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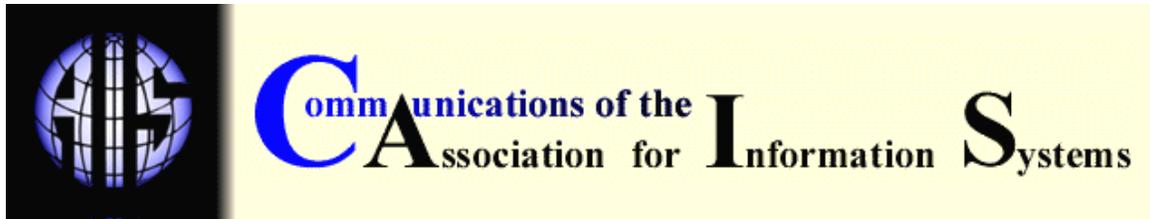
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## GIANT FOOD AND ELENSYS: LOOKING OUT FOR CUSTOMERS OR GROSS PRIVACY INVASION?

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### ABSTRACT

This case describes the privacy issues surrounding Giant Food's decision to outsource a prescription drug compliance program to Elensys. Under the arrangement, Elensys would send refill reminders to Giant's pharmacy customers. As approximately half of all patients stop taking their medication within the first six months of being prescribed, compliance programs which remind patients to refill their prescriptions help address a major public health issue. However, these programs also raise privacy issues because they involve the reuse of sensitive personal information.

The case provides students with an opportunity to assess the privacy issues raised by this situation. The case also provides an opportunity for students to grapple with the challenges of developing a "privacy sensitive" implementation strategy for Giant and for CRM programs more generally.

**Keywords:** privacy, implementation, CRM

### I. INTRODUCTION

Russell B. Fair, Vice President of Pharmacy Operations for Giant Food Inc. was walking his dog early on a Sunday morning in February. As was his custom, he had brought the newspaper with him to read. When he unfolded the front section of the *Washington Post*, the headline leaped out at him: "Prescription Sales, Privacy Fears; CVS, Giant Share Customer Records with Drug Marketing Firm." The story began:

*"Using technology in a new way to market drugs, CVS Corp. and Giant Food Inc. are sending confidential prescription information to a Massachusetts company that tracks customers who don't refill prescriptions, a practice that some experts say raises new questions about medical privacy. The company, a computer database marketing specialist, uses the data to send personalized letters – written on pharmacy letterhead and sometimes paid for by drug manufacturers – that either remind customers to keep taking their medicine or pitch new products that will treat the customer's ailment"* [O'Harrow, 1998].

The article quoted a noted physician,

*"It's a gross invasion...Do you want the great computer in the sky to have a list of every drug you take...all without your permission?"*

"This is trouble," Fair thought to himself as he folded up the newspaper and headed for home. Within a few hours, he began receiving phone calls from the supervisors in the stores who reported they were receiving many complaints from irate customers. Fair knew immediately that Giant had a problem with the fledgling alliance Giant's pharmacy established with Elensys Care Services, Inc. to run a patient education and prescription drug compliance program. When Fair reached Giant's CEO at home and explained the situation, the CEO asked him, "What do you want to do?"

## II. THE COMPANIES

### GIANT FOOD INC.

In February 1936, N.M. Cohen and Samuel Lehrman opened the first Giant food store on Georgia Avenue in Washington, D.C. The store was based on a novel concept for the times: a large self-service store that could offer lower prices to consumers by substituting high volume for high markups. As of 2005, Giant operated 203 supermarkets including 174 full-service pharmacies in Virginia, Maryland, the District of Columbia, Delaware and New Jersey. The Delaware and New Jersey stores operated under the name Super G. Giant also operated two large distribution centers, a bakery, a dairy processing plant, an ice cube processing plant, as well as a soda bottling plant, all in suburban Maryland. The company extensive private label line included as many as 9,000 products carrying the Super G label.<sup>1</sup> Giant was the market leader in the Washington metropolitan area.

