

## Letter From The Editor: New Year, Same Goal. 2011 Marks the Beginning of Another Year for the Government to Continue Old Habits.

by Jamie L. Ghen, Esq., Director of Compliance, Ethics & Legal Affairs, and contributing author Maria Borda, Healthcare Compliance Intern

A New Year's resolution is a commitment made to a project or the reforming of a habit that is generally interpreted as advantageous. The start of a new year usually brings with it a list of resolutions. Some of us promise to eat less, save more money, or quit smoking for good. However, after recently announcing that 4.5 billion in settlements came from Big Pharma in 2010, the U.S. Government's New Year's resolution will likely be to continue to prosecute pharmaceutical companies for alleged violations and in so doing, become more personal to reach its goal.<sup>1</sup> Despite the fact that over the last twenty years the pharmaceutical industry has essentially eclipsed all other industries when it comes to government imposed settlements and penalties, and such settlements and penalties have *significantly* increased over the past five years particularly with respect to off-label marketing allegations, the government clearly feels that the threat of increasingly huge settlements alone will not change the behavior of the industry.



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### In This Issue

- 1 Letter From The Editor: New Year, Same Goal. 2011 Marks the Beginning of Another Year for the Government to Continue Old Habits.
- 4 When Can We Expect Substantive AMP Guidance?
- 5 The Injunction is Lifted! What it Means to Pharmaceutical Manufacturers and Their AMP Calculations
- 6 ACA Annual Fee on Branded Pharmaceutical Manufacturers and Importers
- 8 February 2011 Department of Defense (DoD) Pharmacy & Therapeutics Committee (P&T) Meeting
- 10 2011 Medicare Coverage Gap Discount Program Guidance
- 12 CIS Comments on Proposed 340B Civil Monetary Penalties and Dispute Resolution Processes

In October 2010, Eric Blumberg, the U.S. Food and Drug Administration's (FDA) litigation chief, made it clear that "fines are not working" and the government needs "to put something else on the scale to make people think twice, three times, before they promote drugs for unapproved uses . . . [Executives] need to take this seriously and find out what is going on in the marketing and sales divisions of their companies."<sup>2</sup> Despite having the authority to use criminal proceedings to prosecute over the past seven decades, the FDA is just now deciding to use this power to go after pharmaceutical executives in a seismic shift in the government's efforts to stem the tide of fraud and other alleged illegal pharma marketing practices, which the government believes a raft of million to billion-dollar settlements have so far failed to end.<sup>3</sup> However, alleged illegal pharma marketing practices is not the only area that the government has its eye on.

Back in November 2009, the U.S. Department of Justice (DOJ) announced its intention to use the Foreign Corrupt Practices Act (FCPA) to conduct investigations in the pharmaceutical and device industries.<sup>4</sup> The DOJ's FCPA

and health care fraud units have and continue to work together to investigate potential FCPA violations. According to the Pharmaceutical Research and Manufacturers of America's 2009 membership survey, close to \$100 billion of total sales for its members were generated outside of the United States, where health systems are operated or financed by government entities.<sup>5</sup> Federal prosecutors said that FCPA enforcement in the health care industries is overdue based on extensive government involvement in foreign health systems. For instance, doctors, pharmacists, and lab technicians employed by state-owned facilities could all be considered "government officials" in certain countries and scenarios. The types of corrupt payments targeted by the DOJ are similar to those items of value that would violate the Anti-Kickback Statute (AKS) if given within the United States, such as cash, gifts, travel, meals, educational grants, and honoraria.

