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June 2010 Monthly Newsletter

Featured Articles

What does the OIG have to say about Medicare Part D PDE data?

ICH-Q10 Pharmaceutical Quality System-Change Management

What is MedPAC?

Healthcare Reform Calls Manufacturer to Pay Rebates on Units Dispensed by MCO's SBA Number of Employees - Part I

Letter from the Editor- Social Media Marketing Can Be Embraced Safely with the Implementation of a Social Media Implementation Plan

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[Government Programs PCX](#)
[Clinical R&D PCX](#)
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Incorporating the Requirements of Healthcare Reform with Risk Evaluation and Mitigation Strategies
 July 22nd, 2-3:15PM

What does the OIG have to say about Medicare Part D PDE data?

by **Chris Cobourn, CIS VP of Regulatory Affairs**

As you may be aware, CMS held a day long public meeting on June 1st to talk about its plans for implementing the Medicare Part D Discount Program in January 2011, which would require manufacturers to pay 50% of the Coverage Gap (as mandated by PPACA).

For my summary of the day, and to see CMS' slides, see my recent blog post: <http://www.pharmacomplianceblog.com/blog/?p=2151>

Some of the critical points the manufacturers made at the meeting were the difficulty they will encounter in processing payments based upon summary level PDE data, concerns about their ability to follow sound general accounting practices, and the importance to having an appropriate level of audit. CMS commented during the meeting on the quality and reliability of PDE data.

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ICH-Q10 Pharmaceutical Quality System-Change Management

by **Erica Brooks, CIS Senior Compliance Manager**

In my previous [article](#), I discussed ICH Q10, which specifies the effective quality systems for the pharmaceutical industry. It is designed to be used throughout the lifecycle of a product. The guideline is a compilation of known regulations used in the industry today. The scope of ICH Q10 defines the major components of the product lifecycle, such as pharmaceutical development, technology transfer, manufacturing, and product discontinuation. The Pharmaceutical Quality System consists of four key elements: Process Performance and Product Quality Monitoring system (PP/QM), Corrective Action and Preventive Action (CAPA) system, Change Management system, and Management Review of Process Performance and Product Quality. An effective Change Management system is necessary to evaluate the impact of a change through an expert team to assure there is no impact to product quality.

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What is MedPAC?

by **Craig Kubicek, CIS Compliance Associate**

The new Health Care Reform, H.R. 3590 and H.R. 4872, has created a swirl of polarizing politics, while it has also created a new era for healthcare in the United States. Along with any government funded program comes bureaucracy (whether it be for better or for worse); however, the bureaucratic team I would like to shine some more light on was not constructed as a product of Health Care Reform, it was created as a product of Medicare.

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Healthcare Reform Calls Manufacturer to Pay Rebates on Units Dispensed by MCO's

by **Lauren Pellicciotti, CIS Project Manager**



Before Healthcare Reform (H.R. 3590 and H.R.

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Implementation of the Medicare Part D Coverage Gap Discount Payment and Its Impact on Pharmaceutical Manufacturers
July 29th, 2-3:15PM



4872), there was no prior obligation for pharmaceutical manufacturers to pay rebate units dispensed by Managed Care Organizations ("MCOs") to Medicaid patients. Effective March 23, 2010, under the new legislation (section 1927(b), as amended by section 2501(c) of H.R. 3590), individuals enrolled with a Medicaid MCO are responsible for coverage of such drugs. According to a "Dear State Medicaid Manufacturer" letter dated April 22, 2010:

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SBA Number of Employees - Part I

by Nicole Arend, CIS FSS Manager

I began my quest for clarification of questions that were asked while completing required data within a Federal Supply Schedule solicitation in regards to the size of a business. My need for absolute clarification becomes important at the moment a client asks the question, "Are we a small or large business?"

So how IS a company identified as a large or small business? Who is included in the count to make up the number of employees? After asking these questions and receiving various answers from various government entities, I began my quest for clarification. I began by contacting the entity that wrote the definition of "small business," the Small Business Association (SBA) in Washington D.C

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Letter from the Editor: Social Media Marketing Can Be Embraced Safely with the Implementation of a Social Media Implementation Plan

by Jamie Ghen, Esquire, CIS Director of Compliance, Ethics and Legal Affairs

Although most pharmaceutical companies continue to deal with challenges that could threaten their reputations and ability to manage risks, it comes as no surprise that many pharmaceutical companies are planning to invest large sums of money into effective social media marketing strategies from 2010 through 2015. This will be challenging from both a legal and marketing perspective while the industry awaits guidelines to follow. However, as with other industry areas under increased scrutiny, pharmaceutical companies need to adopt a proactive approach to use social media in their online marketing mix. Such an approach would effectively deal with potential violations and/or complaints as they happen, and help a company's ongoing efforts to rebuild its positive reputation among medical professionals, patients and regulatory bodies. Moreover, a government investigation could be headed and/or damages mitigated if a complaint should occur.

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