HealthWarehouse.com, Inc.
Form 10-K
April 15, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2009

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____

Commission file number 0-13117

HEALTHWAREHOUSE.COM, INC.
(Exact name of registrant as specified in its charter)

Delaware	22-2413505
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Commerce Boulevard, Cincinnati, Ohio	45140
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (513) 618-0911

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of each exchange on which registered
None	None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $.001 par value
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. o Yes x No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. o Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). o Yes o No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Act. (Check one):

Large accelerated filer o Accelerated filer ¨ Non-accelerated filer Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ¨ No x

The aggregate market value of voting and nonvoting stock held by non-affiliates, based on the closing price of the Common Stock, par value $0.001 (the "Common Stock") on June 30, 2009 of $0.165, as reported on the OTC Bulletin Board was $11,236,247. Shares of Common Stock held by each officer and director and by each person who owns 5% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for any other purpose.

There were 197,965,731 shares of Common Stock outstanding as of April 7, 2010.

DOCUMENTS INCORPORATED BY REFERENCE: None

Information Regarding Forward-Looking Statements

This report contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, many of which are beyond our control. Our actual results could differ materially and adversely from those anticipated in such forward-looking statements as a result of certain factors, including those set forth in this report. Important factors that may cause actual results to differ from projections include, but are not limited to, for example:

- adverse economic conditions;
- inability to raise sufficient additional capital to operate our business;
- unexpected costs, lower than expected sales and revenues, and operating deficits;
- adverse results of any legal proceedings;
- the volatility of our operating results and financial condition;
- inability to attract or retain qualified senior management personnel; and
- other specific risks that may be referred to in this report.

All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, financial position, estimated revenue or losses, projected costs, prospects and plans and objectives of management are forward-looking statements. When used in this report, the words "will," "may," "believe," "anticipate," "intend," "estimate," "expect," "project," "plan" and similar expressions are intended to identify forward-looking statemen although not all forward-looking statements contain such identifying words. All forward-looking statements speak only as of the date of this report. We undertake no obligation to update any forward-looking statements or other information contained herein. Stockholders and potential investors should not place undue reliance on these forward-looking statements. Although we believe that our plans, intentions and expectations reflected in or suggested by the forward-looking statements in this report are reasonable, we cannot assure stockholders and potential investors that these plans, intentions or expectations will be achieved. We disclose important factors that could cause our actual results to differ materially from our expectations under "Risk Factors" and elsewhere in this report. These cautionary statements qualify all forward-looking statements attributable to us or persons acting on our behalf.

Information regarding market and industry statistics contained in this report is included based on information available to us that we believe is accurate. It is generally based on academic and other publications that are not produced for purposes of securities reports or economic analysis. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, revenue and market acceptance of products and services. We have no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements. See "Risk Factors" for a more detailed discussion of risks and uncertainties that may have an impact on our future results.

PART I

Item 1: Business.

Overview

We are a U.S. licensed virtual retail pharmacy and healthcare e-commerce company that sells discounted brand name and generic prescription drugs and over-the-counter (OTC) medical products. Our web address is http://www.healthwarehouse.com. At present, we sell:

- a range of prescription drugs (we are licensed as a mail-order pharmacy for sales to 45 states and the District of Columbia);
- diabetic supplies including glucometers, lancets, syringes and test strips;
- OTC medications covering a range of conditions from allergy and sinus to pain and fever to smoking cessation aids;
- home medical supplies including incontinence supplies, first aid kits and mobility aids; and
- diet and nutritional products including supplements, weight loss aids, and vitamins and minerals.

Our objective is to make the pharmaceutical supply chain more efficient by eliminating costs and passing on the savings to the consumer. We are becoming known by consumers as a convenient, reliable, discount provider of over-the-counter and prescription medications and products. We intend to continue to expand our product line as our business grows. We are presently licensed as a mail-order pharmacy for sales to 45 states and the District of Columbia, and we intend to apply for and obtain licenses to sell prescriptions in all 50 states by June 30, 2010.

We have begun accepting health insurance as part of our prescription program, initially contracting with a limited number of insurance providers based on customer demand and business opportunity. Our customers tend to be under- or uninsured consumers who rely on our service for their daily medications. In addition, due to the savings we pass on to the consumer, our prices are often below insurance co-pay, making insurance unnecessary when purchasing from us. We intend to continue expanding the number of health insurance providers we accept as customer demand warrants.