Four months later, the FDA made it clear in a March 4, 2010, letter that it would begin using misdemeanor prosecutions and exclusion provisions to hold corporate executives personally accountable for fraud and abuse violations that occur on their watch.<sup>6</sup> The basis of personal liability was laid out by the U.S. Supreme Court when it concluded that the government may establish a prima facie violation of the federal Food, Drug and Cosmetic Act (FDCA) when "it introduces evidence ... that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."<sup>7</sup> The OIG has already begun using this exclusionary power to target individual pharmaceutical executives convicted of FDCA and other violations. On December 13, 2010, after pleading guilty to charges that the company had misled doctors and patients by claiming for five years that OxyContin was less prone to abuse than similar drugs because it was a long-acting narcotic, three former executives of Purdue Pharma were sentenced to a 12 year ban from participating in all government healthcare programs like Medicare and Medicaid.<sup>8</sup> This case demonstrates that a "responsible corporate officer" has a duty to know about the actions of his or her subordinates and must move to stop any wrongdoing once he or she learns of it.<sup>9</sup> Their status as senior executives, rather than their actual conduct, formed the basis for their liability and this case lends support to prosecutions under the Park Doctrine.<sup>10</sup>

In October 2010, Eric Blumberg told an industry audience that his agency was looking for cases to use what is known as the Park Doctrine as a tool to "change the corporate culture" of firms that have thus far shrugged off other penalties.<sup>11</sup> "I don't know when, where, or how many cases will be brought," Blumberg told a gathering of the Food and Drug Law Institute, "but if you are a corporate executive - or counsel advising such a client - I would not wait for the first case to decide now is the time to comply with the law. They won't get a mulligan on their conduct."<sup>12</sup> Under the Park Doctrine, a corporate officer is liable for illegal corporate actions the officer should have known about or was responsible for preventing. It stems from a 1970 case involving John Park, president of Acme Markets Inc. and the company's receipt of a citation for rodent infestations at a warehouse in Philadelphia. The FDA charged Park personally with violating sanitation laws after other rodent infestations were discovered despite a number of agency warnings. Park argued that as company president he was too far removed from warehouse supervision to be held responsible. The U.S. Supreme Court ultimately agreed with the FDA that Park, as president, was responsible for ensuring rodent-free warehouses. Park got off relatively easy with a \$250 fine. Prosecutors now hope to apply the rationale of Park to pharmaceutical company senior management and extract stiffer penalties, including up to a year in prison and \$100,000 fines. But wait, the government does not plan to stop here.

Last month, Lauren Stevens, former vice president and associate general counsel at GlaxoSmithKline (GSK) was charged by federal prosecutors with obstruction of justice and making false statements during an FDA probe into the company's promotion of a prescription drug in 2002. Stevens was indicted on four counts of making false statements, one count of obstruction of justice, and one count of falsifying and concealing documents. After pleading not guilty in early November, she was released without bond and ordered to surrender her passport. Her trial is scheduled for February 2011 and she could be facing lengthy prison sentences if found guilty. Each obstruction charge carries a maximum penalty of 20 years in prison, while each false statement count carries a maximum penalty of five years in prison. Richard DesLauriers, Special Agent in Charge, FBI, Boston Division, stated "[t]his indictment shows that we will investigate those responsible for unlawful acts done on a company's behalf. When individual employees are identified, they will be held accountable for

their illegal activity. Individual employees now know that concealing information from the government, obstructing investigative activity and making false statements to federal investigators will be investigated and prosecuted.”<sup>13</sup>

According to *Pharm Exec's* legal sources, the DOJ has picked a first case that it is confident it can win a conviction in.<sup>14</sup> Many industry experts believe that the new year will offer other executives at other firms the opportunity to do a “perp walk.”<sup>15</sup>

While the government plays a valuable role in protecting the safety of our pharmaceuticals and ensuring that profit motives do not ultimately drive the medical treatment Americans receive, the past several years indicate that the government has carte-blanche to launch prosecutions. Successful prosecutions create profound changes in how pharmaceutical companies do business and one cannot help but wonder what the impact from the new wave of executive liability will be. As we embark upon 2011 with New Year's resolutions of our own, the US Government will undoubtedly resolve to continue to develop innovative theories to prosecute violations under the FCA, FCPA and FDCA. 2011 also brings the possibility of pharma executives facing personal liability for fraudulent acts performed by their corporations — a prospect most executives should resolve to make every effort to avoid.

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Sources:

<sup>1</sup> <http://www.fercepharma.com/story/pharmas-2010-legal-settlements-top-45-billion/2010-12-23>

<sup>2</sup> <http://www.pbmattorneys.com/news.php?action=view&id=278>

<sup>3</sup> <http://www.cchrint.org/2010/11/17/justice-to-pharma-do-the-perp-walk/>

<sup>4</sup> Lanny A. Breuer, Assistant Attorney General, Criminal Division, Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009).

