



February 2010 Monthly Newsletter

FEATURED ARTICLES

TRICARE Final Rule—Tips for Manufacturers to Ensure That They Are Prepared

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On November 30, 2009, the U.S. District Court for the District of Columbia held that remand of the Final Rule was necessary so that the TRICARE Management Activity (TMA) could exercise its discretion in implementing the statute. However, the court was clear that the Department of Defense (DoD) could, in exercising its discretion, reissue a rule with the same substantive requirements. In view of this conclusion, the court decided not to void the TRICARE Final Rule, thereby leaving the voluntary agreement program in place.

The U.S. District Court has directed TMA to reissue the Final Rule. Specifically, TMA is to remove references in the preamble indicating that the law requires manufacturers to pay refunds for products purchased by the government at a price that was in excess of the calculated Federal Ceiling Price. Currently, the statute requires that FCPs apply to all retail pharmacy program prescriptions filled on or after January 28, 2008. However, the statute does not address who is responsible for the cost differential between the FCP and the actual price paid. In other words, the statute does not specifically state that the manufacturer is on the hook to retroactively reimburse the government for purchase prices greater than the FCP price dating back to January 28, 2008. This was the basis of the case brought on by the *Coalition for Common Sense in Government Procurement* in May, 2009.

Per the U.S. District Court's ruling, TMA was also required to show that it has considered options other than manufacturer refunds for getting to the required FCP price. However, it will be at the discretion of the agency to determine which of the different options is best for implementing the Final Rule. It is most likely that TMA will continue along the manufacturer refund course and document that it has, in fact, evaluated other options.

The court rejected the Coalition's argument that the Final Rule was impermissibly retroactive, on the grounds that it is the statute, not the rule itself, which made transactions on or after January 28, 2008 subject to FCPs. This ruling will most likely be appealed as many legal arguments remain related to this ruling. Currently, the DoD is in the process of collecting comments from the general public before the revised Final Ruling is issued. The comment period ends on March 11, 2010, and any individual who wishes to make an official comment can do so on the Federal eRulemaking Portal at www.regulations.gov.¹

Given all of this information, we are currently recommending that our clients to take a wait-and-see approach, and we recommend the following to ensure potential financial obligations are accounted for and to ensure that companies have unencumbered access to the TRICARE retail market:

1. Calculate and accrue for any retroactive liabilities.
2. Sign a Pricing Agreement with TMA agreeing to pay refunds going forward on a voluntary basis. (This agreement helps to ensure that products are assigned a Tier 1 or Tier 2 Uniform Formulary Status. Tier 1 and 2 products have a \$3 and \$9 co-pay, respectively, while Tier 3 products require a \$22 co-pay.² Further, a pricing agreement can help ensure that there are no pre-authorizations associated with the product.)
3. Wait for a formal request for payment prior to making any refund payments.
4. Monitor progress of any appeals by individual companies or the *Coalition for Common Sense in Government Procurement*.

Sources:

¹ http://www.tricare.mil/pharm_mfg/downloads/PharmFCP-FR2-9-10.pdf

² <http://www.tricare.mil/News/news.aspx?fid=306>

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2011 White House Budget

By John Jordan, CIS Compliance Associate

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February 1, 2010, President Obama released his proposed budget for the fiscal year of 2011. The fiscal year starts in October, 2010. The total for the 2011 budget is \$3.8 trillion. With this said, the current year's deficit will be a record breaking \$1.6 trillion, and 2011 projected deficit would be \$1.3 trillion. As many of us are wondering, how does this affect the Pharmaceutical area? The Department of Health and Human Services received \$81.3 billion in support from the President's budget. This is slightly down from the approximately \$82 billion estimated for 2010.