In March 2007, Hwareh.com, Inc. (“Old HW”), a Delaware corporation formerly named HealthWarehouse.com, Inc., was incorporated to carry on the business of selling OTC products. In November 2007, we began to develop the proprietary software necessary for our business, and in February 2008, version 1 of the http://www.healthwarehouse.com website was successfully launched running on our own proprietary software.

In March 2008, as part of our expansion into prescription drugs, we completed construction of a full service pharmacy within our warehouse in Cincinnati, Ohio. The pharmacy includes a machine which counts and packages prescriptions. This machine can fill up to 1,200 prescriptions per day. Our pharmacy passed inspection by the Ohio State Pharmacy Board in April 2008.

Our growth strategy includes:

- aggressively marketing our website to customers both online and offline,
- expanding and hiring key personnel, and
- continuing to develop our proprietary software and technology.

Corporate Information and History

On May 14, 2009, we completed a share exchange transaction (the "Exchange") with Clacendix, Inc. ("Clacendix") pursuant to the terms of a Securities Exchange Agreement. Under the Securities Exchange Agreement, we acquired all the outstanding capital stock of Old HW. The consideration issued in the Exchange was determined as a result of arm's-length negotiations between the parties.

As a result of the Exchange, Old HW became our subsidiary, with Old HW's former stockholders acquiring 155,194,563 shares, or approximately 82.4% of the then outstanding shares of our common stock. This transaction was accounted for as a reverse recapitalization, whereby old HW is deemed to be the accounting acquirer for accounting purposes. Following the closing of the Exchange, the business of Hwareh.com continues as our sole line of business. Effective August 5, 2009, we changed our corporate name to HealthWarehouse.com, Inc. simultaneously, with our name change, we changed the corporate name of our subsidiary to Hwareh.com, Inc. In connection with the name change, we also obtained a new ticker symbol for quotation on the OTC Bulletin Board (OTC BB), which is "HEWA.OB."

As part of the closing of the Exchange, we assumed Old HW's rights and obligations under Old HW convertible promissory notes with a principal value of $1,200,000 and Old HW warrants to purchase common stock. The Old HW convertible promissory notes and the Old HW warrants relate to Old HW's private placement in April and May 2009, under which Old HW completed a private placement to 18 investors of convertible promissory notes, for gross proceeds of $1,200,000. The convertible promissory notes are convertible into 15,855,227 shares of our common stock at a conversion price of $0.0756848 per share. During our fourth quarter ended December 31, 2009, holders of convertible notes in an aggregate principal amount of $575,000 elected to voluntarily convert their notes, and received a total of approximately 7,597,000 shares of our common stock in exchange. As part of the private placement, Old HW issued warrants expiring on May 31, 2009, June 30, 2009 and December 31, 2009 to purchase up to a maximum of 927,833, 3,570,182 and 3,570,182 shares, respectively, of our common stock (or an aggregate of 8,068,197 shares of our common stock) at an exercise price of $0.0010778, $0.0560196 and $0.0560196 per share, respectively. Of those Old HW warrants, the warrant to purchase 927,833 shares of our common stock has been exercised, and the two warrants to purchase up to 3,570,182 shares of our common stock expired without being exercised.

Prior to the share exchange, Clacendix's predecessor company was formed as a New Jersey corporation in 1982 as MicroFrame, Inc. In March 1999 MicroFrame, Inc. was reincorporated in the State of Delaware and in the process changed its name to ION Networks, Inc. In December 2007, ION sold substantially all of its operating assets to Cryptek, Inc., a Delaware corporation. Pursuant to the Cryptek sale, ION changed its name to Clacendix, Inc. Following the date of the Cryptek sale and until the closing of our share exchange transaction with Old HW, Clacendix existed as a shell company with no operations that was seeking a target company with which to merge or to complete a business combination.

Our Business Model

We break down our business model into three components: commerce, content and community. We seek to build traffic and sales by focusing on these components. We expect that the combination of these three components of our business model will result in proprietary data that can be stripped of personal information for privacy concerns, and then used to help marketers target advertisers.

The commerce aspect of our business model involves sourcing products at the lowest possible prices, or manufacturing the products ourselves in FDA-approved facilities, and selling them direct to the consumer. Our aim is to collapse the current healthcare channel, which typically involves three layers of intermediate costs before reaching the consumer, to one which goes straight from the manufacturer to the consumer.