<sup>5</sup> Id.

<sup>6</sup> Letter from Margaret A. Hamberg, Commissioner of Food and Drugs, to Senator Charles E. Grassley (Mar. 4, 2010).

<sup>7</sup> *United States v. Park*, 421 U.S. 658, 673-74 (1975).

<sup>8</sup> *US ex rel. Radcliffe v. Purdue Pharma, LP*, 582 F. Supp. 2d 766 (W.D. Va. 2008).

<sup>9</sup> <http://www.nytimes.com/2010/12/16/business/16purdue.html>

<sup>10</sup> *US v. Park*, 421 U.S. at 658.

<sup>11</sup> <http://www.pbmattorneys.com/news.php?action=view&id=278>

<sup>12</sup> Id.

<sup>13</sup> <http://www.pharmalot.com/2010/11/pharma-lawyer-indicted-for-obstructing-the-fda/>

<sup>14</sup> Id.

<sup>15</sup> <http://blog.pharmexec.com/2010/11/17/lauren-stevens-charged-with-obstruction/>

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## When Can We Expect Substantive AMP Guidance?

by Chris Cobourn, Vice President of Regulatory Affairs

In my recent blog posting on the lifting of the Average Manufacturer Price (AMP) Injunction (<http://www.pharmacomplianceblog.com/blog/?p=3167>, in case you were on Christmas break and didn't get a chance to read it!), I provide some background and history from the publishing of the AMP Final Rule in 2007, through to the Patient Protection and Affordable Care Act (PPACA) and the October AMP. You may also be aware of CIS' position that we consider the October AMP to be an "interim AMP," in that we only have legislative level language now, and are in a waiting period for substantive guidance (<http://www.pharmacomplianceblog.com/blog/?p=2812>).

As I have been speaking with manufactures about our new world of AMP, the key question always comes up, "When can we expect regulations?" This is a very good question, and here are my personal thoughts on the topic.

First, it is unknown whether there will be any delays or changes due to the new makeup of Congress. With the Democrats still in control of the Senate, and with the veto power of the President, I think that actions taken by the Republicans in the House may be more symbolic at this point, but anything can happen. I base my thoughts below on the assumption that we are working with the current PPACA.

First, by "substantive guidance," I mean regulations. I believe that substantive guidance has to come in the form of regulations, and not "sub-regulatory guidance" (such as emails and/or letters to manufacturers) because of the intense scrutiny this is under. As AMP is now being published and used for federal upper limit (FUL), it is clearly on the radar of the retail industry, which has directly communicated to the Centers for Medicare and Medicaid Services (CMS) that the industry is looking for CMS go through the formal process of issuing regulations (<http://www.pharmacomplianceblog.com/blog/?p=2655>).

Regulations take time, and require a very specific process, starting with issuing Proposed Rules, seeking public comment, and eventually issuing Final Rules and having the

regulations entered in to the Code of Federal Regulations (CFR). If it does not go through this process, it is not a regulation. You may remember from 2007 that CMS issued Proposed Rules in January, the Final Rule was published in the summer and was then put in to effect in October.

So, my thoughts...

I think that regulations would take effect at the beginning of a quarter. Which means that if it is to be in 2011, it would be April, July or October. I think that given the time that it takes to go through the process and the fact that we have not seen Proposed Rules yet, it would be extremely optimistic to expect the process to be completed by the summer. I would not expect anything before October at the earliest.

I would hope that when we do see Proposed Rules, we can at least start getting an understanding of what the Final Rule may look like. I also reiterate from my earlier blog articles that you may want to read the retail industry's letter to CMS, where they outlined their feelings on what the rule should look like.

In the mean time, it is extremely important to document your current position and assumptions on the "interim AMP" that you will consistently follow until substantive guidance is published.

