

Before the
FEDERAL TRADE COMMISSION
Washington, D.C.

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

TO: THE COMMISSION

**COMMENTS OF
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Silverlink Communications, Inc. (“Silverlink”) and Eliza Corporation (“Eliza”) hereby submit comments in this proceeding consistent with their November 29, 2006 Petition and December 7, 2006 letter to the Commission.¹

SUMMARY

Silverlink and Eliza urge the Commission to exempt healthcare communications from its proposed prerecorded call prohibition.² Otherwise, the healthcare sector will be unable to communicate with consumers in the most efficient and effective manner available.

The complex U.S. healthcare system requires constant, efficient, cost-effective communication with consumers. Silverlink and Eliza are corporate competitors whose technology enables millions of customized, automated calls³ a month for healthcare plans, hospitals, pharmacies and other healthcare fiduciaries. Combined, Silverlink and Eliza provide outreach for fiduciaries who serve over 100 million healthcare consumers.

Automated calls are essential to improving efficiency and access to healthcare while decreasing costs for consumers, employers and government. Independent studies demonstrate that such calls achieve better results than email or mail at a fraction of the cost of live calls. The vast majority of consumers appreciate receiving them.

Under congressional mandate to improve the healthcare system by enabling electronic communications, HHS adopted HIPAA privacy rules that permit communications with consumers, without their prior authorization, to encourage the purchase or use of products or services related to healthcare plan benefits, treatment, case management, care coordination or healthcare alternatives. The Commission’s broad definition of telemarketing and proposed prohibition of prerecorded telemarketing calls will now cast uncertainty over the status of many automated healthcare calls. The proposed prohibition thus may deny healthcare fiduciaries use of this highly cost-effective communication tool available for healthcare outreach. The Commission should defer to HHS’s public policy determination by exempting healthcare communications from its proposed prohibition.

Silverlink and Eliza encourage the Commission not to throw out the baby with the bathwater by eliminating automated calls that improve healthcare outcomes and control healthcare costs in its well-meaning attempt to ban other prerecorded telemarketing calls for which there may be no such compelling justification.

¹ The Petition and December 7 letter were filed by Patton Boggs LLP, co-counsel with Duane Morris LLP in this matter.

² Alternatively, Silverlink and Eliza urge the Commission to (1) continue indefinitely its non-enforcement policy for healthcare calls, as set forth in their Petition and December 7 letter, (2) continue its non-enforcement policy for healthcare calls on an interim basis and open a new rulemaking proceeding as described in footnote 4 to the Petition, or (3) continue indefinitely its non-enforcement policy with respect to all prerecorded telemarketing calls to persons with whom the caller has an established business relationships.

³ The Commission has not defined the term “prerecorded calls” as used in the proposed prohibition. The term implies one-way uniformity and lack of recipient interaction. Although all calls delivered by Silverlink and Eliza begin with a prerecorded message, they are automated, interactive calls. See 2.1 *infra*. For purposes of this proceeding, however, Silverlink and Eliza assume that their automated calls constitute “prerecorded calls” under the TSR.

DETAILED ANALYSIS

1. **The Healthcare System Requires Constant, Efficient, Cost-Effective Communications**

The United States spends \$1.6 trillion a year on healthcare - 15% of the economy - with annual costs rising at an unsustainable 7% to 9% rate. The system is known to be inefficient and burdened by suboptimal consumer behavior. Improving the system requires cost-effective and efficient communications.

In the face of severe nursing shortages, overworked physicians and quality-of-care concerns, healthcare fiduciaries are using technology to improve outcomes, decrease costs and engage consumers directly in making informed healthcare decisions.

Getting healthcare consumers to make better and more consistent choices presents a daunting task. Without frequent, individualized communications from healthcare fiduciaries responsible for their care, consumers frequently procrastinate or make ill-informed decisions. Often, the consumers who most need to take steps to promote better health are the ones who fail to do so. They do not undergo regular health exams and recommended screenings. They fail to get recommended immunizations. They let prescriptions run out without refilling them. They incur higher co-pays than necessary and cost their payors more by choosing brand name drugs over generics. They do not participate in available health management programs.