Current Healthcare Distribution Model	Our Distribution Model
Manufacturer	Manufacturer
,	,
Wholesaler	,
,	,
Distributor	HealthWarehouse.com
,	,
Pharmacy	,
,	,
Consumer	Consumer

We have found that consumers will volunteer information where drug prices are the cheapest. Accordingly, we market our prescription and OTC drugs at what we believe are some of the lowest prices available through the Internet in order to gain customers. This is possible because typically we source them at the wholesale level from the manufacturer, eliminating layers of cost in the healthcare channel.

The content aspect of our business model is a means by which we plan to generate traffic and interest in our website. We intend to purchase side effect and drug interaction data for over 115,000 drugs from a content provider to build out our content library. We believe that consumers' search for relevant information will generate traffic and search engine optimization opportunities for us.

In addition to purchasing content, we intend to augment this information base by building applications to enhance the purchased content value to consumers. We envision that consumers will be able to write their own content on drugs (personal experiences, etc.) and we will consider creating an application programming interface (API) that will allow that data to be shared with other websites and developers. As consumers recognize the value of these applications, it is our belief that they will have a beneficial impact on driving traffic to our product sales site and will increase sales.

Our Online Pharmacy

We operate a full-service mail-order pharmacy within our warehouse in Cincinnati, Ohio. The pharmacy includes a machine which counts and packages prescriptions that can fill up to 1,200 prescriptions per day. Our pharmacy passed inspection by the Ohio State Pharmacy Board and we are presently licensed as a mail-order pharmacy for sales to 45 states and the District of Columbia, and we intend to apply for and obtain licenses to sell prescriptions in all 50 states by June 30, 2010. We have also begun accepting health insurance as part of our prescription program, initially contracting with insurance providers based on customer demand and business opportunity.

Our online pharmacy offers the following advantages:

- Legitimacy. We have obtained certifications to separate ourselves from the many uncertified "rogue" pharmacies which exist. Our Pharmacy Checker ID certification allows us to advertise prescription drugs on Google, Microsoft and Yahoo. In addition, we have applied for Verified Internet Pharmacy Practice Sites (VIPPS) accreditation from the National Association of Boards of Pharmacy.

- Convenience. Our online store is available to consumers 24 hours a day, seven days a week through the Internet. All of our products are also available for purchase by phone. We offer additional convenience to our customers through an easy-to-use website, robust search technology, and a variety of features such as multiple checkout options including Google Checkout.

- Selection. Due to our online structure, we are able to offer a significantly broader assortment of products, with greater depth in each product category, because we do not have the shelf display space limitations of brick-and-mortar drugstores.

- Information. We provide a broad array of interactive tools and information on our website to help consumers make informed purchasing decisions. Our information services include detailed product information pages, product user manuals and brochures, links to manufacturer websites, detailed product descriptions which contain the manufacturer's phone number, and customer reviews. Our customer care representatives are available by phone or email to provide personal guidance and answer customers' questions.

- Privacy. When shopping at a brick-and-mortar drugstore, many consumers may feel embarrassed or uncomfortable about buying items or asking questions that may reveal personally sensitive aspects of their health or lifestyle to pharmacists, store personnel, or other shoppers. Our customers avoid these problems by shopping from the privacy of their home or office.

- Value. Our goal is to offer shoppers a broad assortment of generic drugs and health products with competitive pricing. We strive to improve our operating efficiencies and to leverage our fixed costs so that we can pass along the savings to our customers in the form of lower prices and exclusive deals. Since we have drugs manufactured specifically for us or source them direct from the manufacturer at the wholesale level, we believe that we have lower costs than traditional pharmacies which allows us to provide consumers with the better values. We also strive to inform customers of additional cost-saving opportunities when they become available. For example, we show the generic equivalents of all brand name products.

- Customer Service. Our focus has been on customer service and we endeavor to lead the industry in our policies and procedures. We currently offer a satisfaction guarantee with what we believe is an industry-leading 90-day return policy with no restocking fees, and 100% free standard shipping on all orders. As of March 23, 2010, our positive customer satisfaction lifetime rating on Amazon.com was 99%.

Our customer support representatives operate from our call center in Cincinnati, Ohio. Our customer support specialists are available 9 a.m. to 5 p.m. Eastern Standard Time, Monday through Friday, via e-mail, fax or telephone to handle customer inquiries and assist customers in finding desired products. Our online Help Center outlines store policies and provides answers to customers' frequently asked questions.