## The Injunction is Lifted! What it Means to Pharmaceutical Manufacturers and Their AMP Calculations

by Chris Cobourn, CIS Vice President of Regulatory Affairs

The hot news in the GP and Medicaid world last week was the agreement between the retail industry (NACDS and NCPA) and CMS on a motion to dismiss the Medicaid AMP (average manufacturer price) lawsuit. It was not a coincidence that this occurred after CMS published its final rule withdrawing the AMP regulation from the 2007 Final Rule.

The bottom line is that yes, the injunction is lifted. This seemed inevitable, as the retail industry pretty much got what they were looking for with the Patient Protection and Affordable Care Act, but was still holding the injunction out there until they saw where CMS was going with the new AMP (<http://www.pharmacomplianceblog.com/blog/?p=2993>).

So the key question is “what is next,” and when will we get new regulations to replace the withdrawn AMP regulations? To appreciate the importance of this, and to try and predict where it is going, it may be good to give a bit of history and context. Here is a brief history by way of bullet points:

- The 2007 CMS Final Rule defined a new AMP, and specified that AMP should be used for FUL (federal upper limit)
- This changed AMP from being used only for determining Medicaid Rebates that the manufacturer paid to the states, to also being used for establishing the Federal Upper Limit
- This got the retail industry’s attention, as the lower AMPs that would result from the new AMP definition would mean a lower FUL

- The retail industry brought CMS to court, with the argument that AMP as defined by the Final Rule did not reflect the true price at retail
- The Courts found merit in the argument, and put the injunction in place
- CMS told manufacturers to continue to use the AMP definition for their monthly and quarterly reporting
- Fast-forward to 2010..
- The Patient Protection and Affordable Care Act puts a new definition of AMP in place which, for the most part, reflects what the Retail industry was seeking in the injunction
- CMS withdraws the 2007 CMS Final Rule definition of AMP (which had to happen, as you could not have regulation in place that was in conflict with legislation)
- The injunction is dismissed

With the lifting of the injunction, the NACDS and NCPA announced a victory for patient care, and proclaimed that “combined with withdrawal of most of the AMP rule, these victories eliminate the need for the injunction that halted implementation of the AMP rule. Now that all of the issues raised in our AMP lawsuit have been resolved, there is nothing left to challenge at this time, and we are pleased to have reached agreement with CMS on a motion to dismiss the lawsuit.”

As of October, manufacturers are calculating what is considered by most to be an “interim AMP” until CMS issues guidance on how to implement the new definition of AMP (<http://www.pharmacomplianceblog.com/blog/?p=2812> )

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CMS is committed to developing new rules, but this will take time. They have to go through the process of publishing proposed rules, seeking public comment, and then developing the Final Rule so that it can be added to the Code of Federal Regulations (CFR).

If we try to get our arms around what the Final Rule for the new definition of AMP may be, it would be a good start to look at what the retail industry is seeking. I refer you to a blog article by Adam Fein of Pembroke Consulting, where he discusses the July 20 letter sent to CMS by the Retail industry in which they described what they were looking for (<http://www.drugchannels.net/2010/08/secret-amp-letter-emerges-ful-delay.html>).

This letter has a section at the end called NECESSARY REVISIONS TO CURRENT AMP RULE. I suggest that this may be relevant, because for the Retail industry to lift the injunction, they may be expecting that the coming AMP rule definition will incorporate a good deal of what they are seeking. If it does not, they will have the option of bringing it to court again.

There is an inherent difference in the use of AMP for Medicaid URA calculation and the use of AMP for FUL. But now the two are linked, and therefore the very strong voice of the Retail Industry will continue to have an impact on what will eventually become our AMP methodologies.

Thank you all, and I welcome your comments.



## ACA Annual Fee on Branded Pharmaceutical Manufacturers and Importers

by Mike Rowland, CIS Senior Associate

On the 30th of last month, the IRS issued information related to the annual fee for manufacturers and importers of brand name pharmaceuticals under section 9008 of the Affordable Care Act. This notice details the proposed methodology for calculating the annual fee, as well as how the IRS will use various sets of information to provide a preliminary 2011 number.