According to the Budget documentation some of the key highlights include:

- Supports health insurance reform by expanding patient-centered health research to give patients and physicians the best available information on what treatments will work the best for them. Also in supporting investments in health information technology, expanding prevention and wellness activities, and launching payment reform demonstration programs in Medicare.
- Adds \$290 million for healthcare centers to expand health care access to the medically underserved.
- Expands support for biomedical research, by providing an increase of \$1 billion for the National Institutes of Health.
- Invests approximately \$1.4 billion to strengthen food safety efforts.
- Supports over 8,500 healthcare professionals in medically underserved areas through the National Health Service Corps.
- Continues a commitment to invest in the Indian Health Systems.
- Invests more than \$3 billion for HIV/AIDS prevention and treatment activities to expand access to affordable healthcare and prevention services.
- Includes \$25.5 billion for a 6-month extension of the American Recovery and Reinvestment Act (ARRA) temporary increase in Federal Medicaid match.
- Increases funding towards bio-defense medical countermeasure development.
- Places renewed emphasis on preventing, detecting, and recouping fraudulent, wasteful, and abusive payments in Medicare, Medicaid, and Children's Health Insurance Program (CHIP).
- Increase of \$1.6 billion for child care to serve 235,000 more children than could be served without additional funds in 2011 for the programs Head Start and Early Head Start.
- Increases help for families caring for aging relatives at home.

The \$25.5 billion allocated for the 6-month extension of the ARRA is to help States maintain their Medicaid programs during a period of high enrollment and not enough funding within the State revenue systems. This provides the states with fiscal relief for an extended 6-month period. President Obama's budget also has an increase of \$250 million aimed toward the prevention of fraud. This is supposed to ensure that the government, including the Department of Justice, the Office of Inspector's General, etc., will strongly enforce the penalties to a manufacturer if there is a case of fraud towards the Medicaid, Medicare, and CHIP programs.

In addition to those accounts within the Department of Health and Human Services, there were a few changes that took place between the 2010 budget and 2011 budget proposal. The Administration decided to terminate the funding for the projects in the Health Care Facilities and Construction, the Denali Commission, which supports the construction of health facilities in Alaska, and the Delta Health Initiative, which consists of training healthcare professionals, and the purchase of equipment in Mississippi. These programs were designated as being private health care facilities and should not be included in Federal spending.

The Administration feels that it will be saving money in the long run by investing in certain sectors of the Department of Health and Human Services. For example, it feels that for every dollar spent to prevent and fight healthcare fraud and improper payments, approximately \$1.55 will be saved. Another view is that by putting forth legislation to provide additional program integrity authority to the Centers for Medicare and Medicaid Services (CMS), CMS can take specific actions against providers that do not follow appropriate Medicare payment requirements. Another method of fraud prevention is to require States to track and monitor providers' drug billing, tracking, and utilization patterns that could help deduce whether or not payments are being paid inappropriately.

With this budget in place, the President's advisors are predicting that the deficit will decrease in the future and that investing now will pay off in the long. According to an article in the New York Times, "Over 10 years, according to the administration, the budget would save an estimated \$1.2 trillion, mainly by ending the Bush tax cuts for the richest Americans and freezing some domestic spending for three years. But that total is roughly one-fifth of the size of the debt that will pile up from now to 2020, the budget shows." Peter Orszag, President Obama's budget director, also states that Obama will keep his promise towards reducing the deficit in half by the end of his term.

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There is also another side of the argument in regards to the deficit. According to some research, it is shown that the national deficit would reach \$18.6 trillion in the year 2020, if everything is accepted in President Obama's proposal. This statement was made by James Capretta, who served as an associate director at the White House Office of Management from 2001-2004. A deficit that large would likely start an economic crisis. "At some point, the flood of Treasury debt instruments worldwide would lead lenders to demand higher rates of return for their loans, or perhaps to runaway inflation — or more probably both. The result could be quite devastating to private-sector business investment, productivity and job growth, making it all the more difficult to get out from under the debt spiral that would ensue," states Capretta.