2. **Automated Healthcare Calls Enable Effective, Efficient and Essential Communications between Healthcare Fiduciaries and Consumers**

Using automated, interactive speech-enabled technology, Silverlink and Eliza provide outreach solutions to fiduciaries who serve over 100 million healthcare consumers. The companies employ different technologies and approaches but share a desire to provide cost-effective healthcare decision support to individuals, leading to improved health outcomes and cost savings. Automated healthcare calls provide the most cost-effective means of communication, and consumers appreciate such calls and want to continue receiving them.

2.1 **Silverlink and Eliza Deliver Personalized, Interactive, Automated Healthcare Calls**

Silverlink and Eliza deliver automated healthcare calls that are personalized and interactive. These are not one-way “blast” messages or “robo-calls”. They offer recipients a menu of choices that vary depending on the purpose and complexity of the call. Recipients are also able to provide information to the caller during the call. Recipients can respond and navigate through the call using their voice rather than having to push numbers on the phone key pad. Each call is customized, and can be personalized based on the recipient’s needs, type of treatment and insurance coverage. Each call provides a natural experience, often allowing a recipient to repeat information or to transfer to a live agent.

All Silverlink and Eliza calls involving protected healthcare information comply with HIPAA's privacy rules. Recipients may opt out through the existing communication channel between the individual and the HIPAA covered entity.

2.2 Automated Calls Can Be Used To Communicate Vital Healthcare Information to Consumers in a Variety of High-Impact Contexts

Healthcare fiduciaries use automated calls to reach consumers at home to educate, encourage proactive healthcare decisions and collect information across a wide variety of healthcare contexts. Call types range from a simple administrative interaction (to confirm an address, for example) to a sophisticated clinical interaction (a disease specific health risk assessment, for example).

The following is a sampling of calls:

- **Flu shot and other immunization reminders:** Automated calls are used to reach consumers directly to encourage recommended immunizations, such as routine immunizations for children and flu shots for seniors. Automated reminder calls demonstrably improve immunization rates.

Each winter, the flu kills approximately 36,000-40,000 Americans, hospitalizes more than 200,000, and costs the U.S. economy over \$10 billion in lost productivity and direct medical expenses. [Source: Trust for America's Health, 2006]

- **Refill reminder / reorder calls:** Using automated calls, mail order pharmacies contact patients at the appropriate time in their refill cycle to complete a refill order, ensuring that the patient has an uninterrupted supply of his or her medication. Consumers become accustomed to receiving these monthly or quarterly refill calls and benefit from them. Studies show that, in the absence of such refill reminders, up to 70% of patients with long-term prescriptions fall off therapy. Noncompliance with drug regimens can have significant adverse impact, and increase hospitalization, morbidity and mortality rates. For example, failure of a patient with newly diagnosed hypertension to comply with a prescribed course of medication may cause heart attack, stroke or sudden death. Similar to refill reminders, automated calls are used to inform members when one or more of their medical supplies (such as diabetes test strips) is running out and provide the option to reorder.

[Medication non-compliance] is estimated to result in 125,000 deaths due to cardiovascular disease (such as heart attack and stroke) each year. In addition, up to 23% of nursing home admissions, 10% of hospital admissions, and many doctor visits, diagnostic tests, and unnecessary treatments could be avoided if people took their drugs as directed. [Source: The Merck Manual Home Edition for Patients and Caregivers. "Compliance with Drug Treatment." Available at www.merck.com]

- **Migration from branded to generic drugs encouragement:** Automated calls are used to inform consumers of prescription availability in a generic form and the benefits of a change from brand forms. Successful migrations reduce co-payments by the patient and costs to the insurer or healthcare plan provider.

The FDA notes that generic drugs typically cost 50-70 percent less than their brand-name counterparts [Source: www.fda.gov]

Americans could save \$24.7 billion this year if they were prescribed more generics in six major drug classes for treating conditions such as heart disease, ulcers, pain, depression, high blood pressure and high cholesterol. [Source: 2005 Generic Drug Usage Report, Express Scripts, Inc.]

- **Health screening reminders:** When consumers reach appropriate ages or are diagnosed with specific diseases or conditions, automated calls are used to encourage screenings such as mammograms, colonoscopies and blood glucose level checks. These preventative screenings yield tremendous benefit for consumers.