Giant's reputation is a family business with a strong history of service to the community and innovation. In the late 1980's, Giant was the first supermarket chain to install front-end scanning in all of its stores, a feat which as of December 1991 had been duplicated by only a few others.<sup>2</sup> In 1970 it was one of the first food retailers to hire a consumer advocate, former Presidential advisor Esther Peterson. Giant's current Vice President of Consumer Affairs, Odonna Mathews was a familiar figure from Giant's newspaper and television ads, in-store promotions and educational materials. Giant contributed more than \$6 million annually in cash, goods and services to support charitable and community organizations in the markets it served<sup>3</sup>.

In 1964, N.M. Cohen, one of the founders, turned the reins of the business over to his son Izzy, who served on the Board of Directors since its founding. Izzy Cohen served as chairman, president, and CEO until 1992 when he tapped Pete L. Manos to serve in the role of company president. Izzy Cohen died on November 22, 1995. Cohen's commitment to the customer — "There is nothing too good for a Giant customer"—permeated Giant's corporate culture. Cohen's guiding principles endures today: quality, value, and especially service in a warm and friendly atmosphere.<sup>4</sup>

In October 1998, Royal Ahold NV, a Dutch grocery giant, completed a \$2.7 billion cash purchase of Giant. Giant's stock was delisted on the American Stock Exchange on October 30. Pete L. Manos, Izzy Cohen's successor as Giant's Chairman and CEO, announced his retirement after four decades with the firm. In 2003, Royal Ahold announced it would merge Giant and its corporate sibling, Stop & Shop Supermarket Co., consolidating the corporate offices at Stop & Shop's headquarters in Massachusetts.

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<sup>1</sup> Giant Food [1998] Inc. Corporate Profile, May 1998.

<sup>2</sup> Giant Food [2005b] The History of Giant

<sup>3</sup> Giant Food [2005a] Press release, April 19, 2005.

<sup>4</sup> Giant Food [1995a] "Izzy," We News Special Edition, Giant Food publication, November 1995.

## ELENSYS CARE SERVICES, INC.

Elensys, located in Burlington, Massachusetts, was founded in late 1993 by Dan Rubin and Mike Evanisko. Evanisko was an executive with a management consulting firm. Rubin was also a management consultant with extensive experience in the pharmaceutical industry. Based on his experience, he saw an opportunity to address the health care problem of prescription non-compliance, primarily with chronic conditions such as hypertension (high blood pressure), asthma, diabetes, and high cholesterol. Rubin knew that more than half of all patients on these types of medications stopped taking their prescriptions prematurely.

The Elensys programs focused on the development and management of patient compliance programs that educated patients about their medications and reminded patients to refill their prescriptions. The services Elensys offered to its customers, retail pharmacies, included compliance program strategy and planning, communications design, program implementation and performance analysis to ensure maximum program impact. All of Elensys' programs were designed to provide clear therapeutic or economic benefits for patients as their core values illustrate.<sup>5</sup>

Table 1  
Elensys Core Values

<ul style="list-style-type: none"> <li>• Focus on patient health</li> <li>• Patient confidentiality must be absolute</li> <li>• Physicians are the focal point of all patient treatment decisions</li> <li>• Pharmacists play a critical role in counseling and educating patients about their medications</li> </ul>
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Better compliance potentially benefited everyone. For patients, it meant better health. For pharmacies and pharmaceutical companies, it meant increased revenues. Pharmaceutical manufacturers often earned very high gross margins on branded products. These companies made significant sales and marketing investments, typically focused on inducing doctors to write prescriptions for their products. For these firms, non-compliance resulted in billions of dollars in lost revenues. Retail pharmacies would increase their revenues through better compliance due to increased prescription refills plus whatever additional purchases their customers made in the stores with each store visit. As a result of managed care, gross margins in the retail pharmacy industry had declined from 35% to 17-20%. The health care system in general, and the managed care system in particular would also benefit through reduced costs that resulted from better health of the public. The question was who should pay the costs of running compliance programs?

In developing his business model, Rubin spoke with a representative from a major managed health care organization but quickly learned that managed care was not likely to be a viable vehicle for implementing his idea. While increased prescription compliance would likely lead to lower overall costs for these plans, the head of pharmacy at most managed care plans was primarily concerned with controlling prescription costs (i.e. utilization); the programs Rubin envisioned running would lead to increased utilization of prescription medications and therefore drive pharmacy costs up for the managed care plans. Further, people switched health care plans approximately every 18 months, meaning the next plan would reap the benefits of the former plan's investment in the compliance program.