Sources:

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<http://www.nytimes.com/2010/02/02/us/politics/02budget.html>
<http://www.foxnews.com/politics/2010/01/31/obama-offers-budget-deficits-far-number-crunchers/>
<http://www.kaiserhealthnews.org/Columns/2010/February/020410Capretta.aspx>

First Phase of FDA's Transparency Initiative Commences

By Kimberly Gilbert, CIS Senior Compliance Manager

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The U.S. Food and Drug Administration began the first phase of its transparency Initiative in mid-January. The Transparency Initiative is aimed at explaining the agency's operations, how it makes decisions, and the drug approval process. This initiative was first formed in response to the Obama Administration's Open Government Initiative.¹ An internal task force of FDA senior employees was formed and assigned with the effort of how to make the FDA and its processes more transparent to the public. The Task Force is seeking public input from all sectors on issues related to transparency and developing recommendations for making useful and understandable information about the FDA activities and decision making processes more readily available to the public, in a timely manner and a user-friendly format, while appropriately protecting confidential information.²

Last year this initiative was kicked off by several activities aimed at eliciting the public's opinion on improving the agency's transparency. These activities included establishing a public docket, launching an online blog, and holding two public meetings, one in June and one in November. The agency was flooded with ideas, recommendations, and comments from various groups including regulated industry, consumers, patients, and healthcare providers on how to improve transparency, all of which contributed to the agency's decision to proceed with these recommendations in three phases.¹

The first phase of the initiative, which commenced in mid-January, focused on the questions and comments received by the agency regarding how the agency actually works, along with a request from the public for the agency to provide basic knowledge of the agency's operations. An online presentation was given by the chair of the FDA's Transparency Task Force, Principal Deputy FDA Commissioner, Joshua Sharfstein, introducing a web-based curriculum called "FDA Basics," which is aimed at helping the public better understand the inter-workings of the FDA. The curriculum is available and accessible to the public via a link on the FDA website. The curriculum includes questions and answers about the agency and the products it regulates. Short videos explaining various agency activities, as well as conversations with agency personnel about the work of their office, is also included in this online program. Future online sessions are also in the planning stages where senior officials from the FDA product centers and offices will answer questions on various topics. These sessions will be announced on the FDA website.³

The second phase of the Transparency Initiative is targeted to address the FDA's disclosure of information as well as the FDA's explanations to the public about the bases for agency decisions. This is in response to numerous comments the Task Force received about making information regarding agency activities and decision-making more transparent, useful, and understandable to the public. The third phase of the Transparency Initiative is intended to focus on comments the Task Force received about FDA's transparency regarding regulated industry.² The second and third phases of the initiative are sure to raise questions about why certain drug information is kept confidential, such as clinical trial data and drug safety reports. Although the Task Force acknowledges that some proprietary information probably should remain confidential, such as the formula for making a certain pill, and that concerns about patient privacy and other issues may limit full data transparency, the initiative opens the door to broader disclosure of unpublished clinical and preclinical studies, as well as information supporting agency decisions and regulatory actions. Currently, the FDA announces product approvals, but does not publicize when an application is turned down. It is up to sponsors to disclose when they file an application or withdraw a submission. The last two phases of the Transparency Initiative are expected to address complaints that the FDA is not disclosing important relevant information related to the drug approval process by revealing information that can explain agency decisions and hopefully reduce the confusion and scrutiny that the agency is under.⁴

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The major focus of the FDA is to promote and protect the public. The Transparency Initiative is way to promote accountability while increasing the agency's credibility with the general public. It is also a way of prompting the industry that it regulates to perform at a higher standard. By becoming more transparent and releasing information to the public that otherwise used to be confidential, the agency is pressing regulated industries to step up to the plate and provide information that is more thorough and complete the first time around. A prime example of this lack of standards is the current industry practice of rushing application submissions to the FDA to meet an internal deadline, even if the submissions are incomplete and will require an amendment in the end. By delaying an application by a few months, sponsors can ensure a submission is complete and ready for review, which will result in a faster approval than submitting an incomplete application and adding another six-month review cycle for an amendment.

Let's face it, transparency affects all of us working in a regulated industry in some way, including the compliance arena. This highly talked about topic sits at the top of the list when speaking with our clients about how to maintain transparency, while meeting the competitive demands of the industry and remaining compliant with regulatory standards. With all the information that is rapidly emerging, it is an arduous task for companies to determine not only how the information applies to their business specifically, but how to implement transparent practices within their organization to ensure they are in alignment with the FDA's initiative. At CIS, we partner with a wide array of clients across the pharmaceutical spectrum and we take responsibility for ensuring that the clients we work with are prepared and adapting to the shifting needs of the industry. We do this by implementing strategies that are designed and catered specifically to the needs of client, while translating and applying regulations and guidelines into everyday operations across all areas within an organization. We are committed to staying on top of the latest developments in the industry and ensuring our clients are equipped with the knowledge and tools necessary to survive in this challenging, diverse, ever-changing environment!

