Health Information Compliance Alert

INDUSTRY NEWS: Prescription Drug Package Inserts Encourage Better Compliance

Long-overdue redesign improves information but sparks controversy.

The **Food and Drug Administration** wants drug companies to provide better health information for providers and patients and is tightening its package insert requirements.

The potential revisions, which would take effect June 30, 2006, are the first significant changes to package inserts in 25 years and will apply to all new drugs, as well as those the FDA approved within the last five years. The agency hopes the changes will help reduce medication errors, improve physicians' abilities to locate important information about drugs' risks and benefits, and increase adverse reaction reporting among patients.

New Sections Highlight Important Info

The FDA drafted the following changes to incorporate actionable health information on drug labeling:

- A new "Highlights" section at the top of the page to provide health care professionals with quick access to drug benefits and risks. In addition, the Highlights section will list recent major changes to the product's prescribing information, contact information for adverse drug reaction reporting and the drug's initial product approval date to help identify how long the drug has been on the market.
- A new "Contents" section to provide easy reference and navigation to all sections and subsections.
- A new "Patient Counseling" section to help doctors advise their patients about medications' uses and limitations.
- Toll-free contact information and instructions for reporting adverse reactions.
- Minimum graphical requirements.

Additional cosmetic changes bring important sections to the front of the insert, such as "Boxed Warning," "Indications and Usage," "Dosage and Administration," and "Dosage Forms and Strengths." The "Adverse Reactions" and "Warnings and Precautions" sections are now back-to-back to consolidate risk information.

"The new label design makes it easier for doctors to get access to important information about drug safety and benefits, and this in turn will help them have more meaningful discussions with their patients," **Andrew von Eschenbach,** acting FDA commissioner, asserts in an FDA press release.

The new label information will also integrate with the FDA's ongoing electronic health initiatives, including **DailyMed,** an interagency, online health information clearinghouse.

"The revised prescription information format, in combination with new requirements for electronic labels announced earlier this month, and requirements for barcodes on drugs will dramatically improve the way health care professionals and consumers obtain information about prescription drugs," Eschenbach adds.

Revisions Ignite Mixed Reviews

The **American Medical Association** applauds FDA's changes, but consumer watchdog group Public Citizen feels they're

"a sneak attack on consumer rights."

Part D transition problems may continue to crop up until every dual eligible uses the benefit at least once, warns **Centers for Medicare and Medicaid Services** Administrator **Mark McClellan**. Nevertheless, CMS' plan to reimburse states is a temporary provision that ends Feb. 15. **Health and Human Services** secretary **Mike Leavitt** is considering extending the program to select states on an as-needed basis.

Misinformation Sparks Reaction From Health Plans, Senate Groups

After Medicare Part D went into effect Jan. 1, many Medicaid enrollees transitioning to the new plan experienced coverage denials when they attempted to fill their prescriptions. The problem does not stem from health plans, but from last-minute plan switching and inaccuracies in the initial enrollee data file that a private CMS contractor provided to pharmacies, claims **America's Health Insurance Plans** president **Karen Ignagni.**

Once plans receive and verify the correct enrollee data from CMS, reimbursements to states won't take very long, Ignagni says.

Despite commitments from CMS and HHS to address states' stopgap payments, senator groups may continue to move forward with legislative backup plans. Senators **Norm Coleman** (R-MN), **Dianne Feinstein** (D-CA), **Frank Lautenberg** (D-NJ), **Charles Schumer** (D-NY) and **Olympia Snowe** (R-ME) submitted a bill that would require the federal government to directly reimburse states for drug costs, plus interest, by reducing "clawback" payments to the federal government.

"States should not have to wait to be compensated by insurance companies for expenses incurred as a direct result of CMS' errors," asserts Snowe. "The federal government should live up to its new responsibility and reimburse states for these costs."

Senators **John Rockefeller** (D-WV) and **Hillary Rodham Clinton** (D-NY) sponsored a separate bill that would reimburse the costs that pharmacies incurred and require plans to supply at least one-month's medications to benes. Clinton calls the Part D fiasco an "absolute first class piece of evidence of how the Republicans are doing their business and not the business of the American people, [which will] lead to the deterioration of Medicare across the board."

CMS, HHS See States As 'Payers Of Last Resort'

In a closed-door meeting Jan. 25 between CMS, HHS and the Senate Finance Committee, CMS and HHS ironed out their reimbursement plans and established that states are "payers of last resort."

After the meeting, some senators showed signs that they might stop pursuing legislativereimbursement action. "It seems to me that the secretary is really working to make sure this reimbursement occurs," says Snowe, adding that legislation might not be necessary.