Only 49 percent of adults received preventive and screening tests according to guidelines for their age and sex. (Source: U.S. Healthcare System Gets Poor Scores on Quality, Access, Efficiency and Equity, The Commonwealth Fund 9/27/06)

Estimated 37,000-81,000 avoidable deaths in the United States due to variations in care in 2005

Estimated \$2.9 billion - \$3.9 billion in avoidable medical costs due to variations in care in 2005

Estimated \$10.6 billion in lost productivity due to suboptimal care among U.S. workforce in 2005

[Source: National Committee for Quality Assurance, The State of Health Care Quality Industry Trends and Analysis 2006]

- **Enrollment encouragement:** Automated calls are used to encourage members to enroll in disease management programs or treatment programs. Consumers eligible for Medicare and Medicaid might receive an automated call encouraging them to take advantage of their eligibility. This addresses a major challenge in healthcare cost management, ensuring patients are enrolled in insurance plans and management programs.
- **Retail to mail migration encouragement:** Automated calls are used to encourage patients with maintenance medication requirements to use mail

order pharmacies rather than traditional retail outlets to lower costs for both patients and healthcare fiduciaries, and improve convenience.

2.3 Automated Healthcare Calls Provide the Most Cost-Effective Means for Healthcare Fiduciaries To Improve Outcomes

Automated calls provide the most cost-effective means for healthcare fiduciaries to interact with consumers at home. Healthcare fiduciaries using automated calls consistently achieve success rates dramatically higher than those for mail, email or web portals. Automated calls reduce costs and increase effective consumer contact at a fraction of the cost of live calls. Using automated calls is becoming a healthcare reality, particularly because staff limitations often preclude making live calls to large numbers of patients.

The following alternatives to automated calls are significantly less effective and/or more costly for healthcare fiduciaries:

- **Email** – With response rates in the low single digits, email is ineffective. Additional hurdles include lack of current email addresses, inability to comply with HIPAA rules covering protected health information, and limited access to senior citizens.
- **Traditional mail** – With typical response rates ranging in the single digits and teens, traditional mail is slightly more effective than email, but requires interaction through sending paper forms to a recipient, who must then complete and return them by mail, a process that can take weeks or longer, and therefore is still not nearly as effective as automated or live phone calls.
- **Web portals** – Most healthcare fiduciaries have made significant investments in sophisticated websites in recent years. Though these sites have the potential to become effective communication vehicles, current consumer adoption rates remain in the single digits. Because they require the customer to initiate contact, they suffer from the very problem they seek to address through proactive outreach, namely, patient inertia.
- **Live calls** – Live phone calls, which can cost \$6 to \$10 each, are effective and desirable, but usually cost prohibitive.

Overall, automated healthcare calls deliver the best value to healthcare fiduciaries and patients, as indicated by the following sample of published case studies and testimonials:

Automated Speech-Enabled Program Description	Outcomes	Source
Diabetic screening reminder	Diabetic retinal exams increased from 71% to 93% due to the outreach program.	<i>Highlights of GAO-04-022 a report to the Minority Member, Committee on Health, Education, Labor, and Pensions, U.S. Senate</i> Benefits Realized for Selected Health Care Functions Appendix 1 Use of Information Technology for Selected Health Care Functions (p. 107)
Adolescent vaccination reminder	Rate of adolescents receiving full schedule of vaccination increased from 29% to 43% due to the outreach program.	<i>Highlights of GAO-04-022 a report to the Minority Member, Committee on Health, Education, Labor, and Pensions, U.S. Senate</i> Benefits Realized for Selected Health Care Functions Appendix 1 Use of Information Technology for Selected Health Care Functions (p. 107)
National childhood immunization outreach	Project Vaccinate demonstrated an increase from 57.7% to 72.5% in immunization rates for the 4:3:1:3:3 (4 DTap, 3 IPV, 1 MCV, 3 Hib, 3 hep B) in 19-35 month-olds in Newark over the course of one year—a 26% increase	Blue Cross Blue Shield Association
Flu shot reminder program	65% of consumers reached by interactive automated call actually obtained a flu shot.	Proprietary data
Member engagement in cardiovascular disease program	69% of members reported weight loss during the program. Meanwhile, the average LDL reduced from 127.7mg/dL to 87.4mg/dL during participation in the program.	MAMSI Health Plans, 2002