### Proposed Methodology

The proposed methodology will affect covered entities that have over \$5 million of aggregate branded prescription drug sales to the following government programs/entities: Medicare Parts B and D, Medicaid, the TRICARE retail program, and programs procuring drugs for the Department of Veterans Affairs and/or the Department of Defense. Covered entities are considered to be "any manufacturer or importer with gross receipts from branded prescription drug sales" (the manufacturer/labeler is identified by the NDC labeler code).

The ultimate goal will be to determine the ratio of the covered entity's branded sales to the total branded sales for all covered entities. The IRS and Treasury Department will calculate the fee based on information supplied by the other agencies for the second calendar year preceding the fee year. Because of this, an adjustment amount will also be included. The adjustment will be calculated by the IRS for each NDC, applied to the fee and will not be updated for information received after the initial amounts have been reported.

To assist the IRS in determining the calculation amount, information will be requested from both the covered entities as well as other agencies. The information requested from covered entities can be submitted via a Form 8947, available at [www.irs.gov](http://www.irs.gov). These forms should be submitted by every December 15, but will have a January 20, 2011 deadline for the initial submission. Information provided by the Agencies will include data from the following: Medicare Parts B and D, Medicaid, Department of Veterans Affairs, and the Department of Defense.

After receiving data from the Agencies and information from the covered entities, the IRS will calculate each covered entity's branded prescription drug sales for each Program by NDC. Branded drug sales will be calculated as follows:

*“(i) the sum of all the covered entity's branded prescription drug sales reported by the Program, less (ii) the sum of all branded prescription drug sales reported by the Program for each NDC for which the covered entity has appropriately claimed the orphan drug exclusion, less (iii) the sum of rebates reported by the covered entity on Form 8947 for the sales year.”*

To determine each covered entity's fee, the IRS will divide each covered entity's branded prescription drug sales taken into account for purposes of section 9008 by the aggregate branded prescription drug sales of all covered entities and multiply that fraction by the applicable amount for the appropriate year as set forth in section 9008.

#### **Preliminary Calculation**

The IRS will use the methodology described above to provide a preliminary 2011 fee calculation. This will include the fee amount, drug sales by NDC for each program, sales taken into account after application of section 9008 and aggregate sales used for all entities. Preliminary numbers will be sent to entities by May 2, 2011 and calculations will be finalized by August 15, 2011.

#### **Request for Comments**

Any responses should be delivered by June 2, 2011.

Written comments should be submitted to: Internal Revenue Service, CC:PA:LPD:PR (Notice 2010-71), Room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (Notice 2010-71), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC. Comments may be sent electronically to [Notice.Comments@irscouncil.treas.gov](mailto:Notice.Comments@irscouncil.treas.gov), with **Notice 2010-71** referenced in the subject line.

For further information on this notice, contact Celia A. Gabrysh at (202) 622-3130. For further information regarding Form 8947, contact Lou Milano at (908) 301-2106.

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#### Sources:

Internal Revenue Service. Annual Fee on Branded Prescription Pharmaceutical Manufacturers and Importers. Notice 2010-71. <http://apps3.irs.gov/pub/irs-drop/n-10-71.pdf>. Accessed December 9, 2010.



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## February 2011 Department of Defense (DoD) Pharmacy & Therapeutics Committee (P&T) Meeting

by Lisa C. McNair, CIS Senior Manager

An industry forum was recently held to announce the drug classes and drugs that are up for review at the next P&T Committee meeting scheduled for February 16th and 17th.

This year the Pharmacoeconomic Center (POC) is implementing electronic bidding for pharmaceutical manufacturers. The POC will set-up one-on-one's with pharmaceutical manufacturers to introduce them to the process and provide directions for electronic bidding. For the bidding process occurring in February of 2011, the POC will accept both electronic and paper bids.