Sources:

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² <http://nursing.advanceweb.com/News/National-News/FDA-Unveils-Initial-Phase-of-Consumer-Focused-Transparency-Initiative.aspx>

³ <http://www.foodinsight.org/Blog/tabid/60/EntryId/233/FDA-Gets-Back-to-Basics.aspx>

⁴ <http://formularyjournal.modernmedicine.com/formulary/Policy+News/FDA-leaders-stress-safety-transparency-in-drug-dev/ArticleStandard/Article/detail/611696>

The Maine Thing

By Beth Kline, CIS Compliance Manager

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As the FDA is making an effort to streamline many of its processes in order to ensure that information about drugs is disseminated quickly and accurately, some individual states are considering legislation to mandate that in order to market there, sponsor companies must punctually disclose their clinical trial information in the appropriate public database registries. The state of Maine has implemented such legislation.

The state of Maine is requiring that "manufacturers and labelers of prescription drugs and biological products publicly disclose on Internet websites information about clinical trials of drugs or biological products that are or have been FDA-approved for marketing and are or have been dispensed, administered, delivered or promoted in Maine." The Maine law specifies 35 types or pieces of data that may be included when posting clinical trial data on a publicly funded website. These include the nature of the investigation, "the availability and status of the drug or biological product outside any clinical trial protocol," and the primary outcome measure(s).²

Over the past decade there has been a growing consensus that organizations conducting clinical trials on humans should register these trials publicly in the interest of transparency and accountability. While trials for serious and life threatening conditions previously required registration under the Food and Drug Administration Modernization Act 113 (FDAMA), various laws now require registration of most trials in the US and in various countries internationally. Non-compliance with these laws may result in fines, denial for NDA/BLA applications and the inability to market products.¹

The requirements of the Maine law pertain to studies initiated on or after October 15, 2002, Phase II – IV drugs, biologics, or drug/device combinations, and the timeframe for posting is within 21 days of First Patient Visit. As of October 27, 2009, Maine now also requires the registration of observational studies.

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Currently, Title VIII of the FDA Amendments Act of 2007 (the FDAAA) requires the registration of most Phase II, III and IV applicable drug clinical trials.³ Maine is considering an amendment to its disclosure law that would additionally require registration of Phase I trials, as well as making most optional fields mandatory. If passed, these changes would apply to all trials that started on or after October 15, 2002.

Within Maine, the consequences for non-compliance are being barred in the state from advertising prescription drugs on television, radio or in print and a penalty of up to \$10,000 per day. As other states follow Maine's example and institute their own requirements for clinical trial results disclosure, it is going to take staffing and time to ensure that companies are compliant with each and every applicable state and federal requirement. At potentially \$10,000 a day, compliance will certainly be more cost effective than non-compliance!

Sources:

¹ <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/ParticipatinginClinicalTrials/ucm154401.htm>

² http://www.maine.gov/dhhs/boh/clinical_trials.htm - Prescription Drug Clinical Trial Reporting – Final Rule

³ <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsTotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/default.htm>

Letters from a GP SME: Cardinal Health Distributes a Letter to Manufacturers on 340B Sales Reclassification

By Chris Cobourn, CIS VP, Regulatory Compliance

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On February 18, 2010, Cardinal Health distributed a "Dear Valued Supplier" letter to manufacturers explaining its new 340B Purchase Reclassification Policy. Cardinal states that the policy was designed to better serve "our mutual customers." Cardinal has made the policy optional and suppliers are asked to respond via email or fax to agree or decline to participate. Note: Cardinal states that any supplier who does not respond by April 1, 2010 will be considered to be in agreement with the reclassification policy. Suppliers who do not want to adhere to the policy must check the "No" box and return the letter.