- “In 18 months [our use of prerecorded calls] has saved members \$11 million, says Beth Bierbower, Humana's vice president of product innovation.” (U.S. News and World Report online edition Oct. 29, 2006) http://www.usnews.com/usnews/health/articles/061029/6plan_4.htm

- “According to Rees Pinney, senior vice president of sales and marketing for Familymeds, the automated system...received high marks from customers.” (EWeek Oct. 7, 2004)
<http://www.eweek.com/article2/0%2C1759%2C1668068%2C00.asp>
- “Within a week we were finished scripting the calls ... [we] found that 70% of [our] members listened to the automated message ... The lower than expected number of customer service calls—showed that most members were comfortable with interactive phone calls ... The interactive calls have saved us time because they resulted in less disruption in our customer service center ... However, the whole focus was to increase member satisfaction. By giving members the information they need to manage their drugs, we were able to do that.” Ellen Scharaga Director of Pharmacy, Group Health Incorporated (HealthDataManagement Feb. 2005)
- “This innovative way of having a voice-activated, consumer-friendly call [allows us] to reach out to more of our customers in a more timely fashion," [Noreen] Patterson [Vice President of Marketing and Advertising, FamilyMeds] said. The company had used workers at individual pharmacies to do the task, a practice that was time consuming and expensive” (MassHighTech Dec. 15, 2005)

In summary, automated healthcare calls produce positive health outcomes that reduce healthcare expenses, hospitalizations and deaths.

2.4 Automated Healthcare Calls Have a Positive Impact on Call Recipients

Data shows that consumers appreciate and want to receive automated healthcare calls. Trends in managed care are making consumers increasingly responsible for managing and funding their own healthcare. As consumers are required to accept more choice, responsibility and risk, they need and want better access to the information necessary to make the best decisions for themselves and their families. Automated calls enable healthcare fiduciaries to effectively and affordably deliver personalized information when it is most relevant to the recipient.

When consumers receive automated calls from their healthcare fiduciaries, they overwhelmingly respond positively and are willing to engage with the caller. Interaction rates for automated healthcare calls, meaning the percentage of recipients who answer the call and respond to the first question without hanging up, typically exceeds 75% when there is an established business relationship. Interaction rates for other calls are much lower, 17% for financial services and 2% interaction rate for utility services.

Below are further examples of consumer acceptance of automated healthcare calls:⁴

- Of 140,000 consumers receiving an automated call from their pharmacy benefit manager with a refill/reorder offer, only 50 opted out of future calls.
- A covered entity reported that after sending automated interactive calls to 60,000 Medicaid members, only 10 asked not to be contacted again.
- On average, 20% of consumers who receive, by automated call, a message from their healthcare company left on an answering machine or with a household member place a return call.⁵

In some cases, fiduciaries use automated healthcare calls to reach the nation's most vulnerable populations, who might otherwise not be served. Interacting with persons eligible for Medicaid or other public benefits requires a cost-effective approach with a broad reach. Automated calls are often the only way to reach this population in a cost-effective manner. For example, healthcare fiduciaries successfully used automated calls to contact tens of millions of Medicare Part D members, collecting and delivering information with speed and efficiency that would not be possible with any other method.

3. The Proposed Prerecorded Call Prohibition Should Be Revised To Exempt Automated Healthcare Calls.

Given the importance of automated calls to healthcare fiduciaries, and the public policy determinations made by HHS as the agency charged with oversight of the healthcare system,⁶ the Commission should exempt healthcare communications from its blanket prohibition of prerecorded telemarketing calls. The overbroad definition of telemarketing casts doubt over which automated healthcare calls would be prohibited and which would not, and may even cause some fiduciaries to refrain from delivering informational calls that would otherwise be permitted, such as those conveying disease education or healthy lifestyle information. Nor does the Commission's record support a prohibition of healthcare calls. The Commission can readily exempt healthcare communications from

⁴ Additional supportive data was submitted to the Commission on December 7, 2006.