Price and refund quotes for the February meeting are due no later than January 19, 2011. The one-on-one's will be scheduled prior to this date. The following drug classes and pharmaceutical agents are up for review:

### **CLASS: ANTILIPIDEMICS-2**

#### **SUB-CLASS: Bile Acid Sequestrants**

GENERIC NAME	BRAND NAME
COLESEVELAM HCL	WELCHOL
COLESTIPOL HCL	COLESTID
CHOLESTYRAMINE/SUCROSE	QUESTRAN
CHOLESTYRAMINE/ASPARTAME	QUESTRAN LIGHT

#### **SUB-CLASS: Fenofibrates**

GENERIC NAME	BRAND NAME
FENOFIBRATE, MICRONIZED	ANTARA
FENOFIBRATE, MICRONIZED	FENOFIBRATE
FENOFIBRIC ACID	FENOFIBRIC ACID
FENOFIBRATE	FENOGLIDE
FENOFIBRIC ACID	FIBRICOR
FENOFIBRATE NANOCRYSTALLIZE	TRICOR
FENOFIBRIC ACID (CHOLINE)	TRILIPIX

#### **SUB-CLASS: Fibric Acids**

GENERIC NAME	BRAND NAME
GEMFIBROZIL	LOPID



**SUB-CLASS: Omega-3 Fatty Acids**

GENERIC NAME	BRAND NAME
OMEGA-3 ACID ETHYL ESTERS	LOVAZA

**CLASS: GASTROINTESTINAL AGENTS****SUB-CLASS: Acetylsalicylic Acids**

GENERIC NAME	BRAND NAME
OLSALAZINE SODIUM	DIPENTUM
BALSALAZIDE SODIUM	COLAZAL
MESALAMINE	ASACOL
MESALAMINE	ASACOL HD
MESALAMINE	ROWASA
MESALAMINE	PENTASA
MESALAMINE	CANASA
MESALAMINE	LIALDA
MESALAMINE	APRISO

**SUB-CLASS: MISCELLANEOUS**

GENERIC NAME	BRAND NAME
SULFASALAZINE	AZULFIDINE
BUDESONIDE	ENTOCORT EC
ALOSETRON HCL	LOTROXEX
TEGASEROD HYDROGEN MALEATE	ZELNORM
HYDROCORTISONE	COLOCORT
HYDROCORTISONE	CORTENEMA

**CLASS: PANCREATIC ENZYME AGENTS**

GENERIC NAME	BRAND NAME
LIPASE/PROTEASE/AMYLASE	CREON
LIPASE/PROTEASE/AMYLASE	PANCREAZE
LIPASE/PROTEASE/AMYLASE	ZENPEP

Information regarding the upcoming P&T Committee meeting, the drug classes up for review along with utilization information is available on their website at [http://www.pec.ha.osd.mil/pt\\_review.php](http://www.pec.ha.osd.mil/pt_review.php).

Compliance Implementation Services provides DoD formulary assistance to pharmaceutical manufacturers. For additional information, please contact me at [lisamcnair@cis-partners.com](mailto:lisamcnair@cis-partners.com).

## 2011 Medicare Coverage Gap Discount Program Guidance

by Lisa C. McNair, CIS Senior Manager

On December 17, 2010 the Centers for Medicare & Medicaid Services (CMS) issued guidance to pharmaceutical manufacturers in regards to the 2011 Medicare Coverage Gap Discount Program, which becomes effective this Saturday (January 1, 2011).

We have inserted a link to this guidance below, but would like to highlight the following:

### 1. Health Plan Management System (HPMS)

In order to support the Medicare Coverage Gap Discount Program, CMS is updating the HPMS to contain a manufacturer's module which will automate communication and reporting between pharmaceutical manufacturers and CMS. It is the responsibility of the manufacturers to maintain and update their points of contact (POC) and labeler codes.

In order to prepare for the anticipated March 2011 release, pharmaceutical manufacturers must complete and submit the "Application for Access to CMS Computer Systems" to CMS no later than January 21, 2011. The form is located at <http://www.cms.hhs.gov/AccessstoDataApplication/>. Pharmaceutical manufacturers must include their "P" number when completing the form.

### 2. Manufacturer Contact Information

Pharmaceutical manufacturers are responsible for updating CMS when a POC changes. If CMS has not received updated POC information and a deadline is missed or a program requirement not meet, CMS will not waive any **requirements due to the communication going to the incorrect party.**

Pharmaceutical manufacturers may list more than one (1) POC, to do so, the form along with submission instructions are available at [http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp#TopOfPage](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage).