We ship our OTC products to all 50 states, the U.S. Territories, and APO/FPO military and embassy addresses. We process all orders from our primary distribution center in Cincinnati, Ohio. We based our logistics operation there to maintain proximity to UPS, located 90 miles away in Louisville, Kentucky, and FedEx, located in Memphis, Tennessee. Processing from this location allows us to reach 80% of the U.S. population by standard ground shipping in two days. In order to try to maintain high customer satisfaction ratings and quality control over the process, we do not drop ship orders. Due to the relatively short lead time required to fill orders for our products, usually 24 to 48 hours, order backlog has not proven material to our business.

Marketing and Sales

Our marketing strategy aims to build brand recognition, increase customer traffic to our online store, add new customers, build strong customer loyalty, maximize repeat purchases and develop incremental revenue opportunities. It is centered on Internet-based advertising.

Our online advertising campaigns focus on the following areas:

- Search Engines: Google, MSN and Yahoo;

- Price Comparison Engines: Become, Google Product Search, NexTag, PriceGrabber.com, Pronto, Shopping.com, Shopzilla, Smarter and Yahoo Shopping; and

- Social Networking: Facebook, MySpace and Twitter.

To date, our online advertising has proven to be an effective sales strategy for our business. Apart from any personnel involved with our online advertising campaigns, we do not have a dedicated sales force.

Suppliers

There are a number of suppliers available for the pharmaceutical and non-pharmaceutical products that we sell. Our principal suppliers are Masters Pharmaceutical, Inc., from which we source the majority of our supplies, and Allison Medical, Inc., The Harvard Drug Group, LLC, Masters Healthcare, LLC and Prescription Supply, Inc. While we source our supplies from a limited number of suppliers, we do not believe that our business is dependent on any one supplier since the products that we sell are readily available from a number of alternative suppliers. If a supplier, even if a significant supplier such as Masters Pharmaceutical, were to no longer be available to us, we believe that we could source replacement product through one or more alternative suppliers.

Customers

We sell directly to the individual consumers of the pharmaceutical and non-pharmaceutical products that we sell. Accordingly, we are not dependent on any one or any few major customers.

Seasonality

Historically, the largest amount of our net sales occurs during our fourth quarter. As a result, we sometimes experience an increase in our shipping cost due to complimentary upgrades, split-shipments, and additional long-zone shipments necessary to ensure timely delivery during this time of year.

Competition

The market for prescription and OTC health products is intensely competitive and highly fragmented. Our competitors in the segment include chain drugstores, mail order pharmacies, mass market retailers, warehouse clubs and supermarkets. Many of these potential competitors in the market are also established organizations with greater access to resources and capital than we have. In addition, we face competition from foreign online pharmacies that can often sell drugs to U.S. residents at a lower price because they do not comply with U.S. pharmacy regulations, are not subject to U.S. regulatory oversight, or both. We also compete with Internet portals and online service providers that feature shopping services and with other online or mail-order retailers that offer products similar or the same to those that we sell.

We believe that the principal competitive factors in our market segments include brand awareness and preference, company credibility, product selection and availability, convenience, price, actual or perceived value, website features, functionality and performance, ease of purchasing, customer service, privacy, quality and quantity of information supporting purchase decisions (such as product information and reviews), and reliability and speed of order shipment.

Intellectual Property and Technology

We filed for a trademark on the name "HealthWarehouse.com" on August 14, 2007 with the Patent and Trade Office, which trademark was granted with a registration date of May 19, 2009. We also rely on trade secret law and contractual restrictions to protect our intellectual property, and we do not intend to seek patent or copyright protection for our intellectual property at this time.

We have implemented a broad array of services and systems for website management, product searching, customer interaction, transaction processing, and order fulfillment functions. These services and systems use a combination of our own proprietary technologies, open-source technologies and commercially-available, licensed technologies.

We focus our internal development efforts on creating and enhancing the specialized, proprietary software that is unique to our business. For example, our core merchandise catalog, as well as our customer interaction, order collection, fulfillment and back-end systems are proprietary to us. Our systems are designed to provide real-time connectivity to our distribution center systems for both pharmacy and OTC products. They include an inventory tracking system, a real-time order tracking system, an executive information system and an inventory replenishment system.

