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Health Reform Spurs Evaluation of Compliance Strategies

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New pay and practice approaches will favor cost-effective treatments and packaging.

In expanding healthcare coverage—and driving pharmaceutical use and spending—the healthcare reform act includes policies for containing costs and testing new models of healthcare practice and payments.

The emphasis in the Patient Protection and Affordable Care Act on improving patient outcomes and controlling costs will drive evaluation and use of compliance-prompting packaging, speakers said at the Healthcare Compliance Packaging Council's Annual Symposium.

Patients' adherence to medications and the results of medication management will fall under review by a new Center for Medicare and Medicaid Innovation, which will test and evaluate practice and payment reform models.

An Independent Payment Advisory Board will likely evaluate clinical outcomes as it looks for ways to contain per capita Medicare spending, without reducing the quality of care.

The reform includes a national strategy to improve healthcare outcomes. Medicare, for example, will focus on linking payment for services to quality outcomes in a pay-for-performance approach, says Dr. John Michael O'Brien, executive director of the Responsible Health Institute and clinical adjunct professor at the Ernest Mario School of Pharmacy at Rutgers University.

"The healthcare reform bill provides an important opportunity to evaluate and implement new ideas to improve medication adherence—a problem that seriously undermines quality of life and quality of care, patient outcomes, and the value of our healthcare dollars," O'Brien said in a presentation at the HCPC event.

"Prescription drugs are the best value in healthcare, and numerous studies have shown that improving adherence reduces overall healthcare costs," O'Brien says.

EMPHASIZING QUALITY

"Healthcare payors and manufacturers alike will benefit from quality-based payments, and compliance prompting packaging will help improve the cost-effectiveness of prescription medicines," he adds.

Reform bill policies promote practice reforms and healthcare spending accountability that stand to influence packaging choices.

The act seeks to reduce Medicare payments to hospitals by specified percentages to account for excess (preventable) hospital readmissions. "Hospitals may wish to include compliance packaging as a component of their discharge strategy" to drive fewer readmissions, O'Brien says.

"Because the law requires health insurers to provide rebates for excess premium dollars collected but not spent on medical care or programs to improve quality, they may also wish to include programs to improve adherence, when considering how they spend their premium dollars," O'Brien adds.

The reform bill would establish a broad range of pilots and demonstration projects, testing concepts such as integrated care, community-based prevention, and individualized wellness plans.

Payment and practice reform in primary care will emphasize medical homes, a model in which the physician takes responsibility for patients' on-going care, coordinating the services of other healthcare providers. In this model, patients have improved access to caregivers and are more actively engaged in their care.

PAY AND PRACTICE MODELS

The act calls for evaluation of telehealth models for coordinating care among the home-bound chronically ill. Intelligent pharmaceutical packages will support a shift from costly acute care to residential and home care environments, Danevert Asbrink, VP sales, Cypak AB, Stockholm, Sweden said at the HCPC event.

Asbrink described the work of the Continua Alliance, which is promoting standards for interoperability of devices. Microchip-based drug packaging and home monitoring devices designed to standards support real-time intervention by caregivers in connected models. With patients and caregivers communicating with a common protocol, the patient ideally can use one scanning device to convey data from drug packages, blood pressure cuffs, glucose monitors, weigh scales, and other devices.

"You have to build a system based on standards, because patients are on multiple medications," Asbrink said.

The Healthcare Compliance Packaging Council of Europe acquired insights on patients' views of conventional and interactive packaging in a 2009 online Voice of the Patient survey described at the HCPC event by HCPC-Europe executive director Tassilo Korab.

Most respondents were in the 40 to 65 years' age group. Close to 80% took tablet medications, and more than 80% reported removing the tablets themselves. Close to 60% reported finding a package with calendar and weekday printing useful for keeping track of their therapy.

Although most were happy with their current packaging—60% said they would not prefer alternative packaging—respondents were quite open to interactive packaging. Sixty percent said that automatic recording of tablet egress would be helpful, and the same number favored a built-in device for reminders. Forty percent said it would be helpful if packaging could automatically transmit vital data such as blood pressure or blood sugar levels along with a record of medication intake to their doctor or pharmacist.

The reform bill includes grants for pharmacist-provided medication management services and

expands MTM requirements under the Medicare Part D drug benefit. "The new rules will result in more people in Part D receiving more comprehensive medication management services," says O'Brien.