### 3. Covered Labeler Codes

CMS will update the Coverage Gap Participating Labeler Codes on the first business day of each month. The pharmaceutical manufacturer must submit the updated/

new labeler code information at least five (5) business days prior to the end of the month.

It is the responsibility of the manufacturer to ensure CMS has their most current and up to date labeler codes. Per CMS guidance, manufacturers that fail to update their labeler codes per the specified timeframes are not only responsible for paying the invoiced amounts but will not be able to successfully appeal these amounts.

CMS has provided a labeler code template along with instructions for submitting at [http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp#TopOfPage](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage).

### 4. Transfer of Labeler Codes

In the event a labeler code is transferred from one pharmaceutical manufacturer to another, the original manufacturer of the labeler code on file with CMS is responsible for all invoices until the transfer is complete.



CMS has provided explicit guidance to pharmaceutical manufacturers for the handling of this process. **CMS will not transfer individual National Drug Codes (NDCs), all NDCs associated with the labeler code must be transferred.**

[1] Manufacturers must submit a transfer request at least forty-five (45) days prior to the invoice date in order for the change to be included on the invoice. Any requests received after that timeframe will be reflected in the next quarter's invoices. The labeler code owner on record with CMS will remain responsible for the invoices until the transfer process is complete.

[2] The labeler code owner on record with CMS must complete and submit a request for the labeler code deletion. The email request must include the "P" number in the subject line, the pharmaceutical manufacturer assuming ownership and the effective date of the transfer. This request must be submitted to CGDPandmanufacturers@cms.hhs.gov.

[3] CMS will contact the identified new owner to confirm the transfer.

[4] Upon confirmation, CMS will update their records and all transactions will become effective at the beginning of the next quarter.

[5] If by chance the transfer of the labeler codes by CMS does not coincide with the timing of the transfers by the manufacturers, CMS has identified it is the pharmaceutical manufacturer's responsibility to reconcile any payments among themselves without the assistance or involvement of CMS.

## 5. Maintenance of FDA Record

Per the Manufacturers Agreement, manufacturers must ensure that all their NDCs are listed on the FDA NDC Directory. Manufacturers may not successfully appeal invoices based upon inaccurate or out-of-date FDA NDC Directory listings. In the event an update was made to the directory and not appropriately reflected, the manufacturer will need to submit documentation showing the FDA has been notified of an error.

