



October 2009 Monthly Newsletter

FEATURED ARTICLES

Highlight of the 2010 OIG Work Plan

By Katie Lapins, CIS Compliance Director

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At CIS, we encourage GP professionals to be familiar with the Office of Inspector General (OIG) Work Plan, in order to help Senior Management in their companies understand the OIG's increasing focus on proactive audits in the GP area. The OIG just released its [2010 Work Plan](#), which continues to show an increased emphasis on GP Audits. The 2008 Work Plan included a very brief section on GP Audits, which merely stated that the OIG would perform selective audits. The 2009 Work Plan was broader, including specific audit activity the OIG planned to perform. The 2010 Work Plan goes even further.

One of the OIG's objectives is to maintain the integrity of Federal Government Pharmaceutical Programs; this objective is fulfilled through investigations and audits. Historically, investigations were the result of a complaint or allegation made by a "whistleblower," but over the last two years, the OIG was provided funding to conduct proactive audits and investigations. We at CIS expect this trend to continue and, one day, we envision OIG audits related to GP participation to be routine, similar to those conducted by the FDA.

Some of the questions highlighted in the OIG 2010 Work Plan, with respect to pharmaceutical manufacturers, are similar to those in the 2009 Work Plan, and include:

1. Did manufacturers submit Average Manufacturer Price (AMP) by the deadline required for each time period? (It is also worth noting that the impact on PHS price is an additional reason for the importance of timely reporting.)
2. Was the methodology used by manufacturers to calculate AMP and Best Price (BP) correct, especially in light of changes in the Deficit Reduction Act and related Final Rule?
3. If a manufacturer restated baseline AMP as allowed by the DRA, was the methodology correct?

4. Were Medicaid claims made by States accurate, and were rebate payments made by manufacturers correct?
5. Were Medicaid claims submitted, and subsequently paid, for drugs dispensed to children that were not approved by the FDA for use in children?
6. Were Medicaid claims submitted and subsequently paid for non-FDA approved drugs?
7. Are States properly submitting Medicaid claims for drugs with a Unit Rebate Amount (URA) of \$0.00, and are manufacturers paying these invoices correctly?
8. Is the additional Medicaid rebate amount related to inflation, and based on the Consumer Price Index, being paid correctly by manufacturers?

From 2005 through 2008, the Department of Justice recovered approximately \$7 billion from pharmaceutical manufacturers. In 2009, we've already seen \$3.7 billion recovered from just two cases. As budget deficits grow, pharmaceutical manufacturers are likely to continue to be in the spotlight. According to Taxpayers Against Fraud:

"Total False Claims Act recoveries (Federal and State) since the 1986 amendments now total over \$25 billion.. In the health care arena, the U.S. Government is recovering \$15 back for every \$1 invested in False Claims Act health care investigations and prosecutions."

The OIG's 2010 Work Plan can be viewed in its entirety at: http://oig.hhs.gov/08/Work_Plan_FY_2010.pdf

If reading about the OIG's continued focus on pharmaceutical manufacturers gives you concern, contact CIS to conduct an audit or assessment, and ensure your organization is audit-ready.

Sources:

<http://www.taf.org/statistics.htm>

http://oig.hhs.gov/08/Work_Plan_FY_2010.pdf

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New Guidance for Vermont's Prescribed Products Law for FY 2010 Disclosures

By Amanda Zanetti, CIS Compliance Associate

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Since 2002, the state of Vermont has been one of the few states involved in lawmaking for pharmaceutical marketing activities. The recent passage of Chapter 59 of the Vermont Acts of 2009 (Senate Bill 48), tightened Vermont's regulations around marketing activities. The law, which was signed on June 8th, 2009, is being called the strictest state reporting law to date for pharmaceutical and medical device manufacturers.¹ There are several key elements to the Act, which:

- **“Extends** the reach of the law to biological product and medical device manufacturers.
- **Bans** most gifts from manufacturers of prescription drugs, biologics and medical devices to doctors, nurses and health care facilities. The ban also extends to food and free meals.
- **Strengthens** Vermont's existing disclosure law by requiring all manufacturers of prescribed products to report annually all allowable expenditures, including expenditures relating to clinical trials. Transactions that are exempt from disclosure include royalties and licensing, samples of prescription drugs, and rebates and discounts; disclosure is delayed for two years for payments relating to clinical trials.
- **Eliminates** the provision in the prior law that protected trade secrets from disclosure.”²

To provide guidance on the new law, Vermont has published a “Guide to Vermont's Pharmaceutical Marketing Disclosure Law for FY 09 Disclosures”³ published on June 15th, 2009 and “Guide to Vermont's Prescribed Products Law for FY10 Disclosures.”⁴ The “Guide to Vermont's Prescribed Products Law for FY10 Disclosures” was originally published on August 25th, 2009 and provided guidance on the following topics:

- Manufacturers affected
- The gift ban
- How to report
- What to report
- Public disclosure of reported information
- Penalties for failure to report and/or comply with gift ban

The guidance further breaks down the topics listed above to provide comprehensive guidance to the pharmaceutical and biological products and medical device industries. Manufacturers with expenditures over \$0 have until July 1st, 2010 to send in their annual registration fee of \$500. The deadline for disclosures will also change after this year from November 1, 2009 for FY09 to October 1, beginning next year.

While this might all seem like old news, it should be noted that on October 1, 2009, the latest publication of the “Guide to Vermont's Prescribed Products Law for FY 10 Disclosures” was published. This release notes the **NEW** additions and modifications to the guide, which are summarized below:

- Free samples of prescription drugs provided to a health care professional for free distribution to patients, and the labels and package inserts approved by the FDA for the samples, do not have to be disclosed; however, free samples of biologics and medical devices must be reported.
- The fair market value (FMV) of the economic benefit of the samples, rounded to the nearest dollar, must be reported.
- Loans of medical devices and free samples of biologics and medical devices must be reported with a monetary value of \$0 for the value/amount of the expenditure.
- For gifts that are not banned but are of FMV below \$25, the manufacturer may elect to report the expenditures for all Vermont prescribers or institutions in the aggregate.
 - ◆ The value given to items that are not customarily sold is the manufacturer's cost of production.
 - ◆ The value given to items that are produced for national use is the portion of the manufacturer's cost attributable to Vermont.

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- The value of a permitted gift or allowable expenditure provided to a practice with multiple prescribers must be allocated among the relevant prescribers.
- The nature of the economic benefit given (e.g. cash/check, educational materials, donated demonstration or evaluation of medical devices, loan of medical devices, free samples of biologics or medical devices, loan of medical devices, free samples of biologics or medical devices, other or an out of state gift or allowable expense) to a Vermont-licensed prescriber must be identified.
 - ◆ An “out of state gift or allowable expenditure” can only be used if the recipient does not regularly practice in Vermont and the value, nature, and purpose of the expenditure is reported.
- The primary purpose of the expenditure must be identified (e.g. conference sponsorship, speaker honoraria or expenses for serving on seminar faculty, seminar scholarship for unidentified medical students, technical training on a medical device, bona fide clinical trial, research project, gift to academic institution or to a professional, educational, or patient organization representing or servicing health care providers or consumers, or other marketing).
 - ◆ Expenses for clinical trials need not be reported until the earlier of the fiscal year in which the FDA has approved or cleared the prescribed product or the second fiscal year after the payment was made.
 - ◇ Notification to the Vermont Attorney General must be given if there is a delay in the disclosure of an expenditure for a clinical trial.
- The names and types of recipients must be identified as part of the “recipient information.”
 - ◆ Manufacturers must include the Vermont license number of the prescriber or pharmacist (All license numbers are in the form of three digits, dash, seven digits (i.e. xxx-xxxxxxx)).
 - ◆ Reportable expenditure must be disclosed even if the prescriber’s license number is unknown. Contact should be made with the recipient for his or her license number or for the license number(s) of the appropriate prescriber(s) to whom the expenditure should be associated.
 - ◆ A license number of “000-0000000” should be used for any recipient who is not a prescriber or pharmacist.
- The cost of maintaining a table at a conference or seminar that is outside of Vermont, and not limited to Vermont prescribers or institutions, need not be reported. If payment for the table would be made to a Vermont health care provider, it is presently banned under the law. If the conference is in Vermont and is organized by an academic institution or a professional, educational, or patient organization, it is permitted if it meets the definition of an “allowable expenditure,” and must be reported.⁵