⁵ In the notice of the proposed prohibition, the Commission asked about the impact of leaving messages on answering machines. *See* 71 F.R. 58733 (questions 5-7). Silverlink and Eliza believe that the healthcare benefits far outweigh any perceived cost resulting from leaving messages on answering machines. The messages left are brief and do not disclose protected health information. In addition, HIPAA's privacy rule permits healthcare providers to leave messages for patients on their answering machines. *See* <http://www.hhs.gov/ocr/hipaa> (Frequently Asked Questions).

⁶ Congress enacted the Health Insurance Portability and Accountability Act (HIPAA) on August 21, 1996 to "improve portability and continuity of health insurance coverage . . . , to combat waste, fraud, and abuse in health insurance and health care delivery, . . .to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes." HIPAA is codified primarily in Titles 18, 29, and 42 of the United States Code. Along with the administrative simplification provisions, Congress recognized the need to maintain strict privacy protection for health information and therefore directed the Department of Health and Human Services to promulgate regulations, which are codified at 45 C.F.R. §§ 160 and 164 and known collectively as the HIPAA privacy rules.

its proposed prohibition by reference to HSS's exemption for healthcare communications contained in the HIPAA privacy rules.

3.1 Under Congressional Mandate To Encourage Electronic Healthcare Communications, HHS Adopted HIPAA Privacy Rules That Permit Communications with Consumers, without Their Prior Consent, To Encourage the Purchase or Use of Products or Services Related to Healthcare Plans, Treatment and Case Management

A decade ago, in enacting HIPAA, Congress embraced advanced communications technology as a way to "improve ... the efficiency and effectiveness of the health care system by encouraging ... the electronic transmission of certain health information."⁷

HIPAA established standards under which the healthcare sector could share and use health information, and communicate with consumers. In enacting HIPAA, Congress recognized that the use of advanced communications technology could compromise an individual's privacy interests. Congress therefore directed HHS to promulgate rules that would appropriately balance consumer privacy interests with its "objective of reducing the administrative costs of providing and paying for healthcare."⁸

In promulgating the HIPAA privacy rules regulating communications that encourage consumers to purchase or use products or services, HHS expressly exempted communications:

- (i) To describe a health-related product or service . . . that is provided by, or included in a plan of benefits of, the covered entity making the communication . . . ; (ii) For treatment of the individual; or (iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.⁹

Thus, healthcare fiduciaries do not need prior authorization to communicate with consumers about their health plan benefits, treatment, case management, care coordination or healthcare alternatives, and the healthcare sector has relied on this exemption in developing its practices, procedures and policies for the use of communication technology.

HHS's decision to exempt healthcare communications from its privacy rule was not inadvertent, but instead based on an extensive record and deliberate balancing of interests.¹⁰ HHS had originally proposed privacy rules that would not have excluded

⁷ See P.L. No. 104-191 sec. 261. HIPAA's administrative simplification provisions are codified as amended at 42 U.S.C. § 1320d.

⁸ P.L. No. 104-191 sec. 1172(b), codified as amended at 42 U.S.C. § 1320d-1(b).

⁹ 45 C.F.R. § 164.501.

¹⁰ See 67 F.R.14778-80; 14789-91.

healthcare communications from their patient authorization requirement. This proposal generated much backlash from healthcare providers who felt the rule would be too burdensome and would materially affect the quality and efficiency of healthcare.

Based on the feedback from interested parties, HHS concluded that the public interest in unfettered communications for healthcare purposes outweighed intrusion on privacy interests, and its final HIPAA privacy rules exempted healthcare communications from any patient authorization requirement. Silverlink and Eliza urge the Commission to defer to HHS's public policy determination to balance these interests by exempting automated healthcare calls from its proposed prohibition of prerecorded telemarketing calls.

3.2 As Proposed, the Prerecorded Call Prohibition Would Significantly Restrict or Deter Automated Healthcare Calls

As currently written, the proposed prohibition of prerecorded telemarketing calls would undermine the use of automated calls to serve the healthcare sector. Silverlink and Eliza believe that neither the public nor the Commission considered this impact in prior proceedings.

The TSR broadly defines “telemarketing” as “a plan, program, or campaign which is conducted to induce the purchase of goods or services.” In our market-based healthcare system, virtually every decision by a healthcare consumer involves a purchasing decision, whether the decision involves plan participation, screening, examination, preventive care, treatment or therapy. At one extreme, the patient pays the full price for the healthcare goods or services involved. At the other extreme, the patient pays nothing, but even then the patient’s decision usually requires his or her healthcare plan, employer or other benefits provider to pay for the healthcare goods or services involved. In the middle, which is the vast majority of cases, the patient pays some of the cost, through a co-payment, deductible or subsidized price.