Plans are required to enroll beneficiaries using an opt-out method and offer a minimum level of MTM services that include quarterly and annual medication reviews and individualized written summaries of interactive person-to-person consultations.

At least once a quarter, plans must attempt to enroll beneficiaries who have three or more chronic diseases, target people who have at least four of seven core chronic conditions and are taking eight or more Part D drugs, or who are likely to incur annual costs for covered Part D drugs that exceed \$3000 (down from \$4000 in 2009), O'Brien says.

"I am hearing more interest today in compliance packaging than ever before, but also cost pressures are being applied as never before," says Ward Smith, director of marketing, Keystone Folding Box Co. (Newark, NJ).

"Customers realize the value of compliance packaging. The question is can it overcome their budget restraints."

A focus on outcomes places an emphasis on packaging that has a demonstrated effect on patient adherence. The reform bill is therefore likely to sway the balance toward further adoption of compliance prompting packaging.

KEYSTONE FORMAT MINIMIZES COSTS

Keystone Folding Box's Key-Pak features a two-ply construction in a single fold-and-seal design that minimizes material and manufacturing costs. The patient pushes out the tablet after tearing a tab to expose the blister's foil backing. The format was used in 547 clinical trials—with 9 million cards produced—in 2008, says Keystone's Smith.

The Key-Pak has recently gained use in commercial applications. A generic steroid drug adopted the format last year for packaging a titration regimen. Tabs were designed to expose multiple pills for some doses, which guides the patient and aides in compliance.

"We have a brand company switching from another compliance package to the Key-Pak in the third quarter this year," Smith says.

"With the Key-Pak, each dose is CR enabled, so there is no need for the patient to reactivate or reengage a package CR mechanism. In CPSC testing, the package had zero failures with children, and 100% of seniors accessed the doses in the required time," Smith says.

The CR function is provided by the blister card in the Key-Pak Plus, a cartoned Key-Pak format in which the carded blister stays attached to the sleeve. In flexibly packaging different regimens, pills can interlock when the panels are folded. The Key-Pak Plus provides bill-boarding space in a more self-contained package for pharmacy-shelf merchandising, Smith says.

"As with the Key-Pak, with the Key-Pak Plus, we are reducing the steps required in manufacturing. It is quite easy to run from a fulfillment standpoint," he adds.

PROTECTING FRAGILE TABS

For compliance blister packaging of GlaxoSmithKline's Lamictal ODT (orally disintegrating tablets), Anderson Packaging Inc. (Rockford, IL) created, in collaboration with GSK and Meadwestvaco, a unique design using MWV's Dosepak Express format. The patient accesses the friable tabs simply by peeling the backing on individual units of the sleeved uncarded blisters.

For providing five weeks of therapy for a family of Lamictal (lamotrigine) products, Anderson developed kits for three titration therapies and four maintenance therapies for the trade product, as well as three physician sample packs.

Lamictal XR (extended release), a more robust tablet, is packaged in MWVs peel-push child-resistant Perfpak format with similar package color differentiation and dosing configurations. The Lamictal ODT Patient Titration Kit features a Dosepak with a fifth and sixth panel glued to a second Dosepak with a fifth panel.

GSK blisters the tablets, with weeks and days of therapy printed on the lid stock. Anderson developed a custom assembly line built around the MGS Stealth cartoner from MGS Machine Corp. Two blisters are glued face-to-face and loaded into the Dosepak sleeve. An automated process is used for gluing the two Dosepaks together. A package insert and Med Guide are adhered to the package.

"We bar code scan every component that goes into the Dosepak, each blister, insert, and Dosepak sleeve. There are over seven different printed components included in the final assembly. We have to be absolutely sure we have the correct strength in the correct location," says Justin Schroeder, director of marketing and business development, Anderson Packaging.

The package includes opening instructions with pictorial diagrams, along with guidance on using the Med Guide.

"The intent is to make sure the patient is reading the dosing instructions printed on the package, and make sure they are not pushing the tablets through the blister," says Schroeder. Child resistance is provided via the CR functionality of the Dosepak, rendered in a heavy-weight 24 pt caliper paper board. In CPSC testing, the package met the threshold for access by children determined by the product's toxicity, earning an F-4 rating.

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(navigator.userAgent.indexOf("Gecko")!=-1) { document.write('<VSCR' + 'IPT>'); }
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