So, whether you produce pharmaceuticals, biologics, or medical devices, be sure to pay attention to Vermont’s reporting laws to ensure you remain in compliance with the ever-changing requirements.

You can read the Guide to Vermont’s Prescribed Products Law for FY10 Disclosures in its entirety at the follow link; <http://www.atg.state.vt.us/assets/files/FY10%20Pharmaceutical%20Marketing%20Disclosure%20Law%20Guide.pdf>.

If you have any questions, comments or concerns regarding Vermont’s disclosure laws feel free to contact [CIS](#).

Sources:

¹ <http://www.mondaq.com/article.asp?articleid=81964>

² <http://www.mondaq.com/article.asp?articleid=81964>

³ <http://www.atg.state.vt.us/assets/files/FY09%20Pharmaceutical%20Marketing%20Disclosure%20Law%20Guide.pdf>

⁴ <http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php>

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The Trend Toward Transparency Continues

By Gary Miller, CIS Senior Compliance Associate

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Glaxo Smith Kline announced new standards for funding accredited, continuing medical education (CME) for healthcare professionals, to ensure the programs result in improved patient health.¹ Deirdre Connelly, GSK’s President, North America Pharmaceuticals, said of the announcement,

GSK will not support as many medical education programs, but we will continue funding those with the greatest potential to improve patient health. Continuing medical education offers healthcare professionals important information on disease prevention, diagnosis and management. Independent and balanced information on the latest discoveries about disease and treatment options helps healthcare professionals make higher quality decisions and achieve better patient health outcomes.¹

GSK will invite grant applications from approximately 20 medical education providers, with a documented track record of developing and delivering high quality medical education programs, which have a measurable impact on improving patient health. Potential grant applicants will be limited to academic medical centers and their affiliated teaching and patient care institutions, as well as national-level professional medical associations that represent healthcare professionals responsible for the delivery of patient care. All selected providers must be directly accredited by a recognized accrediting body. GSK will no longer fund CME by commercial providers, including medical education and communication companies (MECCs), under the policy, which takes effect immediately.¹

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As reported on the GSK United States website, additional initiatives to increase public access to information about company decisions, funding and research include:¹

- Reporting fees paid to US healthcare professionals for speaker and advisory services on the company's website.
- Publicly disclosing research payments to healthcare professionals and institutions.
- Publishing all clinical research results in the scientific literature.
- Reporting clinical trial investigator names and institutions.
- Stopping all corporate political contributions globally.

These initiatives announced by Glaxo Smith Kline follow suit in a now increasing line of major pharmaceutical manufacturers to "combat growing public criticism that they have too much financial influence over the medical community."² Last September, Merck & Co., and Eli Lilly & Co., announced that they would begin publicly disclosing payments to physicians.² These actions by manufacturers may also be a preemptive move while they await the outcome of the Physician Payments Sunshine Act, which was reintroduced into legislation by Sen. Charles Grassley in January of this year.

If passed, beginning in 2010, the government will require yearly reporting of all physician payments over a cumulative value of \$100 dollars - with the first report being due by March 31, 2011 - and made available to the public by September 30, 2011.³ The legislation has been referred to the Senate Finance Committee, where it currently resides in its journey through the approval process.