Rubin subsequently identified retail pharmacies as the potential partner with both a financial interest and a "professional obligation" to provide such services. This business model was attractive because pharmacies maintained an electronic record of every pharmacy transaction.

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<sup>5</sup> Elensys Care Services, Inc. [1998]

These data were needed to allow for timely communications with patients and to measure the effectiveness of these communications in improving compliance. The pharmacy data could help identify specific points or activities in a patient's therapy, such as missing a refill or obtaining their last refill without a new prescription. Further, many pharmacies did not possess the in-house information systems resources to develop the database and tracking capabilities needed to manage compliance programs. In the Gallup surveys of public perceptions of the most trusted professions conducted early in 2002 and 2003, the public rated pharmacists in the top ten<sup>6</sup>. Elensys' business model would build on this relationship between the consumer and the pharmacist by providing communication and prescription education materials about the consumer's specific medications to the consumer from their local pharmacy.

The Elensys compliance programs were funded in one of two ways. Many were funded by the pharmaceutical manufacturers who approached a pharmacy to run a compliance program for all of the pharmacy's patients for whom a specific drug was prescribed. Pharmacies could also pay Elensys themselves to run a program on their behalf.

The business was launched in July 1995 with two regional pharmacy chains as customers. Employees included two former Vice Presidents of Pharmacy at major pharmacy chains, and clinical pharmacists with both research and practical experience. By 1998, the firm grew to approximately twenty employees. At that time, Elensys received prescription data from approximately 15,000 pharmacies [O'Harrow 1998]. New customers were acquired primarily by making sales calls and by exhibiting at trade shows.

All communications to patients were sent on behalf of and at the direction of Elensys' customers, the pharmacies. Thus, nothing was ever sent to a patient that hadn't been previously reviewed and approved by the participating pharmacy chain. For example, once the pharmacy decided to run a compliance program for a particular medication, Elensys would enable the mailing of personalized letters to a pharmacy's patients on the pharmacy's letterhead, educating patients as well as reminding them to refill their prescriptions. The format of the letter could be customized based on the patient's demographics using research on effective communication strategies for that demographic sub-group.

### III. PHARMACEUTICAL INDUSTRY TRENDS

In the 1990's, the move to managed care brought significant changes to the healthcare system and placed enormous pressures on the profits of the pharmaceutical industry. In the U.S., which constituted one-third of the world's pharmaceutical market, 80% of the population was covered by managed care in 1993. In 1995, managed care organizations controlled 75% of the drug purchases in the U.S. The majority of these organizations employed formularies, a list of approved medicines, as one method of cost control; the insurance company would only pay for drugs listed on the formulary. By the mid-1990's, the same price pressures had also reached Europe with governments imposing price reductions on many drugs.<sup>7</sup>

Further, by 1996, approximately 86% of health maintenance organizations (HMO's) routinely substituted generic products for patented drugs whenever possible, further reducing the profitability of the drug manufacturers. This trend away from the need to prescribe more-expensive branded drugs was accelerated by the 1984 Waxman-Hatch Act which reduced barriers to entry in the pharmaceutical industry by accelerating the FDA approval process for bringing generic drugs to market. As a result of formularies, generics, and other cost pressures, pharmaceuticals appeared to be headed for commodity status. In an effort to combat these trends

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<sup>6</sup> Veverka [2000]. In this survey, pharmacists ranked second, after nurses.

<sup>7</sup> Harvard Business School [1998]

and to address a public health problem, prescription medicine noncompliance, the pharmaceutical companies initiated patient education programs<sup>8</sup>.

### **PATIENT EDUCATION PROGRAMS**

During the 1990's, recognition of the importance of patient education concerning their conditions, their prescribed treatments, and their treatment options grew. This recognition was reflected in two regulatory programs:

1. In 1990, Congress required pharmacists to offer to discuss any information they deemed significant with any patients receiving benefits under Medicaid. Subsequently, some states adopted laws requiring counseling for all patients.

2. In 1996, Congress required pharmacists to disseminate "useful written information" to all consumers about their prescription drugs. Pharmacists responded to this requirement with a variety of tailored printed materials that they provided to consumers in a face-to-face encounter when people received their prescriptions. Because of the costs associated with developing and disseminating this information in a format that satisfies the requirements of the law, the materials were often funded by pharmaceutical manufacturers<sup>9</sup>.