Our website at http://www.healthwarehouse.com is hosted on the Amazon EC2 platform due to the platform's perceived cost effectiveness and scalability. EC2 allows us to pay only for bandwidth used. In addition, due to Amazon's lengthy experience at running servers capable of serving one of the largest commerce sites on the web, our site remains scalable on days where our traffic spikes.

Our website was developed using 100% open source code. We use a 100% open source platform which runs on Linux, Apache, MySQL and PHP (LAMP).

In addition, we have utilized open source software from other vendors to speed up our development time. For management of our content and commerce catalog, we utilize Magento, an open source e-commerce platform. For our reporting and tools, we utilize Google Analytics. Our checkout process has two options including Google Checkout for OTC orders and our own proprietary checkout for OTC and prescription orders which uses Authorize.net.

Government Regulation

Federal and state laws and regulations govern many aspects of our business and are specific to pharmacies and the sale of OTC drugs. Our pharmacy passed inspection by the Ohio State Pharmacy Board and we are presently licensed as a mail-order pharmacy for sales to 45 states and the District of Columbia, and we intend to apply for and obtain licenses to sell prescriptions in all 50 states by June 30, 2010. We ship our non-prescription products to all 50 states, the U.S. Territories, and APO/FPO military and embassy addresses.

We believe we are in substantial compliance with all existing legal and regulatory requirements material to the operation of our business. We have standard operating procedures and controls designed to assist in ensuring compliance with existing contractual requirements and state and federal law. We diligently monitor and audit our adherence to these procedures and controls, and we take prompt corrective and disciplinary action when appropriate. However, we cannot predict how courts or regulatory agencies may interpret existing laws or regulations or what additional federal or state legislation or regulatory initiatives may be enacted in the future regarding healthcare or the pharmacy industry, and the application of complex standards to the operation of our business creates areas of uncertainty.

In addition, we may in the future participate in federal and state programs such as Medicare and Medicaid. If we do, we would be subject to extensive government regulation including numerous state and federal laws and corresponding regulations directed at preventing fraud and abuse and regulating reimbursement.

Among the federal and state laws and regulations that currently affect or may reasonably affect in the future aspects of our business are the following:

Regulation of Our Pharmacy Operations.

The practice of pharmacy is generally regulated at the state level by state boards of pharmacy. Our pharmacy must be licensed in the state in which it is located. In some states, regulations require compliance with standards promulgated by the United States Pharmacopeia (USP). The USP creates standards in the packaging, storage and shipping of pharmaceuticals. Also, many of the states where we deliver pharmaceuticals, including controlled substances, have laws and regulations that require out-of-state mail-order pharmacies to register with that state's board of pharmacy or similar regulatory body. In addition, some states have proposed laws to regulate online pharmacies, and we may be subject to this legislation if it is passed. Furthermore, if our pharmacy dispenses durable medical equipment items, such as infusion pumps, that bear a federal legend requiring dispensing pursuant to a prescription, we would also be regulated by applicable state and federal durable medical equipment laws.

Federal agencies further regulate our pharmacy operations. Pharmacies must register with the Drug Enforcement Administration (DEA) and individual state controlled substance authorities in order to dispense controlled substances. Currently, we do not sell any controlled substances and therefore do not require a DEA license. In addition, the FDA inspects facilities in connection with procedures to effect recalls of prescription drugs. The Federal Trade Commission (FTC) also has requirements for mail-order sellers of goods. The U.S. Postal Service (USPS) has statutory authority to restrict the transmission of drugs and medicines through the mail to a degree that could have an adverse effect on our mail-order operations. The USPS historically has exercised this statutory authority only with respect to controlled substances. If the USPS restricts our ability to deliver drugs through the mail, alternative means of delivery are available to us. However, alternative means of delivery could be significantly more expensive. The Department of Transportation has regulatory authority to impose restrictions on drugs inserted in the stream of commerce. These regulations generally do not apply to the USPS and its operations.

Additionally, under the Omnibus Budget Reconciliation Act of 1990 and related state and local regulations, our pharmacists are required to offer counseling to our customers about medication, dosage, delivery systems, common side effects, adverse effects or interactions and therapeutic contraindications, proper storage, prescription refill and other information deemed significant by the pharmacists. We are also subject to requirements under the Controlled Substances Act and federal DEA regulations, as well as related state and local laws and regulations, relating to our pharmacy operations, including registration, security, recordkeeping and reporting requirements related to the purchase, storage and dispensing of controlled substances, prescription drugs and some OTC drugs.

