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April 2010 Monthly Newsletter

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Pharma Compliance INSIGHT:

Send an email to info@cis-partners.com to sign up for our upcoming **Complimentary Webinars:**

TRICARE Upates
Date TBD

Key note speaker: Lisa McNair who was instrumental in assisting with the development and implementation of the DoD/TRICARE Retail Refunds Program and the TRICARE Pharmacy Benefit Program.

How will the Healthcare Reform Affect Your Government Pricing Program?

by **Lauren Pellicciotti, CIS Compliance Manager**

On April 14th, 2010, CIS hosted a webinar addressing how the Healthcare Reform will affect your Government Pricing programs. Due to the overwhelming request and feedback after the webinar session presented by CIS' Chris Coburn, VP of Regulatory Compliance, Bill Baxter, Strategic Advisor of Government Affairs, and Amy VanDeCar, Director of US Commercial Compliance and Government Programs, many of our clients and outside spectators have been looking to CIS for a specific summary that addresses all of the Government Pricing impacts that have been driven from the Patient Protection and Affordable Healthcare Act ("PPACA"). Our Subject Matter Experts ("SMEs") have been addressing the specific questions regarding the changes and thought it would be appropriate to summarize at a high-level what are the specific changes that affect GP and when they are occurring. Please feel free to reference our grid below. Click on image and print for best results.

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U.S. Government Gears Up to Fight Healthcare Fraud

by **Gary Miller, CIS Senior Compliance Associate**

As evidenced by the high profile cases that have been in the news over the past few years, compliance is as important as ever in the pharmaceutical industry, and is an essential piece of the corporate culture needed to avoid ever increasing fines and penalties for compliance violations and fraud. By reviewing the various announcements by government departments and agencies that have been made over the last few months, in addition to the provisions in the recently passed Patient Protection and Affordable Healthcare Act (PPACA), one can easily see that a dedication to compliance, not only for the pharmaceutical industry, but also for the entire healthcare industry, will only become more important. Government entities including the Food and Drug Association (FDA) and the Department of Justice (DOJ) have both recently announced revised plans, along with increased funding for the DOJ to step up fraud and compliance investigations, with subsequent prosecutions becoming more and more likely. The crackdown on non-compliance will cover a wide range of issues, from Medicare fraud to drug safety



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Gout and the Law of Unintended Consequences

by **Matt Hotz, CIS Senior Compliance Associate**

Most days, I listen to sports talk radio in the car during my morning commute and again on the way home. I've become very familiar with the hosts, of course, but also with the ads.

In the last few months, I noticed a new ad in the rotation that featured a man talking about the pain of gout flares. The ads didn't mention any specific products - they just directed listeners to a website to find out more about treating gout flares.

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FDA Unveils (Then Delays) New Tool in Fight Against Fake Drugs



**VA Contracts -
Understanding the Ins and
Outs of Renewals** June
24th at 2pm EST

Key note speaker: Dave Rice
an FSS Contracting,
Compliance, and Pricing
expert. With Contract
pricing going up and the
September deadline
looming, Dave will help you
focus on the tasks involved
in the arduous process of
contract renewal.

by Craig Kubicek, CIS Compliance Associate

On May 18, 2009, the senate voted to confirm Dr. Margaret Hamburg as the 21st commissioner of the Food and Drug Administration. Another colleague at CIS has touched upon the changes Dr. Hamburg will be facing with her new position. The related article can be found here: <http://pharmacomplianceblog.blogspot.com/2010/01/new-year-new-resolutions.html>

One of Dr. Hamburg and the FDA's changes is to include a new system entitled "Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting" (PREDICT) that will assist in targeting import shipments that possibly contain fake or misbranded drugs. The system is to be rolled out for use this summer by the FDA. Currently, New York is using the system and Los Angeles is testing PREDICT
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"Who Ya Gonna Call?" Part III



**by Bill Baxter, Strategic Advisor,
Gov't Affairs**

Current Health Care Reform (HCR) legislation includes the obligation for manufacturers with Medicaid rebate agreements to provide the same rebates for products dispensed to valid Medicaid Managed Care Organization (MMCO) patients as required for Medicaid fee-for-service utilization. While much is still to be determined regarding the mechanics

of the requirement, one question stands out very clearly: "what rebate exposure does this generate for my company?"

Two things are VERY clear; 1) this will significantly increase rebates for most if not all participating manufacturers, and 2) the impact will vary by a company's product mix, current utilization in the fee-for-service program, and formulary position on most large MMCOs.

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