Pharmacies also engaged in three other kinds of direct-to-patient (DTP) messaging.

1. Compliance messaging encouraged proper use of prescribed medications. In particular, the pharmacy or the pharmacist might remind a patient to finish a course of treatment such as taking all prescribed antibiotics, or to refill a prescription. In developed countries, on average only 50% of prescriptions are taken as prescribed, and nearly half of all patients stop taking their medication within the six months of being prescribed<sup>10</sup>. Further, noncompliance, or the failure of an individual to take medication as prescribed, was estimated to account for over \$100 billion in costs to the U.S. healthcare system.

Compliance programs were particularly important for chronic conditions such as diabetes, high cholesterol, or hypertension (high blood pressure). For example, a study conducted by the University of Southern California School of Pharmacy found that non-compliant patients with high blood pressure cost the California Medicaid system \$591.46 more per patient than those who maintained their therapy during a twelve month period<sup>11</sup>.

2. The second DTP program involved messages about treatment alternatives or adjunctive therapies. For example, the pharmacy might notify a consumer about a lower-cost generic drug that was equivalent to a more expensive brand name drug the patient was currently taking, or the pharmacy might notify the patient about alternative medications that were covered by the individual's health insurance plan. These types of messages were sometimes viewed as controversial if they were sponsored by a pharmaceutical manufacturer. These messages also raised concerns about interfering with the doctor-patient relationship.

3. The third type of DTP messaging involved educating consumers about their conditions; for example, educating people with diabetes about ways to manage their disease. Pharmacists traditionally viewed this type of messaging as central to their professional responsibilities. However, these messages could also be viewed as controversial when they were funded by third parties such as pharmaceutical manufacturers.

The pharmaceutical companies were losing approximately \$35 billion annually to unfilled prescriptions. DTP messaging programs potentially provided a way for pharmaceutical

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<sup>8</sup> Castagnoli [1995], p. 46-53.

<sup>9</sup> National Consumers League [2004]

<sup>10</sup> World Health Organization [2003]

<sup>11</sup> McCombs et al. [1994]

companies to reduce these losses. For example, prior research found that reminders, either by mail or telephone, increased prescription refill compliance.<sup>12</sup> McKesson, a healthcare supply management company, operated a Patient Care Enhancing Program (PCEP) in collaboration with 500 pharmacies nationwide. Compliance for Coumadin, a blood thinner from Dupont Pharma, increased 25% after patients received a PCEP reminder to refill their prescriptions.<sup>13</sup>

However, a letter from a physician to the editor in the *Journal of the American Medical Association* raised ethical concerns about compliance programs financed by pharmaceutical companies that only included consumers who were prescribed a specific drug from that manufacturer excluding the rest of the pharmacy's customers who suffered from the same condition. "It appears that the true motivation for this campaign lies in the drawers of their cash registers," the physician wrote.<sup>14</sup>

#### IV. PRIVACY ISSUES

The use of DTP messaging also potentially raised privacy issues. In 1993, the *Harris-Equifax Health Information Survey* found that 60% of the public felt it was not acceptable for pharmacists to provide names and information of customers taking certain medications to pharmaceutical companies for direct marketing without first obtaining the individual's consent.<sup>15</sup> The Direct Marketing Association, a trade association that represented pharmaceutical companies through its healthcare marketing group, formulated voluntary privacy guidelines for marketing use of health and medical data. Because of the sensitivity of medical data, information derived from the patient-care provider relationship should never be used for marketing purposes. Other health and medical data voluntarily disclosed by the consumer should be treated as sensitive, and rented, sold, transferred or exchanged only where appropriate safeguards were in place. To participate in the McKesson PCEP for example, patients needed to register for the program and could "opt out" of the program at any time by calling a telephone number found in all mailings they received.