"Compendial standards," which can also be called "official compendium," means the standards for drugs related to strength, purity, weight, quality, labeling and packing contained in the official Pharmacopeia of the United States, official National Formulary, or any supplement to any of them. Under the Food, Drug and Cosmetic Act of 1938, a drug recognized by the Homeopathic Pharmacopeia of the United States must meet all compendial standards and labeling requirements contained therein, or it will be considered adulterated (for example, lacking appropriate strength, quality or purity; or containing poisonous or unsanitary ingredients) or misbranded (for example, having a false or misleading label; or a label containing an inaccurate description of contents). If we add homeopathic remedies to our product offerings, we will be required to comply with the Food, Drug and Cosmetic Act. The distribution of adulterated or misbranded homeopathic remedies or other drugs is prohibited under the Food, Drug and Cosmetic Act, and violations could result in substantial fines and other monetary penalties, seizure of the misbranded or adulterated items, and/or criminal sanctions.

We also are required to comply with the Dietary Supplement Health and Education Act when selling dietary supplements and vitamins.

We believe that our operations have the appropriate licenses required under the laws of the states in which they are located and that we conduct our pharmacy operations in accordance with the laws and regulations of these states.

Drug Importation

In the face of escalating costs for plan sponsors providing a prescription drug benefit for their employees, and uninsured individuals seeking to lower their drug costs, the issue of importing drugs from Canada or other foreign countries has received significant attention. Drug importation, sometimes called drug re-importation, occurs when prescription medicines from other countries are imported for personal use or commercial distribution. Individual importation activities are generally prohibited under U.S. law, and the FDA has issued warnings and safety alerts to a number of entities seeking to promote or facilitate systematic importation activities. However, there has been considerable legislative and political activity seeking to change the FDA requirements to enable drug importation, and we are evaluating appropriate actions if such legislation were to be enacted.

Health Management Services Regulation

All states regulate the practice of medicine and require licensing under applicable state law. It is not our intent to practice medicine and we have tried to structure our website and our business to avoid violation of state licensing requirements. However, the application of this area of the law to Internet services such as ours is not well established and, accordingly, a state regulatory authority could at some time allege that some portion of our business violates these statutes. Any such allegation could harm our business. Further, any liability based on a determination that we engaged in the unlawful practice of medicine may be excluded from coverage under the terms of our general liability insurance policy.

Consumer Protection Laws

Most states have consumer protection laws designed to ensure that information provided to consumers is adequate, fair and not misleading. We believe that our practices conform to the requirements of state consumer protection laws. However, we may be subject to further scrutiny under these laws as they are often interpreted broadly.

Regulation Relating to Data Transmission and Confidentiality of Patient Identifiable Information

Dispensing of prescriptions and management of prescription drug benefits require the ability to utilize patient-specific information. Government regulation of the use of patient identifiable information has grown substantially over the past several years. At the federal level, Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which extensively regulates the transmission, use and disclosure of health information by all participants in healthcare delivery, including physicians, hospitals, insurers and other payors. Our pharmacy operations are covered entities, which are directly subject to these requirements. Additionally, regulation of the use of patient-identifiable information is likely to increase. Congress is currently reviewing proposals that would alter HIPAA, which would create additional administrative burdens. Many states have passed or are considering laws addressing the use and disclosure of health information. These proposals vary widely, some relating to only certain types of information, others to only certain uses, and yet others to only certain types of entities. These laws and regulations have a significant impact on our operations, products and services, and compliance with them is a major operational requirement. Regulations and legislation that severely restrict or prohibit our use of patient identifiable information could materially adversely affect our business.

Sanctions for failing to comply with HIPAA standards include criminal and civil penalties. If we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for significant damages, fines or penalties.

Fraudulent Billing, Anti-Kickback, Stark, Civil Monetary Penalties and False Claims Laws and Regulations

Our operations may in the future participate in federal and state programs such as Medicare and Medicaid. If we do, we would be subject to extensive government regulation including numerous state and federal laws and corresponding regulations directed at preventing fraud and abuse and regulating reimbursement. The government's Medicare and Medicaid regulations are complex and sometimes subjective and therefore may require our management's interpretation. If we were to participate in federal and state programs such as Medicare and Medicaid, our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG), the Centers for Medicare and Medicaid Services (CMS), the Department of Justice (DOJ), and the FDA. To ensure compliance with Medicare, Medicaid and other regulations, government agencies conduct periodic audits to ensure compliance with various supplier standards and billing requirements. Similarly, regional health insurance carriers routinely conduct audits and request patient records and other documents to support claims submitted for payment.

