come to rely. Like Access, many of the HIPAA-regulated entities that rely on these calls to deliver health-related messages to patients are small and lack the resources necessary to develop a new system or to obtain the written consent of all patients within such a short period of time. In addition, many of the patients currently relying on these messages are elderly and chronically ill and are not likely to respond by January 2, 2007 to a request for written permission to continue receiving these messages. Indeed, Access developed its current system of automated, interactive calls based in part on its conclusion that written communication with its patients would be less effective. As a result, it is likely that many, if not all, of these calls will abruptly be ceased without any effective replacement. The public health likely will suffer from an interruption in these services, for example, through missed prescription refills and other gaps in healthcare services.

Continuation of the FTC's current non-enforcement policy permitting these automated health-related calls by HIPAA-regulated entities also would prevent unnecessary expenditures of time and money by these entities to develop alternative systems until the Commission considers the comments submitted in response to the Notice and issues its final rulemaking. If the Commission ceases its current non-enforcement policy next month, these entities will need to invest heavily in developing an alternative system or begin soliciting written consent to receive such calls, either of which will require significant time and expense. Should the Commission ultimately decide in its final rulemaking to allow these calls, this time and money, which could have been dedicated to providing healthcare services, will be wasted.

In addition to extending the non-enforcement policy for health-related calls by HIPAA-regulated entities, the Commission should amend the TSR to allow automated "health-related" calls by HIPAA-regulated entities. Telemarketing Sales Rule, 16 C.F.R. Part 310 (2006). These are valuable and beneficial calls and are expressly permitted under the HIPAA Privacy Rule. Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164 (2006) ("Privacy Rule"). Moreover, these calls are not the type of unwanted prerecorded telemarketing messages that consumers might reasonably consider "abusive" and an invasion of privacy.

Entities regulated by HIPAA are subject to the HIPAA Privacy Rule, a major goal of which is to ensure that patients' health information is properly protected, while at the same time allowing the flow of health information needed to provide and promote high quality health care and to protect the public health and well being. *See* Standards for Privacy of Individually Identifiable Health Information; Final Rule, 65 Fed. Reg. at 82,461, at 82,463 (2000); *see generally* 45 C.F.R. Parts 160 and 164 (2006). This Rule limits the marketing activities of

"covered entities" and their "business associates," requiring a patient's authorization before engaging in any "marketing" activities. *Id.* at § 160.103. They exclude from the definition of marketing, however, and therefore permit, calls regarding patient treatment, such as Access' refill reminder calls, health screening reminders, and immunization reminders, as well as certain other calls related to healthcare plans and benefits. ("health-related calls"). *Id.* at § 164.501. Amending the TSR to allow these health-related calls therefore would be consistent with the Department of Health and Human Services' ("HHS") recognition of the value of health-related calls and its decision to ensure that they continue to be available.

These health-related calls also are not the types of calls that the Commission is trying to eliminate by proposing to amend the TSR to prohibit prerecorded telemarketing calls to consumers who have not previously expressly consented in writing. These health-related calls are essential to public health and help to reduce healthcare costs. In its October 4 Notice, the Commission bases its decision not to amend the TSR to include a safe harbor for prerecorded calls to established customers in part on its conclusion after reviewing the record that there is "virtually no consumer support for allowing the use of prerecorded messages." 71 Fed. Reg. at 58,723. The Commission goes on to explain that such a safe harbor might be appropriate if the "consumer aversion" to prerecorded calls did not apply to these calls. *Id.* It may be true that the overwhelming number of comments submitted in response to the Commission's November 17, 2004 Notice of Proposed Rulemaking suggest that consumers do not wish to receive prerecorded telemarketing calls even if they have an established relationship with the caller. There is no support in the record, however, for the conclusion that consumers equally are against receiving these health-related calls, especially from trusted healthcare providers with whom they have longstanding relationships. On the contrary, these health-related calls are beneficial to the public and generally are accepted by consumers. Results from a survey on automated health-related

calls conducted this month by Zoomerang Online Survey Service on behalf of Silverlink Communications Inc. reveal that consumers are not opposed to receiving health-related calls. The record therefore simply does not support an amendment to the TSR that would prohibit these automated health-related calls. Without "consumer aversion" to these calls, the Commission should amend the TSR to continue to allow them.

