

HealthWarehouse.com, Inc.
Form 10-K
March 30, 2015
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year Ended December 31, 2014

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
(State or other jurisdiction of
incorporation or organization)

22-2413505
(I.R.S. Employer
Identification No.)

7107 Industrial Road, Florence KY
(Address of principal executive offices)

41042
(Zip Code)

Registrant's telephone number, including area code: (800) 748-7001

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.

Yes 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. Yes 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 No

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). Yes 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.

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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 Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of voting and nonvoting common equity held by non-affiliates, based on the closing price of the common stock, par value \$0.001 (the “Common Stock”) on June 30, 2014 of \$0.16, as reported on the OTCQB market tier was approximately \$2,968,000. 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 37,570,383 shares of Common Stock outstanding as of March 27, 2015.

DOCUMENTS INCORPORATED BY REFERENCE: None

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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 any forward-looking statements include any forward-looking statements:

significant changes in consumer demand for our products, resulting in volatility of our operating results and financial condition;

our ability to effectively respond to changing market conditions;

whether as a result of market conditions, or our financial condition or otherwise, the possibility that we will not be able to raise sufficient additional capital needed to operate our business;

unexpected costs, lower than expected sales and revenues, and operating deficits;

our ability to obtain supply at favorable rates;

unexpected changes in our industry’s competitive forces including the manner and degree in which our competitors serve our target market;

our ability to attract or retain qualified senior management personnel; and

other specific risks that may be referred to in this report including those in Part I, Item 1A, “Risk Factors.”.

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 statements, 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.

If you are interested in HealthWarehouse.com, Inc. stock, we recommend that, at a minimum, you read the SEC Forms 10-K, 10-Q and 8-K each filed by HealthWarehouse.com, Inc. (the “Company”) with the SEC and available at <http://www.sec.gov>.

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PART I

Item 1: Business.

Overview

HealthWarehouse.com, Inc. (“HEWA” or the “Company”) is America’s Trusted Online Pharmacy, licensed in 50 states and the District of Columbia to focus on the out-of-pocket prescription drug market, a market which is expected to grow to \$80 billion in 2015. HealthWarehouse.com is currently 1 of less than 40 Verified Internet Pharmacy Practice Websites (“VIPPS”) accredited by the National Association of Boards of Pharmacy (“NABP”) and is the only VIPPS accredited pharmacy licensed in all 50 states that processes out-of-pocket prescriptions online. The Company markets a complete range of generic, brand name, and pet prescription medications as well as over-the-counter (“OTC”) medications and products.

Consumers who pay out of pocket for their prescriptions include those:

- With no insurance coverage;
- With high insurance deductibles or copays;
- With Medicare Part D plans with high deductibles;
- With Health Savings Accounts (HSA) or Flexible Savings Accounts (FSA);
- With insurance through the Affordable Care Act (ACA) with high deductibles;
- With drug exclusions and quantity restrictions placed by insurance companies.

Our objectives are to utilize our proprietary technology to make the pharmaceutical supply chain more efficient and to pass the savings on to the consumer. We are becoming known by consumers as a convenient, reliable, discount provider of over-the-counter products and prescription medications. We intend to continue to expand our product line as our business grows. Our customers include uninsured, under-insured, and insured consumers with high insurance co-payments who rely on our service for their daily prescription medications. With many brand name drug patents continuing to expire over the next several years and a general trend of rising insurance co-payments and deductibles due to the Affordable Care Act, our service is expanding to mainstream insured consumers of prescription medications, as the market continues to move away from brand name prescription drugs to generics. Once the patent on a branded drug has expired, we can typically sell its generic equivalent for less than the purchaser’s insurance co-payment. Accordingly, we are focused on the cash paying customers and do not accept consumer insurance payment.

Historical Background

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 1.0 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 licensed pharmacy within our warehouse in Loveland, Ohio. This pharmacy passed inspection by the Ohio State Pharmacy Board in April 2008.

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, and our Common Stock currently trades on the OTCQB Market Tier under the symbol, "HEWA."

On February 14, 2011, Hocks Acquisition Corporation ("Hocks Acquisition"), a wholly-owned subsidiary we formed for the purpose of the acquisition, entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Hocks Pharmacy of Hocks Pharmacy, Inc., an Ohio corporation ("Hocks Pharmacy"), to purchase, for \$200,000 in cash all of the inventory and fixed assets (the "Purchased Assets") owned by Hocks Pharmacy and used in the operation of its internet pharmacy business (the "Internet Business"). The Internet Business consists primarily of the internet sale of over-the-counter health and medical products and supplies. That same day, we acquired all of the intangible assets of the internet business, including domain names and customer accounts, in a reverse merger of Hocks Acquisition into Hocks.com Inc. ("Hocks.com"), a newly formed Ohio corporation and then wholly-owned subsidiary of Hocks Pharmacy. As a result, Hocks.com Inc. became our wholly-owned subsidiary.

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On June 15, 2011 the Company commenced a lease on a new facility in Florence, KY. On August 1, 2011, the Company transferred its operations to the new facility.

Our Business Model

Our business model seeks to improve both the efficiency and convenience by which consumers obtain prescription medications. To increase efficiency, we make efforts to source products from either the manufacturer or wholesaler level, eliminating unnecessary costs associated with distribution. In addition, we distribute medications to the consumer from a single warehouse, as opposed to retail locations, which we believe eliminates unnecessary costs such as real estate, rents, inventory, and personnel. By going directly to the consumer via the Internet, we reduce our marketing expense and increase convenience for consumers, especially those taking maintenance medications for conditions ranging from diabetes to high blood pressure.