On April 14, 2001, U.S. Department of Health and Human Services (HHS) issued a Privacy Rule which meant that for the first time, the privacy of medical information in the United States was protected by law. HHS issued final modifications to the Privacy Rule on August 14, 2002. The Privacy Rule was required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and covered health insurance plans, health care clearinghouses, and health care providers who conducted health care transactions electronically. The majority of covered organizations were required to comply with the Privacy Rule by April 14, 2003. Small health plans were given until April 14, 2004 to comply. Appendix 1 provides an overview of the provisions of the final Privacy Rule. A separate rule on information security took effect on April 20, 2005 for most covered entities. Small health plans had until April 14, 2006 to comply with the security rule. The security rule required organizations to "reasonably safeguard" protected health information from intentional or unintentional use or disclosure that violated the standards and further specified implementation standards for administrative, physical and technical standards<sup>16</sup>.

Rubin knew from day one that privacy would be an issue for Elensys. The following steps were taken to protect the privacy of the pharmacies' customers.

1. The database for each pharmacy was split into two parts: one part contained name and address information, the second part contained prescription information but no personally

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<sup>12</sup> Stockwell and Schulz [1992]

<sup>13</sup> McLaughlin [1998]

<sup>14</sup> Hirsch, Sherwood and Denman [1998]

<sup>15</sup> Louis Harris & Associates [1993]

<sup>16</sup> See: <http://www.hhs.gov/ocr/hipaa/> for complete information about the HIPAA Privacy Rule. A summary of the Rule is available at <http://www.hhs.gov/ocr/privacysummary.pdf>. The marketing provisions of the Rule are available at <http://www.hhs.gov/ocr/hipaa/guidelines/marketing.pdf>. Information about the Security Rule is available at <http://www.cms.hhs.gov/hipaa/hipaa2> [Accessed April 23, 2005].

identifiable information, so analysis could be done without knowing the patient's identity. To generate mailings, the two files could be linked through a unique I.D. assigned to each patient's records. The database had extraordinary security; even the CEO did not have access to the information.

2. Postcards were never used for mailings. Instead, all mailings were sent by first class mail using window envelopes so there was no chance of the wrong letter getting into an envelope. The pharmacy signed off on all communications.

3. Elensys considered itself a true partner and it would caution pharmacies not to accept any inappropriate programs to avoid potential trouble.

4. Patients could "opt out" of any compliance program at any time through a number of easy methods including a postage paid business reply envelope (BRE) and a toll free phone number included on all mailings.<sup>17</sup>

5. Elensys did not run marketing programs, it only ran compliance programs. It did not send coupons to patients nor did it run any "switch" programs where letters would be sent to patients taking one drug suggesting they ask their doctor to switch them to another drug or engage in other forms of direct marketing. These switch programs were a legal form of DTP communication and while other firms in this industry were running these types of programs, all of Elensys' programs provided information only about the specific drug prescribed by the patient's physician.

6. Elensys never provided or sold patient prescription information to pharmaceutical companies. Such an action would violate the contract between Elensys and the pharmacy.

## V. GIANT AND ELENSYS

Giant began investigating the feasibility of providing a prescription compliance program in early 1997. In addition to the public health issues noncompliance raised, unfilled prescriptions resulted in lost revenue streams for Giant. The companies viewed compliance programs as benefiting consumers through better health in addition to increased sales for retailers and manufacturers.

Like other large chains, Giant was previously approached by pharmaceutical companies hoping to gain access to Giant's customers to do DTP marketing. Giant declined these offers because it was not comfortable with what the pharmaceutical companies wanted to do and felt these offers were not appropriate. Giant also was concerned about mailing reminders to their customers. However, the trade publications suggested that everyone was running compliance programs, and no legal or other problems were reported with consumers. State attorney generals and consumer advocates had not raised any concerns about these programs. Russell Fair talked to other chains and found they were running similar programs. Further, Giant's own customers would bring in letters they received from competitors such as CVS. In short, nothing suggested that these programs raised a red flag.

Giant first investigated the feasibility of running a compliance program in-house. However, the information systems requirements were too large. For example, to develop the tracking database needed to monitor compliance would tie up too many resources versus partnering with an organization that already developed this technology. Giant decided to outsource the compliance program.

Fair learned about Elensys from reading articles about what other companies were doing in trade journals such as *Drugstore News* and *Chainstore Age*, and from attending trade shows where Elensys exhibited. He liked that fact that Elensys was the only independent company running compliance programs. The others all were associated with a pharmaceutical manufacturer. Fair

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<sup>17</sup> The national "opt-out" rate for programs administered by Elensys was less than 3%.

didn't trust the firewalls these companies established between the compliance programs and the other parts of the business.