Although the outcome of this industry changing piece of legislation remains to be seen, it seems that some of the biggest pharmaceutical manufacturers are not waiting to find out. Whether it is to set industry best practice, curtail federal intervention, or improve public perception, it is clear that the trend towards transparency is continuing in the industry.

Sources:

¹ GSK limits medical education funding to independent programs with highest impact on patient care; Monday, 21st September 2009, Research Triangle Park, NC; http://us.gsk.com/html/media-news/pressreleases/2009/2009_us_pressrelease_10062.htm

² Glaxo to change training-payment practices; Tues., Sep 22, 2009; Maria Panaritis; http://www.philly.com/philly/business/20090922_Glaxo_to_change_training-payment_practices.html

³ Physician Payment Sunshine Act 2009 Introduced; January 22, 2009; Thomas Sullivan; <http://www.policymed.com/2009/01/physician-payment-sunshine-act-2009-introduced.html>

GCPs Go Global

By Kimberly Gilbert, CIS Senior Compliance Manager

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The U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) announced in early August an agreement to launch a bilateral Good Clinical Practices (GCPs) Initiative, designed to ensure that clinical trials submitted in drug marketing applications in the United States and Europe are conducted uniformly, appropriately and ethically. The initiative commenced on September 1, 2009 with an 18-month pilot program designed to focus on a collaborative effort to inspect clinical trial sites and studies. The initial focus of the initiative will only include a subset of products regulated by the FDA's Center for Drug Evaluation and Research in the United States, and by the EMA for the European Union.¹ This joint initiative is further evidence that clinical development of medications really is a global undertaking, especially since, in most cases, the same clinical trials are used to support Marketing Authorization Applications (MAAs) to the EMA, and New Drug Applications (NDAs) and Biologics License Applications (BLAs) to the FDA.²

The initiative is a means for regulators in the US and European Union (EU) to ensure that clinical trials in their own countries, as well as in other regions of the world, are conducted ethically, and in accordance with GCPs. Because the majority of the trial subjects participating in the pivotal clinical trials that support these marketing applications are recruited in the US and Europe, regulators need to also be certain that clinical trials are carried out in concurrence with the protocol/investigational plan, and that, globally, the data has been reported correctly. This has become increasingly difficult in recent years, due to the increasing globalization of clinical research and the limited inspection resources available. Therefore, this initiative allows regulators to work in a collaborative and synergistic manner to carry out GCP inspections and implement information exchanges, which results in a more efficient use of GCP inspection resources. Sponsors can also aid in this process by informing regulators in the US and the EU of a joint filing, which can be coordinated in both regions.²

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The key objectives of the EMEA-FDA GCP Initiative are:

1. To conduct Periodic Information Exchanges on GCP-related Information
 - a. To streamline the sharing of information relevant to GCP inspection planning so that the selection of studies and sites is well informed, and inspection coverage is improved.²
 - b. To exchange GCP-related information contained in applications for scientific advice, orphan medicines designation, pediatric investigational plans, marketing authorization or post-authorization activities of significant public health interest.²
 - c. To communicate effectively and in a timely manner on inspection outcomes (negative or positive) and their potential impact, where the clinical trials and/or inspected sites/organizations are of common interest.²
2. To Conduct Collaborative GCP Inspections
 - a. To build mutual understanding of, and confidence in, the GCP inspection processes utilized by the EU/EMEA and FDA through the sharing of information, experience and inspection procedures, and cooperation in the conduct of inspections.²
 - b. To improve the effectiveness of inspections by sharing best-practice knowledge in order to enhance inspection techniques and processes.²
3. To Share Information on Interpretation of GCP
 - a. To keep each other informed of GCP-related legislation, regulatory guidance documents, position papers, and policy documents that might be in draft or finalized form.²
 - b. To identify and act on areas where greater convergence could be achieved to the benefit of the clinical research process.²