III. The TSR Should be Amended to Allow Automated Calls to Established Customers of Medicare-Enrolled Durable Medical Equipment Suppliers

In addition to being subject to regulation under HIPAA, automated, interactive calls by Medicare-enrolled DME suppliers also are subject to regulation under the Medicare program. First, the Medicare program requires that for a supplier to be enrolled in the program it must meet (and continue to meet) certain quality standards. *See* 42 C.F.R. §§ 424.57(c) and 424.58. The Social Security Act also generally prohibits unsolicited telephone calls by DME suppliers regarding the sale of a Medicare-covered item. 42 U.S.C. § 1395m(17) (2000); *see also* 42 C.F.R. § 424.57(c)(11) (requiring an agreement from suppliers to comply with this prohibition in order to receive payment for a Medicare-covered item). The Act expressly excludes from this prohibition, however, calls to a patient who has purchased a covered item within the preceding fifteen months regarding the purchase of additional covered items. *Id.* In fact, these calls not only are permitted under Medicare, they often are necessitated by Medicare rules. For example, the Medicare Local Coverage Determination ("LCD") for Glucose Monitors (L11520) (which governs Medicare coverage for diabetic testing supplies) requires the supplier to obtain the permission of a patient before sending the patient's refill diabetic supplies and to keep documentation of the frequency at which the patient is actually using his or her supplies. Likewise the LCD for Nebulizers (L5007) (which governs Medicare coverage for respiratory supplies) lists the typical frequency of replacement for Medicare-covered respiratory supplies

and requires documentation for claims more frequent than the typical maximum replacement amount. These Medicare rules necessitate a business model in which DME suppliers have regular (monthly or quarterly) contact with their patients to confirm their need for additional medical supplies and to have documentation of their patients' replacement orders and representations regarding their need for additional medical supplies. Given these Medicare regulations and the necessity and beneficial nature of these calls, they should continue to be allowed under the TSR. The Commission should not interfere in the provision of healthcare services that already are subject to regulation by other federal agencies.

A. Automated Telemarketing Calls to Established Customers of Medicare-Enrolled DME Suppliers Should be Allowed Because They Are Not Likely To Cause the Harms Targeted by the TSR and, in Fact, Have a Distinct Public Benefit

The Telemarketing Act and Consumer Fraud and Abuse Prevention Act, 15 U.S.C. §§ 6101 – 6108 (the "Telemarketing Act"), directed the FTC to include in the TSR "a requirement that telemarketers may not undertake a pattern of unsolicited telephone calls which the reasonable consumer would consider coercive or abusive of such consumer's right to privacy." 15 U.S.C. § 6102(a)(3)(A). Based on this directive, the FTC proposes to amend the TSR to expressly ban prerecorded calls without the prior written consent of the consumer because consumers "overwhelmingly consider prerecorded calls coercive and abusive of their right to privacy." 71 Fed. Reg. at 58,726. Automated, interactive calls seeking confirmation from patients regarding their need for refill prescriptions of diabetic and respiratory supplies simply bear no relationship to the typical prerecorded telemarketing messages opposed by consumers and deemed by the Commission to be coercive and abusive. Indeed, they more closely resemble automated informational messages, of which the FTC notes that the "relatively few supportive

consumer comments" wholly supported.[1] *Id.* at 58,720. Accordingly the FTC's rationale for determining that prerecorded calls should be prohibited does not apply to these calls. They are personalized, interactive, and relied upon by millions of elderly and chronically ill people in this country and should not be prohibited.

Instead of causing the harms targeted by the Commission, these automated, interactive messages regarding replacement of medical supplies provide many public benefits. First, they help to reduce the costs of the Medicare and Medicaid programs, taxpayer-supported government-funded healthcare programs. Using an automated, interactive system is significantly more cost-effective than live sales representatives and the Commission itself has acknowledged this substantial cost differential. *See* 71 Fed. Reg. at 58,724 (noting a "substantially lower cost of prerecorded message telemarketing (compared to live telemarketing campaigns with sales agents)"). These calls also improve the lives of individuals living with chronic illnesses, such as diabetes and asthma, by helping to prevent costly and often deadly complications commonly associated with these diseases. Patients, many of whom are elderly, have come to rely on these calls as reminders to order their replacement medical supplies and remain compliant with their physicians' orders. As a result, these calls drive consumers' healthcare behaviors, measurably improving compliance rates with home treatment regiments and resulting in improved clinical outcomes and reduced complications.

[1] The Commission notes "the majority of these relatively few supportive consumer comments indicated that they did not want the Commission to prohibit prerecorded informational messages such as reminder messages—although such messages have never been covered, much less barred, by the TSR." 71 Fed. Reg. at 58,720 (citations omitted).

B. Medicare-enrolled DME Suppliers Benefit from Using Automated Messages Because Such Messages Ensure Better Quality Service to Patients and Allow for An Accurate Record for Medicare Purposes

Using automated, interactive messages helps eliminate the risk that the intended message will vary from call to call. While this benefit previously was enumerated in several comments supportive of the Commission's proposed safe harbor for prerecorded calls to established customers, it is even more critical to companies such as Access who are providing medical supplies and using these calls to build a record for Medicare purposes. *See* 71 Fed. Reg. at 58,719 (citing to several industry comments noting this benefit). It is important that patients of Access, many of whom are elderly and all of whom are chronically ill, receive clear and well-articulated messages to ensure that they understand the message that their medical supplies may need to be renewed. Moreover, Medicare as well as HIPAA privacy regulations require quality control and certain disclosures; these calls are carefully scripted to ensure compliance with these regulations. Using a live sales representative might jeopardize this compliance due to human error and possible call clarity issues.