Fair decided to partner with Elensys. In his discussions with legal and risk management professionals all agreed the program raised privacy concerns. They were also concerned about other business risks. However, since so many other pharmacies were already participating in similar programs, they decided the downside risks were manageable. Giant's legal department negotiated the contract with Elensys. With many of its other customers, Elensys negotiated directly with the pharmaceutical companies for program funding. However, Giant chose to tightly control the environment by negotiating its own agreements directly with the pharmaceutical companies. Giant alone would determine what communications were sent to its customers. They would avoid offers for "controversial" drugs such as Prozac. Giant did not want to risk customers inferring that "Giant knows 'X' about me."

Once Giant negotiated with a pharmaceutical company to do a compliance program for a particular drug, the relevant consumers would be identified using Elensys' proprietary database software. Each consumer would be sent a letter introducing the program and inviting them to participate. An 800-number was provided for the consumer to opt out of the program. If no response was received, additional educational letters would go out on Giant letterhead. Separate letters were sent for each drug; no mass mailing was to go out to all Giant customers.

Elensys also provided periodic measurement reporting so Giant could assess the performance of the compliance program. Analysis was performed using non-identifiable data through proprietary techniques which used the Elensys database software, and could quantify the impact of the compliance programs statistically on increasing patient retention on their prescribed medications.

In December 1997, Giant began sending its pharmacy transaction data to Elensys to test the database design and so that Elensys could begin to identify trends. Each week, Giant would send the transactions for that week. Giant did not provide Elensys with its entire customer database (Appendix 2 lists the fields that were provided for each customer transaction). To track compliance, a baseline of 6-8 weeks of transaction data was needed. At Elensys, Giant's data were stored in a separate database that only contained data from Giant, running on hardware that was only used for processing Giant's data. Fair felt it was essential that no one else could gain access to Giant's customer data. However, as of mid-February when the article appeared in the *Washington Post* about the program, Elensys had yet to send out a single communication on behalf of Giant.

## **DEALING WITH THE IMPENDING CRISIS**

Fair arrived at work early Monday morning. He met with Oonna Mathews, Giant's Vice President-Consumer Affairs, who was not involved in the original Elensys decision. The two of them quickly agreed on a course of action.

## **ACKNOWLEDGMENTS**

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EDITOR'S NOTE: The following reference list contains the address of World Wide Web pages. Readers who have the ability to access the Web directly from their computer or are reading the

paper on the Web, can gain direct access to these references. Readers are warned, however, that

1. these links existed as of the date of publication but are not guaranteed to be working thereafter.
2. the contents of Web pages may change over time. Where version information is provided in the References, different versions may not contain the information or the conclusions referenced.
3. the authors of the Web pages, not CAIS, are responsible for the accuracy of their content.
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## **APPENDIX I. OVERVIEW OF THE FINAL HIPAA HEALTH PRIVACY RULE<sup>18</sup>**

The regulation established national standards to control the flow of sensitive patient information and penalties for the misuse or disclosure of the information. The regulation covers medical records and other individually identifiable health information related to treatment, payment and health care operations held or disclosed by a covered entity (health care providers and health plans which transmit health information for standard transactions electronically). The regulation includes the following protections.

### **CONSUMER CONTROL OVER HEALTH INFORMATION**

Patients must be provided with notice of the patient's privacy rights and the privacy practices of the covered entity. Consent for routine health care delivery purposes is not required. However, treatment providers are required to make a good faith effort to obtain the patient's written acknowledgment of the notice. Consent is required for other uses of personal information.

### **BOUNDARIES ON MEDICAL RECORD USE AND RELEASE**

With limited exceptions, an individual's health information can be used or disclosed for health purposes only. Entities covered by this regulation may disclose health information to a business associate, and may allow a business associate to create or receive health information on its behalf if the entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A business associate is a third party that may provide services on behalf of the entity on a contractual basis (e.g. outsourcing).

### **ESTABLISH ACCOUNTABILITY FOR MEDICAL RECORDS USE AND RELEASE**

Entities covered by the regulation must adopt written privacy policies, train employees, designate a privacy officer, and establish grievance processes for patients. The detailed policies and procedures for meeting the standards specified in the regulation are left to the discretion of each covered entity.