More specifically, the TSR may classify as “telemarketing” automated healthcare calls that encourage: (1) immunizations, which typically require fees or co-pays and thus may be viewed as purchases; (2) refills and reorders, which inherently involve purchases of goods; (3) branded to generic migrations, which always involve purchases of goods; (4) health screening, which typically requires a co-pay, and hence is a purchase of services; (5) enrollments, which may have associated fees and constitute purchases of services; (6) retail to mail migrations, which always involve the sale of goods; and (7) even appointment confirmations, which encourage the purchase of services.

In the public notice of its proposed prohibition, the Commission assured the public that “informational” calls are not covered under the TSR. Though the Commission gave several examples of “informational” calls, it did not define the term. Nor did the Commission acknowledge or address the inherent overlap between “informational” and “telemarketing” calls. For example, notwithstanding the Commission’s assertions that appointment reminders are informational, they nevertheless encourage the purchase of services, which, though scheduled, can frequently be canceled without financial penalty. The Commission could have, but did not, enumerate many other services that healthcare

fiduciaries consider “scheduled” under an established healthcare benefit or care plan. For example, initial prescriptions often authorize multiple refills of medication, and cancer screenings should occur at defined intervals. In both cases, reminder calls are triggered if the anticipated recurring activity does not occur or ceases early. The existing and proposed rules thus do not clarify at what point during the sales process a vendor’s encouragement ceases to be marketing and instead becomes merely informational.

The Commission did, however, acknowledge the confusion among businesses and consumers over what types of calls are covered. For example, the Commission opined:

[T]he majority of ... [the] 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. These consumers expressed appreciation for prerecorded informational messages about delivery dates for previously purchased goods or services, medical prescription order notifications, flight cancellation alerts, and overdue bill and appointment reminders.¹¹

Several industry comments posited that consumers are interested in receiving prerecorded messages. ... [M]any of the examples, if not most, were informational messages that are not covered by the TSR at all. . . because they are not “telemarketing” as defined by the Telemarketing Act or the Rule.¹²

In fact, the Commission’s public notice may create more confusion than it alleviates. For example, we have difficulty reconciling the Commission’s expansive reading of its abandoned call prohibition as already amounting to a prerecorded call prohibition with its assurances that the newly proposed prerecorded call prohibition will not impact informational calls. In any case, Silverlink and Eliza are gravely concerned that their healthcare fiduciary customers will be deterred from making important types of these automated healthcare calls they currently make if the proposed prohibition goes into effect in its current form. Healthcare fiduciaries generally have strict compliance programs and would not want to risk actual or alleged noncompliance with the TSR. They can thus be expected to curtail their use of automated calls, reverting to more expensive and cumbersome, yet less effective, means of communications or even eliminating altogether communications that could improve health outcomes or reduce costs.

3.3 The Record Does Not Support a Ban on Automated Healthcare Calls

The record does not support a ban on automated healthcare calls. The Commission’s rationale for its proposed prohibition does not apply to healthcare calls. In addition, the Commission’s previous proceedings did not adequately notify the healthcare sector and

¹¹ 71 F.R. 58720 (emphasis added).

¹² *Id.* at 58719.

healthcare consumers of its intention to prohibit prerecorded calls, and therefore the record did not reflect the views of the healthcare sector.

The Commission concluded from the record that it should prohibit prerecorded telemarketing calls because: (1) consumers have an aversion to prerecorded calls even when the calls are made to established customers; (2) the harm to consumer privacy is not outweighed by the value of the prerecorded calls; and (3) there is nothing unique about the relationship between sellers and their customers that gives sellers sufficient incentive to self-regulate and avoid prerecorded telemarketing campaigns that their customers would consider abusive.¹³

However, the research and data introduced in these Comments and in the earlier filings by Silverlink and Eliza in this proceeding demonstrate the benefits of, and consumer appreciation for, automated healthcare calls. Consumers generally do not consider such calls to be abusive; their benefits far outweigh any intrusion on privacy interests; and in promulgating its HIPAA marketing restrictions, HHS has already developed narrowly tailored definitions of the types of healthcare communications that should be permitted without consumer authorization.