It is important to understand what is meant by "reclassifications." According to the letter, if a customer who makes a purchase from a wholesaler, either under a contract or at WAC, subsequently dispenses the product under 340B eligible criteria, the customer can request that Cardinal Health "reclassify" the purchase as a 340B purchase. Essentially, Cardinal will consider the non-340B purchase to be a 340B purchase, as long as requests for Purchase Reclassification are received within 30 days of the close of the quarter in which the transaction took place.

So what impact could the Purchase Reclassification program have on pharmaceutical manufacturers and on Government Programs specifically? CIS has received numerous inquiries from manufacturers asking this question, and wondering what they should consider when determining whether or not to participate. One consideration is the value of Cardinal managing this process for manufacturers in an automated fashion, another is the potential complications for manufacturers who have Cardinal automatically reclassify the sales. Some of these complications could include:

- Reconciling changes to historical chargebacks
- The treatment of the sales in Statutory Pricing calculations, where a commercial sale in a previous period has to be reclassified as Government (potentially requiring a recalculation)
- The impact on the GPO administrative fee, where the original sale would have been included in the administrative fee calculation

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Another question for consideration is whether manufacturers are required to honor reclassification requests, or will have the option to do so. Given a situation in which an entity could have purchased under the 340B program but didn't, and then subsequently asks for the price retroactively, would the manufacturer be obligated to reclassify the purchase (thus granting the price retroactively)? I am not aware of any guidance that suggests that the manufacturer is required to grant a price retroactively in that situation. Additionally, if an entity is eligible to purchase under the 340B program there are restrictions on their purchasing under a GPO contract. These are questions and issues that you may want to discuss with your legal counsel before determining how to proceed with the reclassification policy.

In evaluating this specific reclassification scenario, manufacturers should not confuse it with other common historical PHS pricing issues, such as the following basic scenarios. (Note: These thoughts represent my opinions on 340B pricing issues; I am not providing guidance or legal advice!)

1. A 340B entity purchases at the offered 340B price, and subsequently it is determined that the price was too high (perhaps due to restatement of Medicaid Pricing by the manufacturer). In this scenario, I think the current and expected practice is for the manufacturer to correct the overcharge and make the entity whole (if the entity was undercharged, the manufacturer has no recourse).
2. A Non-340B eligible entity purchases at the 340B price; however, it is subsequently identified that the entity should not have purchased at that price. It is standard practice for the manufacturer to show sufficient due diligence to recover the under charge, as to not create a potential Medicaid Best Price violation.
3. A 340B entity makes a purchase, but at a "commercial price," such as off of a GPO contract, and later identifies that it could have purchased at the 340B price; this is the scenario that could allow a purchase to be reclassified under the Cardinal Health Purchase Reclassification policy. Manufacturers should consider the guidance on this, check with legal counsel if necessary, determine whether they are obligated to grant the price historically, and make a business decision on whether to grant the price.

If you are a manufacturer, make sure to fully evaluate the potential impact of the reclassification, especially on your GP calculations, as you determine how to follow Cardinal's new policy.

Additional Note: Upon inquiry – the OPA currently has no position on this letter.

Thank you, I appreciate any questions or comments,

Chris Cobourn

Baltimore IIR Summit Scheduling Update

Dear Readers,

Before the snow storm hit Baltimore, CIS was scheduled to run a full-day Advanced GP Workshop during IIR's GP Summit in February (GP 201). The Workshop was scheduled to include a Roundtable discussion involving different agencies; OIG, CMS, VA and OPA.

IIR's GP Summit has been rescheduled for Monday, March 22nd and Tuesday, March 23rd at the Hilton, Baltimore. The Conference will consist of a full two day agenda that will cover both GP 101 and 201 topics.

A finalized agenda from IIR is expected shortly, and some of the topics CIS will present include:

- GP Audit Approach
- Recalculations and Restatements: Understanding the Guidance
- Mergers, Acquisitions and Divestiture and the Impact on GP
- Hot Topics: Agency Round Table Discussion

We hope you will be able to make it to Baltimore. If you have any questions or suggestions regarding our sessions, please feel free to contact me.

Hope to see you there,

Chris Cobourn



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