Health plans, providers and clearinghouses that violate these standards are subject to civil penalties. Federal criminal penalties apply if covered entities knowingly and improperly disclose information or obtain information under false pretenses.

### **RULES RELATED TO MARKETING**

Health organizations covered by this rule (covered entities) must obtain the patient's written authorization to use or disclose protected health information for marketing. Marketing is defined as "communication about a product or service that encourages the recipient to purchase or use the product or service." Excluded from this definition are communications related to treatment, payment, or operations:

- That describe a health-related product or service that is provided by the covered entity;

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<sup>18</sup> See: <http://www.hhs.gov/ocr/hipaa/> for complete information about the HIPAA Privacy Rule. A summary of the Rule is available at <http://www.hhs.gov/ocr/privacysummary.pdf>. The marketing provisions of the Rule are available at <http://www.hhs.gov/ocr/hipaa/guidelines/marketing.pdf>. Information about the Security Rule is available at <http://www.cms.hhs.gov/hipaa/hipaa2/>

- That describe a health-related product or service that is provided by the covered entity;
- That describe health-related products or services available to health plan enrollees that add value to (and are not part of) the plan's benefits; or
- Are related to treatment of the individual including to direct or recommend alternate therapies, providers or settings of care.

Examples of communications that are not considered marketing include:

- A health plan sends a mailing to its subscribers approaching Medicare age with materials describing its Medicare supplemental plan;
- A pharmacy or other health care provider mails prescription refill reminders to patients, or uses a business associate to do so;
- A hospital uses its patient list to send a mailing announcing the acquisition of new equipment

For any permitted communications, a covered entity is allowed to disclose protected health information to a business associate to assist with the communication. The business associate is prohibited from using the information for any other purposes.

Protected health information may also be used for fundraising under a limited set of circumstances. In this case, the fundraising materials must describe how the individual can opt out of future fundraising communications.

Covered entities may not sell lists of patients or enrollees to third parties for the marketing activities of the third party without the individual's authorization. For instances where authorization is required, the authorization must disclose if the marketing involves remuneration to the covered entity by a third party. Simply put, an entity covered by HIPAA may not sell health information protected by HIPAA to a business associate or any other third party for that party's own purposes. Further, covered entities may not sell lists of patients or enrollees to third parties without obtaining authorization from each person on the list.

## **APPENDIX 2. TRANSACTION DATA SUPPLIED TO ELENSYS**

Customer Name

Customer Address

Date of Birth

Gender

Prescription Components:

- Drug
- Prescription #
- Quantity
- Date Supplied
- Number of Refills
- Doctor

Elensys' proprietary database was structured in two separate parts. One part contained the patient's name, address information, and an indicator of whether or not the patient had "opted in"

or "opted out"<sup>19</sup> of the program. The second part contained prescription and analysis information. This separation made it possible to do data mining operations on the prescription information without ever linking this information to specific patients. Data mining operations involved sophisticated analysis based on the unique medical and pharmaceutical knowledge of Elensys employees, and went well beyond simple rules of the type "If patient X has prescription Y, send mailing."

Elensys did not own any of the patient data in their database. They were legally prohibited from selling or providing in any way any of the data they acquired from the pharmacies to pharmaceutical manufacturers or others.

## ABBREVIATIONS

BRE: Business reply envelope

CRM: Customer relationship marketing

DTC: Pharmaceutical direct to consumer advertising

DTP: Pharmacy direct to patient messaging

HHS: U.S. Department of Health & Human Services

HIPAA: Health Insurance Portability and Accountability Act

HMO: Health Maintenance Organization

## ABOUT THE AUTHOR

**Mary J. Culnan** is the Slade Professor of Management and Information Technology at Bentley College. Her current research interests include online communities, information privacy, and the implications of unsecured home PC's for critical infrastructure protection. Her research appears in *Journal of Public Policy and Marketing*, *The Information Society*, *Journal of Interactive Marketing*, *Organization Science*, the *MIS Quarterly*, and *Management Science*. She serves on the editorial board of *The Information Society*.

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<sup>19</sup> With "opt-in," the patient will not receive any mailings unless they have consented. With "opt-out", the patient will be sent mailings unless they object.



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