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

Our target is consumers who are paying out-of-pocket for their medications. Out-of-pocket consumers have increased significantly since insurance co-pays are rising and high deductible plans are becoming more prevalent due to the Affordable Care Act.

Our VIPPS Accredited Online Pharmacy

We operate a full-service online pharmacy within our warehouse in Florence, Kentucky, 15 miles south of Cincinnati, Ohio. The pharmacy includes two robotic machines, which can each count and package 1,200 prescriptions per day. Our pharmacy passed inspection by the Kentucky Board of Pharmacy, and we are presently licensed as a mail-order pharmacy for sales to all 50 states and the District of Columbia.

Our online pharmacy offers the following advantages:

Legitimacy. We have obtained state licenses and certifications to separate ourselves from the many uncertified “rogue” pharmacies which exist. We are the 19th pharmacy in the U.S. to receive Verified Internet Pharmacy Practice Sites accreditation, issued by the National Association of Board of Pharmacy. Google, Yahoo, and Bing now all require VIPPS as a requirement to advertise on their sites.

Convenience. Our online store is available to consumers 24 hours a day, 7 days a week through the Internet. We deliver medications with available free shipping to any location in the United States including Alaska and Hawaii. We offer 6-month and 12-month supplies of medications to reduce the need for refills. 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 auto-refill.

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.

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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 source drugs direct from the manufacturer at the wholesale level and eliminate third party payors such as insurance companies, we believe that we have lower costs than traditional pharmacies which allows us to provide consumers with 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 and also offer 6 and 12 month supplies of our medications to consumers to reduce refills and provide better value.

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 available free standard shipping. We are prevented by law from accepting returns for any prescription medication. We have received numerous awards for customer service and satisfaction.

Our customer support representatives operate from our call center in Florence, Kentucky. Our customer support specialists are available 9 a.m. to 9 p.m. Eastern Time, Monday through Friday, and 9a.m. to 5p.m. Eastern Time on Saturday and Sunday, via e-mail, online chat, 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 products to all 50 states, the U.S. Territories, and APO/FPO military and embassy addresses. We process all orders from our distribution center in Florence, Kentucky, 15 miles south of Cincinnati, Ohio. We based our logistics operation there to maintain proximity to UPS, located 90 miles away in Louisville, Kentucky. Processing from this location allows us to reach up to 80% of the U.S. population by standard ground shipping in two days from shipment date. In order to try to maintain high customer satisfaction ratings and quality control over the process, we avoid drop shipping 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. In addition, we focus on providing fast, transparent filling of prescriptions and increase word of mouth marketing to consumers. We focus on search engine marketing with Google as well as targeted areas within Google like Google Shopping, which require VIPPS to advertise. As the only VIPPS accredited pharmacy licensed in all 50 states and the District of Columbia that sells to consumers online, we believe this provides the company with a unique avenue to reach customers with limited competition. In addition, the Company focuses on targeted referral sites such as GoodRX and Nextag which direct consumers to low cost options for their prescription medications and other medical supplies. We continue to utilize social media, including Facebook and Twitter as a way to reach consumers and build a dialogue with them.

Suppliers

There are a number of suppliers available for the pharmaceutical and non-pharmaceutical products that we sell. Our principal suppliers are Amerisource Bergen, Cardinal Health, Allison Medical, Inc and Indigo Distributors as well as many direct manufactures like Anda, Nipro, Parmed, and Camber. 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. Even if a significant supplier were to no longer be available to us, we believe that we could source replacement product through one or more alternative suppliers without having a significant effect on our business.

Customers

We sell directly to individual consumers who purchase prescription medications and OTC products. We have seen a transition from uninsured consumers to more than 90% of our customers having insurance. Rising insurance co-pays and high deductible plans due to the Affordable Care Act, have created more consumers paying out-of-pocket. This market was estimated to be \$45 billion in 2011 is expected to grow to \$80 billion by the end of 2015.

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Competition

The market for prescription and OTC health products is intensely competitive and highly fragmented. However, there are fewer competitors focusing on the out-of-pocket prescription market. Our competitors in the segment include chain drugstores, mail order pharmacies, pharmacy benefits managers (PBMs), 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 includes 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 U.S. Patent and Trademark Office, which trademark was granted with a registration date of May 19, 2009. On February 14, 2011, we acquired the registered trademark “Hocks.com” in connection with our purchase of the online reseller business of Hocks Pharmacy Inc. 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 (“EC2”) 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).

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 Kentucky Board of Pharmacy and we are presently licensed as a mail-order pharmacy for sales to 50 states and the District of Columbia. 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.

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In addition, although we presently do not accept insurance reimbursement nor do we participate in federal and state programs such as Medicare and Medicaid, this may change in the future. If in the future we do accept reimbursement from commercial or governmental payers, 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. We sell controlled substances and therefore require a DEA license and maintain 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 USP, 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 (DSHEA) when selling dietary supplements and vitamins. The DSHEA generally governs the production, sale and marketing (including labeling) of dietary supplements, and it requires reporting to the FDA of certain adverse events regarding dietary supplements.

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.

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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 payers. To the extent that our pharmacy operations engage in certain electronic transactions (including claims for reimbursement by third-party payers), we may be a covered entity which is 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