In addition to ensuring that the intended message is consistent from call to call, using automated, interactive calls to alert patients of the need to replace their medical supplies enables Access to maintain accurate records required by Medicare rules. For example, the Medicare LCD for Glucose Monitors (L11520) requires a supplier to keep documentation of the frequency at which the patient is actually using his or her diabetic supplies. Likewise the LCD for Nebulizers (L5007) requires documentation for claims more frequent than the typical maximum replacement amount of nebulizer accessories, such as respiratory supplies. Access and other companies offering these supplies use automated, interactive calls with their patients to establish the record required under these

rules. By using automated messages rather than a live sales representative, a Medicare-enrolled DME supplier can ensure that the question to which its patients are responding is precisely the same in each call. As a result, the supplier can rely on a record of its patients' "yes" or "no" responses with confidence that it accurately reflects the information needed under the Medicare rules.[2]

C. The Commission is Authorized to Exempt an Industry from the TSR and, in fact, Similar Exemptions Exist for Industries Whose Calls are Subject to Regulation by Another Agency

The Commission has the authority to exempt an industry from the TSR, and in fact, has previously done so. Congress gave the Commission express authority to exempt any person from a rule when it finds that application of that rule is unnecessary to "prevent the unfair or deceptive practice to which the rule relates." 15 U.S.C. § 57a(g)(2). Application of the TSR to automated, interactive calls by Medicare-enrolled DME suppliers to remind their patients to order replacement medical supplies is wholly unnecessary to prevent the coercive and abusive invasions of privacy that the TSR is intended to prevent. The Social Security Act regulates DME suppliers' unsolicited calls to Medicare patients regarding the sale of Medicare-covered items. 42 U.S.C. § 1395m(17) (2000). The Social Security Act expressly generally prohibits these calls, but excludes certain calls that HHS has determined provide benefits sufficient to justify their use. For example, the Social Security Act exempts from this prohibition calls to a patient who has purchased a covered item within the preceding fifteen months regarding the purchase of additional covered items. *Id.*

[2] At any time, however, the patient may opt to speak with a live sales representative.

In addition, to be enrolled in the Medicare program, a DME supplier must meet and maintain certain quality standards. For example, the supplier must (1) advise patients that they may either rent or purchase inexpensive or routinely-purchased DME; (2) honor all warranties under applicable state law; (3) maintain a primary business telephone number listed under the name of the business locally or toll-free; (4) answer questions and respond to complaints a patient has about the Medicare-covered item; (5) maintain and replace at no charge or repair Medicare-covered items it has rented to patients; (6) accept returns of substandard quality; (7) verify that the patient has received equipment, items, and services; and (8) provide the patient with information and telephone numbers for customer service assistance regarding regular business hours, after-hours access, item repair, and emergency coverage. This regulatory oversight, which is carefully and proactively monitored by a government contractor known as the National Supplier Clearinghouse, should be more than sufficient to ensure that Medicare-enrolled DME suppliers do not subject their patients to abusive or coercive marketing tactics and therefore makes unnecessary application of the TSR to these suppliers' automated, interactive telephone calls.

Indeed, in enacting the Telemarketing Act, Congress recognized that the primary purpose of the Telemarketing Act, to provide "consumers necessary protection from telemarketing deception and abuse," could be achieved without requiring that the TSR be universally applicable. 15 U.S.C. § 6101(5). Congress understood that certain entities that may use telemarketing were governed by other federal agencies and that those other agencies could be entrusted to carry out the purpose of the Telemarketing Act. *See* 139 Cong. Rec. 932 (1993) (statement of Rep. Swift) (explaining that exemptions to the Telemarketing Act were added because "dual regulation would [not] be helpful in

combating fraud and deception"). Accordingly, the Telemarketing Act specifically permits the Securities and Exchange Commission ("SEC") to enact telemarketing rules modeled after the TSR when such rules would provide protection to consumers that is not provided by existing SEC rules and are in the "public interest," and exempts from the TSR entities subject to these SEC rules. 15 U.S.C. §§ 6102(d)(1)(B) and 6102(d)(2)(A). Likewise, the Telemarketing Act exempts from the TSR persons governed by the Commodities Futures Trading Commission ("CFTC"). 15 U.S.C. § 6102(e). The CFTC is authorized to promulgate its own telemarketing rules, similar to those promulgated by the SEC and the Commission, by the Commodities Exchange Act. 7 U.S.C. 9(b).

Application of the TSR to automated calls by Medicare-enrolled DME suppliers would be precisely the sort of "dual regulation" that would not help combat the fraud and deception at which the TSR is aimed. The Commission therefore should amend the TSR to allow automated calls by Medicare-enrolled DME suppliers to established customers.

Respectfully submitted,

ACCESS DIABETIC SUPPLY, LLC

Neely B. Algin
FULBRIGHT & JAWORSKI L.L.P.
801 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 662-4723

December 15, 2006