The record is devoid of healthcare-related comments on the Commission's rulemaking because, until this proceeding, the Commission did not provide adequate notice of its intention to ban automated healthcare calls. Indeed, even in this proceeding, the Commission's assurance that informational calls, such as appointment reminders, will not be prohibited may lull many impacted parties and the general public into believing the proposed prohibition does not affect healthcare calls. Under the Administrative Procedure Act, the Commission is required to provide notice that "fairly apprise[s] the interested parties of the subjects and issues before the Agency," and thereby "affords interested persons a reasonable and meaningful opportunity to participate in the rulemaking process."¹⁴ In prior proceedings, the healthcare sector was not fairly apprised of the Commission's proposed ban on prerecorded calls.

The Commission asserts that the call abandonment rule in the TSR already prohibits prerecorded telemarketing calls. Silverlink and Eliza were not aware of this interpretation until the Commission published its notice of the currently proposed rule. The Commission's prior proceedings were captioned as the proposed elimination of abandoned calls and the proposed established business relationship exception to the elimination of abandoned calls.

The Commission's broad interpretation of the existing abandoned call rule as prohibiting prerecorded calls strains the language in the rule and goes far beyond the rule's original purpose. The TSR defines "abandoned calls" as those where "the telemarketer does not

¹³ *Id.* at 58723.

¹⁴ See 5 USC § 553(b)(3), (c); see, e.g., *American Iron and Steel Institute v. EPA*, 568 F.2d 284, 291 (3d Cir. 1977); *American Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994).

connect the call to a sales representative within two (2) seconds.”¹⁵ Although we now understand the Commission’s position that prerecorded calls would fall within this definition if the term “sales representative” were construed as referring to a live agent, nothing in the existing rule dictates this limitation. Indeed, the E-Sign Act¹⁶ expressly contemplates the use of electronic agents in communications, and likewise the term “sales representative” could be construed as referring to an automated agent, such as the systems operated by Silverlink and Eliza, as well as to a live agent.

The record shows that the Commission’s original intent in adopting its abandoned call rule was to prohibit calls that result in hang-ups or dead space when a telemarketer uses predictive dialing and the consumer answers the call before a live sales representative is available to take the call.¹⁷ This original intent is consistent with the healthcare industry’s understanding of the abandoned calls term.

In making automated healthcare calls, the healthcare sector heretofore has relied on the established business relationship safe harbor contained in both the TSR and the FCC’s rules. Specifically, under section 310.4(b)(1)(iii)(B)(ii) of the TSR, telemarketers may call persons listed on the do-not-call registry maintained by the Commission if the telemarketer has an established business relationship with such person. The language of the TSR’s do-not-call provision and established business relationship exception does not distinguish between live calls and prerecorded calls. The FCC’s regulations generally prohibit the use of automated dialing-announcing devices, but that provision includes an established business relationship exemption.¹⁸

Given the information now offered for the Commission’s consideration, we are confident it will agree that the delivery of automated healthcare calls is not an “abusive” practice but rather should be preserved and encouraged.

3.4 The Definitions Developed by HHS under HIPAA Enable the Commission To Formulate a Narrowly Tailored Exemption for Automated Healthcare Calls

Silverlink and Eliza are asking the Commission to exempt from the proposed prohibition the same types of communications the HIPAA privacy rule already excludes from its definition of “marketing.”¹⁹ Such a narrowly tailored exemption would avoid a

¹⁵ 16 C.F.R. §310.4(b)(iv).

¹⁶ See Electronic Signatures in Global and National Commerce Act, 15 U.S.C. §§ 7001-7031.

¹⁷ 68 FR 4641-42. We do not understand the logic of either an established business relationship or written consent exception to an “abandoned calls” provision. Presumably, the Commission does not intend for either exception to apply to a truly abandoned call.

¹⁸ See 47 CFR 64.1200(a).

¹⁹ The Commission has requested suggested modifications to its proposed amendment, but the same result could also be achieved by redefining “telemarketing” to be consistent with HIPAA’s definition of “marketing.”

constitutionally impermissible overbroad restriction on valid commercial speech, and would defer to HHS’s fully informed public policy judgments embodied in the HIPAA privacy rule.

