**Pharmacy compliance in the cloud** — **and at the counter**

*New cloud-based software helps independent community pharmacists go paperless and meet regulatory and training challenges*

By Mark J. Rubin, R.Ph.

Independent pharmacists share a persistent headache: completing the ever-increasing stacks of paperwork needed to maintain regulatory compliance, document training programs, and demonstrate quality assurance. Historically, finishing this paperwork promptly and accurately has been a critical, yet painstaking, process.

DrugStore Compliance (www.drugstorecompliance.com), a new cloud-based software solution for the independent pharmacy industry, delivers a sustainable answer to the paperwork challenge. It enables independent pharmacies to “go green” while streamlining compliance requirements, automating policy and procedure (P&P) manuals, and creating a more fail-safe audit process. Pharmacy owners and managers can document and organize each aspect of compliance, staff training, and continuous quality improvement — enhancing efficiency, reducing the likelihood of errors, and saving time and costs.

**An increasingly complex environment**

Independent pharmacies today have many storms to weather, from escalating compliance pressures and encroaching national-chain competition to growing labor costs and shrinking margins. These pressures have taken their toll on the industry. A report from IMS Health finds that from 2010 to 2011 (most recent data available), independent pharmacies lost both absolute number of prescriptions (down 1.1%) as well as market share (–24 basis points). Over a nearly 20-year period, 1992 to 2011, independents’ share of prescriptions has declined from 37.1% to 17.6%.

Along with the moment-by-moment imperative to dispense medications safely, independent pharmacists must comply with an ever-increasing array of state and federal rules and regulations covering virtually every aspect of pharmacy operations. USP 797, USP 795, HIPAA, and a host of other regulations require pharmacies to record data meticulously and to vigilantly track the latest revisions in guidelines. This continuous process of documentation and monitoring is time-consuming and labor-intensive, particularly for compounding pharmacies that follow more complicated procedures.

**Regulatory compliance and audit preparedness**

Each state has a plethora of laws and regulations guiding pharmacy standards, requirements, and licenses needed for each facility and its employees. Jurisdictions have requirements also for secure storage, up-to-date record-keeping, patient prescription forms, labeling standards, and product safety protocols. And, in the aftermath of the October 2012 national meningitis outbreak, resulting from contaminated products sourced to the New England Compounding Center, lawmakers are pressing to give the US Food and Drug Administration new regulatory authority as lead auditor for compounding pharmacy operations. In the months and years ahead, the industry can expect regulations and inspections to tighten and intensify.

If materials requested for the audit are well-organized, fully complete, and easily retrievable, the process can go smoothly. However, if records are scattered, incomplete, or not readily available, the auditor may be more likely to stay longer — and look deeper. Any in-depth audit will use the pharmacy’s P&P manual as the benchmark for reviewing pharmacy operations. Partial or unclear policies will make it more difficult for pharmacy managers to defend their activities in any type of legal action.

DrugStore Compliance meets the compliance challenge by creating, organizing, and managing a detailed electronic database of regulations, procedures, and licenses. System users can conveniently access and reference this information at any time, from anywhere — at the pharmacy from a countertop computer or on the go from a mobile device.

Highly flexible and customizable, the software provides a step-by-step guide and resources to complete each compliance requirement. It also issues reminders for upcoming compliance deadlines and license renewal dates, automates task lists, and enables prompt response to audits and regulatory agency inquiries. P&P manuals can be easily automated for continuous updates of protocol, procedures, and job responsibilities. With this auditable trail of compliance processes and documents, pharmacies can be well-prepared for, and well-informed in, any audit — reducing the risk of hefty fines, lost revenue, and damaged reputation.

**OIG Exclusion** **List verification**

The Office of Inspector General (OIG) imposes stiff penalties on organizations that hire or do business with anyone on the OIG Exclusion List, the database of businesses and individuals who have violated federally funded health care programs. Verification checks must be conducted each month for all employees, wholesalers, and vendors, and any individuals or entities appearing on the Exclusion list must be immediately terminated.

DrugStore Compliance consistently checks licenses for OIG/System for Award Management exclusions, automating the verification process and protecting pharmacies from potential monetary consequences.

**Room certifications**

Today, every pharmacy has a mound of requirements for checking refrigerator and freezer temperatures daily, cleaning rooms and equipment daily, and conducting deep cleans each month. Activity is typically tracked on paper logs and posted throughout the facility.

DrugStore Compliance provides an electronic database of maintenance logs for recording air temperature, pressure, humidity, and cleaning activity. It issues proactive alerts when any steps are missed, organizes all information for instant retrieval, and saves valuable staff time.

**Training and continuous quality improvement**

All pharmacy employees, from front end to back end, are required to maintain their competency through ongoing education, training, and development — in topics ranging from preventing fraud, waste, and abuse to following standard operating procedures and using materials safety data sheets.

With DrugStore Compliance, pharmacies can provide customized digital staff training, creating their own training software complete with learning modules, quizzes, and evaluations. Employees are kept up-to-date on the latest policies and regulations, while employee accountability is reinforced and any problems escalated through appropriate channels. Proactive alerts notify staff of any training requirements not yet completed. Training metrics can help identify recurring trouble spots, improve processes, and avoid costly compliance issues. Staff can also confirm their attendance at continuous quality improvement meetings from their laptops, tablets, or smartphones, providing a permanent and readily retrievable record of individual compliance.

**Sharing of best practices**

Independent pharmacies often find themselves in isolation, without the means to share with, or learn from, their industry peers. Opportunities are missed to collectively brainstorm and collaborate in solutions to industry-wide challenges.

Through its “Share” function, DrugStore Compliance users can disseminate best practices to their counterparts. From effective compliance strategies to innovative employee training programs, pharmacies can submit their ideas to DrugStore Compliance by using the site’s Share button. Leading-edge ideas and materials may then be available for download by pharmacy peers nationwide.

**The cloud advantage**

The cloud offers a powerful, highly secure, professionally managed network of shared computers and computing resources. Instead of buying services and managing their own information technology system, DrugStore Compliance users in essence “rent” server and processing power from these mega datacenters. Data is backed up automatically, and redundancies in the cloud infrastructure ensure that servers are always working. An unlimited number of active users with right of entry to a pharmacy’s secure cloud can remotely access all applications and data anywhere from any device.

Previously, automated compliance solutions have been available only to large chains with huge technology budgets or an extensive staff of in-house developers. DrugStore Compliance widens the playing field, enabling efficiencies that give community-focused, independent pharmacists more ways to adapt to and thrive in today’s highly competitive, and tightly regulated, environment. Most importantly, tracking and managing pharmacy data with greater ease and precision can help pharmacists achieve their ultimate goal: ensuring the safety and quality of every prescription, every time, for every valued customer.

*DrugStore Compliance is offered through a monthly or annual subscription plan. It will be available in the third quarter of 2013. For more information, visit www.drugstorecompliance.com.*

**About the author**

|  |  |
| --- | --- |
|  | Mark J. Rubin, R.Ph., of Royal Palm Specialty Pharmacy in Webster, MA, has 23 years of experience in the pharmacy industry. He is the CEO of AMR Software LLC, developer of the DrugStore Compliance software solution for independent pharmacists.  |