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May 2010 Monthly Newsletter

Featured Articles

How will the Healthcare Reform Affect Your Government Pricing Program? U.S. Government Gears Up to Fight Healthcare Fraud

Gout and the Law of Unintended Consequences FDA Unveils (Then Delays) New Tool in Fight Against Fake Drugs

Letter from a GP SME: Manufacturers and the Medicare Coverage Gap Discount Program: 2011 and Beyond

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Pharma Compliance INSIGHT:

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

HR 3590 and the Physician Payments Sunshine Act - Part I: June 16th at 2PM

CIS will offer a parallel review of the individual state requirements that will allow you to look at your current solutions from

Healthcare Reform: Part I: The Principles of a Risk Based Compliance Program

by **Clarissa Crain & Chrissy Spicer, CIS Commercial Compliance Directors**

A Risk-Based Compliance Program is a program built on the effective and meaningful evaluation and mitigation of risk. The establishment and maintenance of a Risk-Based Compliance Program starts with risk planning and identification. Through continued evaluation of business risk, as well as ongoing auditing and monitoring, the end result is often the need to develop policies and procedures to manage and/or mitigate these identified risk areas.

Policies and procedures are at the core of maintaining compliance within a company. Outlining a company's interpretation and implementation of respective regulation, statute, and guidance; policies and procedures are the communication tool used to articulate the company's commitment to, and mechanisms for, compliance. Ensuring consistent application and execution of process, policies and procedures further assist with the evaluation of risk. By building and embedding preventative controls within business processes, and building detective controls to assess process execution, companies can proactively identify and respond to risk.

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FDA and NIH Propose New Rules Requiring Transparency

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

Last year, shortly after President Obama's inauguration, I wrote a two-part feature on transparency, a term which formed a substantial plank in the Obama platform. The first article focused on what transparency would mean for pharmaceutical manufacturers, while the second article focused on the connection between transparency, health care reform, and economic recovery. Two recent federal proposals, one from the Food & Drug Administration (FDA) and one from the National Institutes of Health (NIH), have prompted me to revisit the topic of transparency.

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FDA Rolls Out 'Bad Ad Program'

by **Kimberly Gilbert, CIS Senior Compliance Manager**

On May 11, 2010, the Food and Drug Administration (FDA) announced the latest effort aimed at increasing regulation of the pharmaceutical industry's multibillion-dollar marketing machine. The FDA is now asking doctors to keep an eye out for misleading drug advertisements. The initiative referred to as the "Bad Ad Program" asks doctors to report ads and sales pitches that violate FDA rules. The program is also targeted at consumer ads that downplay drug risks and effectiveness (1). The agency's Division of Drug Marketing, Advertising, and Communications (DDMAC) in the Center for Drug Evaluation and Research will be responsible for overseeing this program. DDMAC's mission is to protect the public health by assuring prescription drug information is truthful, balanced, and accurately communicated, as well as to guard against false and misleading advertising and promotion through comprehensive surveillance, enforcement, and educational programs.

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FDA's Proposed Rule on Reporting Falsification of Clinical Study Data



a fresh perspective with a proactive approach to evaluating systems, processes, training, monitoring, and auditing.

Click [here](#) to register

TRICARE Updates 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.

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 Suma Kallurkar, CIS Senior Compliance Manager

The FDA is proposing a new rule that would require sponsors of clinical studies to report information that indicates whether a person has, or may have, been involved in the falsification of data. This includes falsification of study results as well as "...proposing, designing, performing, recording,

supervising, or reviewing studies that involve human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor."¹ The proposed rule would require individuals to report such information to the FDA within 45 days after becoming aware of it. The FDA would then utilize the information to identify trends and determine the requirement for further investigation.

The FDA reviewed numerous cases of falsification of data in the 1990's, and found cases where falsification of data by one individual impacted multiple studies and multiple sponsors. These events led the FDA to evaluate the problem further and come to conclusions that ambiguity exists in the current regulations around reporting of falsification of data.

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Letter from a GP SME: Manufacturers and the Medicare Coverage Gap Discount Program: 2011 and Beyond

by Chris Cobourn, CIS VP, Regulatory Affairs

On June 1, Bill Baxter, CIS Strategic Advisor, Government Affairs, and I had the opportunity to attend the full-day "Manufacturers and the Medicare Coverage Gap Discount Program: 2011 and Beyond" session in Baltimore, hosted by CMS, to discuss the Medicare Coverage Gap Discount Program.

This was an interesting and informative day attended by representatives across the industry (with the majority being manufacturers), which provided some discussion, some answers, and left us with important questions that will require clarification and guidance (see <http://www.cms-cpcevents.org/cms/events/baltimore-june-2010/>). The session was recorded, and will be available through the [CMS-CPC Events website](#).

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