According to Murray M. Lumpkin, M.D., Deputy Commissioner for International Programs, "This is another initiative that will further strengthen the very robust relationship between the FDA and the EMEA. This will allow both the FDA and the EMEA to leverage each other's GCP inspectional resources so both of us can use our resources to assure more of the clinical trials submitted to both agencies are of the highest quality."¹

At the conclusion of the 18-month pilot phase, a joint assessment will be made by the FDA and the EMEA, at which time the process will be amended and the scope will be modified as needed. This initiative marks another important step for the US and EU towards building a global regulatory network for the supervision of the conduct of clinical trials.³

Sources:

¹ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm174983.htm>

² http://www.emea.europa.eu/pdfs/general/direct/internationalcoop/EMEA_FDA_GCP_Initiative_2009.pdf

³ <http://www.pharmanews.eu/emea/285-emea-and-fda-launch-good-clinical-practice-initiative>

The Statin Dilemma

By Sabrina Skari, CIS Business Development Manager

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Statins are among the most prescribed drugs in the world; in fact, a branded statin ranked as the #1 most prescribed drug in the United States in 2008.¹ Widespread dosing is prevalent because statins provide the foundation for the treatment of cardiovascular disease, the leading cause of death in the United States. In fact, more people die from heart disease than from all types of cancer combined. Furthermore, of the top ten leading causes of death, statins treat three: Heart Disease, Stroke and Diabetes.² So why are statins so effective in treating heart disease? Statins are designed to lower cholesterol, and are particularly effective at lowering LDL cholesterol, also known as "bad cholesterol," which acts by inhibiting cholesterol synthesis in the liver.³ This is extremely important to note when commenting on the statin debate because most circulating cholesterol that causes cardiovascular disease is manufactured internally, and is not actually consumed via poor diet choices.⁴ Thus, for people with numerous cardiovascular risk factors, maintaining a healthy diet is simply not enough.

Now, let me provide a basis for my opinions regarding the use of statins. I sold a statin to primary care physicians for almost three years, so of course I was "brain-washed" to a degree (full disclosure). However, my professional life melded into my personal life when my mother suffered from a cardiovascular event. Keep in mind that my mother is not your "typical" statin patient. She is 5'1, 115 pounds and has been a vegetarian for as long as I can remember. She doesn't smoke cigarettes and she works out regularly. In fact, she could be the poster child for healthy living. However, as I heard her cardiologist once say, "You can make all the right decisions, but you can't pick your parents." Genetics play the most important role in determining cardiovascular risk.

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Nine years ago she was diagnosed with Long QT syndrome, a rare congenital heart disorder associated with arrhythmias and sudden death. As a result, she had a defibrillator permanently implanted in her chest to regulate her heart beat. Additionally, she has always had high cholesterol (atherosclerosis), but like many people was afraid to start a statin. She increased her exercise and dropped her total cholesterol by 100 points in less than a year- an amazing feat. By all accounts she was doing well. Well enough that her physician didn't press the matter of statin treatment. However, she still had a stubborn sales rep for a daughter who pushed the issue regularly. I was well versed on the statistics and constantly warned of heart attacks, strokes and even death. Still, like many other Americans, she had read enough articles stating the risks of statin treatment that she wanted to stay as far away from them as possible.

Very early on a Monday morning, I received a phone call alerting me that my mother was in the Intensive Care Unit at the Hospital at the University of Pennsylvania. She had woken up in the middle of the night, unable to see or to feel her arms and legs, and immediately called 911. I rushed to the hospital and as it turned out, the arteries going into her colon had been completely blocked by atherosclerotic plaque, which caused the event. She didn't have a heart attack or stroke, and she didn't die- thank goodness- so she didn't even count among the standard "statistics." She was diagnosed with Peripheral Artery Disease and the first thing her cardiologist did was question why she wasn't taking a statin.