Specifically, Silverlink and Eliza propose the following modification (in underlined bolded text) to the Commission’s proposed TSR amendment:

C.F.R. TITLE 16: Commercial Practices
PART 310 – TELEMARKETING SALES RULE
§ 310.4 Abusive telemarketing acts or practices

...
(b) *Pattern of calls.*

(1) It is an abusive telemarketing act or practice and a violation of this Rule for a telemarketer to engage in, or for a seller to cause a telemarketer to engage in, the following conduct:

...
(v) Initiating any outbound telemarketing call that delivers a prerecorded message when answered by a person, unless the seller has obtained the express agreement, in writing, of such person to place prerecorded calls to that person. Such written agreement shall clearly evidence such person’s authorization that calls made by or on behalf of a specific party may be placed to that person, and shall include the telephone number to which the calls may be placed and the signature of that person; provided, however, that prerecorded calls permitted for compliance with the call abandonment safe harbor in § 310.4(b)(4)(iii), do not require such an agreement. **Provided further that § 310.4(b)(1)(iv) and this § 310.4(b)(1)(v) do not apply to any outbound call that delivers a prerecorded healthcare message made by, or on behalf of, a covered entity or its business associate as such terms are defined in 45 C.F.R § 160.103 (i.e. HIPAA-regulated entities).**

The terms used in the proposed modification above are defined in 45 C.F.R. § 160.103, which is part of the HIPAA privacy rule. The relevant definitions are as follows:

Covered entity means:

(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Health plan means:

an individual or group plan that provides, or pays the cost of, medical care [citation omitted],” including a group health plan, a health insurance issuer, an HMO, Part A or Part B of Medicare, Medicaid, an issuer of a Medicare supplemental policy, an issuer of a long-term care policy, an

employee welfare benefit plan, and other types of health care programs enumerated in the definition.

Health care clearinghouse means:

a public or private entity . . . that does either of the following functions: (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction. (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means:

a provider of services [citation omitted], a provider of medical or health services [citation omitted], and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Business associate means:

(1) Except as provided in paragraph (2) of this definition . . . with respect to a covered entity, a person who: (i) On behalf of such covered entity or of an organized health care arrangement . . . performs, or assists in the performance of: (A) A function or activity involving the use or disclosure of individually identifiable health information . . . ; or (B) Any other function or activity regulated by this subchapter; or (ii) Provides . . . management, administrative, accreditation, or financial services to or for such covered entity or arrangement, . . . where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

These terms and definitions, established by HHS based on a fully developed record, enable the Commission to modify its proposed prohibition with a narrowly tailored healthcare exemption by deferring to HHS's expertise in the healthcare sector and without the Commission expending additional time and resources. This approach will also synchronize compliance with both sets of regulations, and thereby minimize compliance costs and any adverse impact on effective healthcare communications.

Further, the proposed amendment would not result in an overbroad restriction of valid commercial speech with respect to healthcare communications.²⁰

CONCLUSION

The Commission's well-meaning effort to curb perceived abusive practices has resulted in a proposed amendment to the TSR that will have overbroad unintended consequences to the healthcare sector and its consumers. The Commission should exempt automated healthcare calls from its proposed prohibition of prerecorded telemarketing calls. Alternatively, the Commission should (1) continue indefinitely its non-enforcement policy with respect to automated healthcare calls, as set forth in the Petition and December 7 letter submitted on behalf of Silverlink and Eliza, (2) continue its non-enforcement policy with respect to automated healthcare calls on an interim basis and open a new rulemaking proceeding as described in footnote 4 to the Petition, or (3) continue indefinitely its non-enforcement policy with respect to all prerecorded telemarketing calls to persons with whom the caller has an established business relationship.

To the extent others respond to these Comments or file comments that relate to the issues discussed, Silverlink and Eliza respectfully reserve the right to file supplemental materials after December 18, 2006.

Respectfully submitted,

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²⁰ Under HIPAA, HHS provided for a 24-month general phase-in period and 36 months for small health plans. P.L. No. 104-191 sec. 1175(b)(1), codified as amended at 42 U.S.C. § 1320d-4.