Federal law prohibits the payment, offer, receipt or solicitation of any remuneration that is knowingly and willfully intended to induce the referral of Medicare, Medicaid or other federal healthcare program beneficiaries for the purchase, lease, ordering or recommendation of the purchase, lease or ordering of items or services reimbursable under federal healthcare programs. These laws are commonly referred to as anti-remuneration or anti-kickback laws. Several states also have similar laws, known as “all payor” statutes, which impose anti-kickback prohibitions on services not covered by federal healthcare programs. Anti-kickback laws vary between states, and courts have rarely interpreted them.

Courts, the OIG and some administrative tribunals have broadly interpreted the federal anti-kickback statute and regulations. Courts have ruled that a violation of the statute may occur even if only one of the purposes of a payment arrangement is to induce patient referrals or purchases. Should we enter the government payor sector, it is possible that our current practices in the commercial sector may not be appropriate in the government payor sector.

The Ethics in Patient Referrals Law (Stark Law) prohibits physicians from making a referral for certain health items or services if they, or their family members, have a financial relationship with the entity receiving the referral. No bill may be submitted in connection with a prohibited referral. Violations are punishable by civil monetary penalties upon both the person making the referral and the provider rendering the service. Such persons or entities are also subject to exclusion from Medicare and Medicaid. Many states have adopted laws similar to the Stark Law, which restrict the ability of physicians to refer patients to entities with which they have a financial relationship.

The Federal False Claims Act prohibits the submission of a false claim or the making of a false record or statement in order to secure a reimbursement from a government-sponsored program. In recent years, the federal government has launched several initiatives aimed at uncovering practices that violate false claims or fraudulent billing laws. Civil monetary penalties may be assessed for many types of conduct, including conduct that is outlined in the statutes above and other federal statutes in this section. Under the Deficit Reduction Act of 2005 (DRA), states are encouraged to pass state false claims act laws similar to the federal statute.

Sanctions for fraudulent billing, kickback violations, Stark’s law violations or violations of the False Claims Act include criminal or civil penalties. If we do participate in federal payor programs and are found to have violated any state or federal kickback, Stark Law or False Claims Act law, we could be liable for significant damages, fines or penalties and potentially be ineligible to participate in federal payor programs.

Legislation and Regulation Affecting Drug Prices and Potentially Affecting the Market for Prescription Benefit Plans and Reimbursement for Durable Medical Equipment

Recently, the federal government has increased its focus on methods drug manufacturers employ to develop pricing information, which in turn is used in setting payments under the Medicare and Medicaid programs. One element common to many payment formulas, the use of "average wholesale price" (AWP) as a standard pricing unit throughout the industry, has been criticized as not accurately reflecting prices actually charged and paid at the wholesale or retail level. The DOJ is currently conducting, and the House Commerce Committee has conducted, an investigation into the use of AWP for federal program reimbursement, and whether the use of AWP has inflated drug expenditures by the Medicare and Medicaid programs. Federal and state proposals have sought to change the basis for calculating reimbursement of certain drugs by the Medicare and Medicaid programs.

The DRA revised the formula used by the federal government to set the Federal Upper Limit (FUL) for multiple source drugs by adopting 250 percent of the average manufacturer's price (AMP) without regard to customary prompt pay discounts to wholesalers for the least costly therapeutic equivalent. On July 17, 2006, HHS published a Final Rule for the Medicaid Prescription Drug Program implementing the DRA in which AMP was defined to exclude discounts and rebates to pharmacy benefit managers and include sales to mail-order and specialty pharmacies in the AMP calculation by manufacturers.

These proposals and other legislative or regulatory adjustments that may be made to the program for reimbursement of drugs by Medicare and Medicaid, if implemented, could affect our ability to negotiate discounts with pharmaceutical manufacturers. They could also impact the reimbursement we may receive from government payors in the future. In addition, they may affect our relationships with health plans. In some circumstances, they might also impact the reimbursement that we would receive from managed care organizations that contract with government health programs to provide prescription drug benefits or otherwise elect to rely on the revised pricing information. Furthermore, private payors may choose to follow the government's example and adopt different drug pricing bases. This could affect our ability to negotiate with plans, manufacturers and pharmacies regarding discounts and rebates.

Relative to our durable medical equipment operations, The Medicare P