My mother is not the only person to delay treatment with a statin. Many people do the same exact thing and I heard every potential reason during my time in primary care offices. There was the "I'm afraid I will think of it like a diet pill and eat MORE because I am on a statin" excuse, which makes little sense when you understand what the drug is for. There was also constant concern about the cost of adding a new script to already over-loaded drug regimens. Still, by far the most common reasons not to take a statin were fear of side effects, and safety concerns. A recent article asked the very topical questions: "Are statins safe? Is the sky blue?" As the article states, if you ask a simple question you should expect a simple answer- yes.⁵ Yet, it is important to ask another question- why is safety of statins questioned so often?

Perhaps no other class of drugs has been researched more than statins. Every major clinical trial of statins included more than 10,000 patients, and statins have been on the market for almost 20 years.⁵ Yet every time you turn on the TV, you can hear a commercial with a long list of potential safety risks at the end, which fuel these concerns.

The most common side effect of statins is muscle pain and this is discussed by manufacturers because of the risk of rhabdomyolysis [6]. Commonly referred to as rhabdo, it's the breakdown of muscle fibers causing their release into the bloodstream, which may cause damage to the kidneys. It is a very rare occurrence associated with the use of statins.⁶ So rare that only 0.004% of people taking a statin each year end up with rhabdo and this statistic is the same for patients who are treatment-naïve.⁷ The main cause for controversy is that in 2001, Baycol, a statin, was taken off the market due to deaths related to rhabdo. Much has been debated about why Baycol had a higher incidence of rhabdo than other statins and it has been theorized that there were structural or pharmacological differences.

The only way to determine whether a patient has rhabdo is to have blood work done and to check for elevated creatinine kinase (CK) levels. However, as I previously mentioned, the physical manifestation of rhabdo causes muscle pains and aches⁸, which brings us back to the mainstream complaints that patients voice each day. Muscle aches continue to be the most common side effect associated with statins, but the irony is that most men start statin treatment in their mid-40's and the 50's for women. This happens to be the same time that most people begin to experience aches and pains anyway. It is human nature to look for a scapegoat, and it can be increasingly gratifying when that scapegoat is the pharmaceutical industry. However, it's just as likely that the pain was caused by lifting a grandchild, mowing the lawn or bending the wrong way.

It is important to question the necessity of any medical treatment, but we must also look at who is asking these questions and what their background or motive may be? Many people, much like my mother, can be scared off from taking potentially life-saving medication when non-experts publicize their doubts. If we're going to break down the risks of a drug, conversely we should also look at all of the potential benefits of the drug. One meta-analysis of seven clinical trials examined almost 43,000 patients, half of whom were treated with a statin and the other half treated with placebo- 90% of whom had no prior cardiovascular disease. Results of this study, over a 5 year period, showed a 29.2% reduction in major coronary events, a 14.4% reduction in cerebrovascular events such as stroke, a 31.7% reduction in non-fatal heart attacks and a 33.8% reduction in revascularization procedures such as angioplasty and bypasses.⁹ There is even new data suggesting that statins are beneficial to people with completely normal cholesterol levels due to their inflammatory benefits.¹⁰ This would fuel the case made by many physicians I know who suggest statins are safe enough that they could be put in bottled water (also not true, don't try that at home).

Obviously, this debate is impassioned and there are myriad statistics and case studies to fuel either side of the dilemma. My hope is just that people will continue to ask the right questions of their physicians, scholars and the media when making up their minds about statins. It is certainly a case by case determination, but one that I know many people, including myself, can relate to due to the high prevalence of heart disease in America.

Sources:

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² <http://www.cdc.gov/nchs/FASTATS/deaths.htm>

³ <http://www.americanheart.org/presenter.jhtml?identifier=163>

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⁵ <http://www.policyed.com/2009/09/letters-from-grassley-are-statin-safe-is-the-sky-blue.html>

⁶ <http://www.statinanswers.com/effects.htm>

⁷ <http://www.medicine.ox.ac.uk/bandolier/booth/cardiac/statmusc.html>

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⁹ <http://www.medicalnewstoday.com/articles/57687.php#>

¹⁰ <http://www.npr.org/templates/story/story.php?storyId=97007885>



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