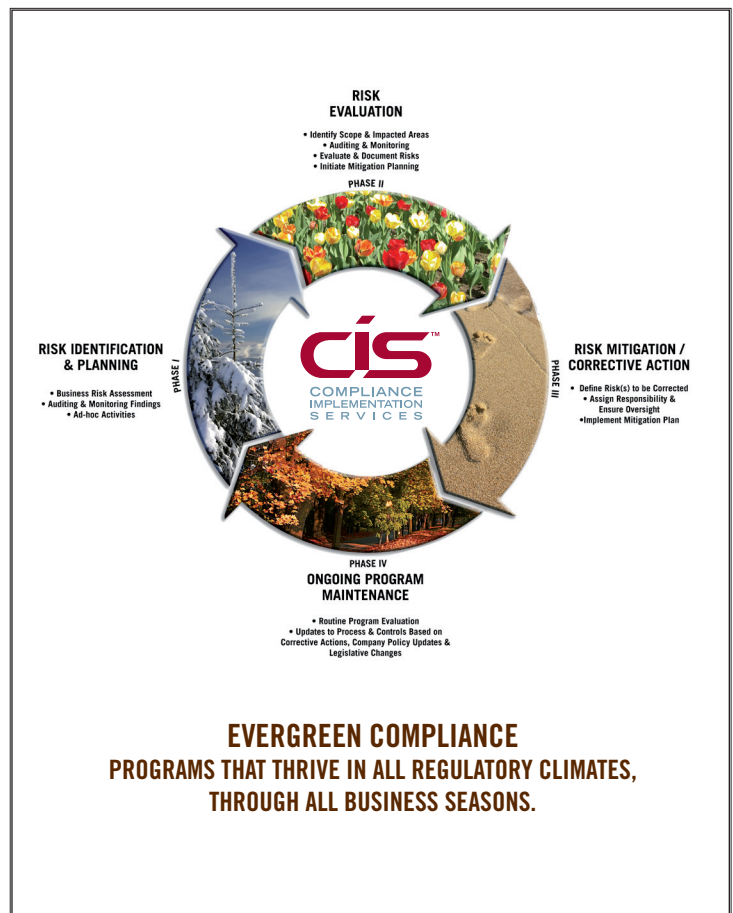
## 6. Miscellaneous Information

- Quarterly invoices are billed on the last business day of the month following that quarter.
- Invoices are based upon the Prescription Drug Event (PDE) activity received by CMS during the quarter.
- PDE's may include claims from prior quarters' dates of service. Manufacturers whom assume liability for discounts that were associated with another labeler will receive invoices for any events that occurred prior to the transfer of the labeler code.

Happy New Year!

Sources:

Guidance Document: [https://www.cms.gov/PrescriptionDrugCovContra/Downloads/manufacturerguidance\\_12162010.pdf](https://www.cms.gov/PrescriptionDrugCovContra/Downloads/manufacturerguidance_12162010.pdf)



## CIS Comments on Proposed 340B Civil Monetary Penalties and Dispute Resolution Processes

by Brian Coleman, CIS Senior Associate

On September 20, 2010, the Health Resources and Services Administration (HRSA) released two Advanced Notices of Proposed Rule Making (ANPRM) in response to section 7102 of the Patient Protection and Affordable Care Act (PPACA), which requires the Health and Human Services Department (HHS) to develop and issue regulations that establish (1) civil monetary penalties for manufacturers that knowingly and intentionally overcharge a covered entity for a 340B drug, and (2) a dispute resolution process between participating manufacturers and covered entities in the 340B Drug Pricing Program. HRSA released these ANPRM to allow covered entities, manufacturers and interested parties, an opportunity to provide comments in response and potentially help shape the proposed processes.

While the deadline for comments has come and gone (November 19, 2010), we at Compliance Implementation Services (CIS) have done our part to provide meaningful feedback to the HRSA which we hope addresses many of the concerns and uncertainties with the proposed processes from a pharmaceutical manufacturer standpoint. For those of you who are interested in what we had to say, a summary of our comments to the HRSA on the ANPRM for civil monetary penalties for manufacturers and the dispute resolution process is provided below. Enjoy!

### Summary of CIS comments on the proposed 340B civil monetary penalties

- Allow Manufacturers a 3 year window to proactively identify and correct unintentional errors in government pricing calculations that impact PHS pricing, without facing penalties.
- Provide clarification as to whether the authority to terminate a Manufacturer from the 340B Drug Pricing Program will be extended to the OPA.
- Provide clarification as to the definition of the term “knowingly and intentionally”, with the intent to distinguish between Manufacturers that proactively correct errors and those that intentionally overcharge covered entities.
- Establish thresholds that define the bar of materiality for reasonable changes in PHS pricing

that will not be subject to penalties, thus limiting penalties for routine, minor pricing changes.

- Establish a hearing process which allows for full discovery of how the pricing error occurred and judgment as to whether or not the overcharge was truly executed “knowingly and intentionally.”

### Summary of CIS comments on the proposed 340B administrative dispute resolution process

- HHS should provide operational guidelines for identifying and seeking resolution with purchasing entities for purchases that are out of compliance with the 340B Drug Pricing Program.
- Purchasing entities should be required to provide a sufficient level of documentation to evidence the appropriateness of a purchase under the 340B Drug Pricing Program. In addition, Manufacturers should have the ability to request specific documentation and records relating to a purchase in question, in lieu of a full scale audit (which can represent a heavy burden).
- Manufacturers should not be required to accommodate 340B Drug Pricing retroactively in situations where a purchasing entity realizes it was eligible for Public Health Service (PHS) pricing after the fact.
- Clearly define the role of the Office of Pharmaceutical Affairs (OPA) in the dispute resolution process.
- Establish a reasonable dispute materiality threshold, under which dispute resolution is not required.
- Allow for dispute resolution of both Manufacturers’ under and over-charges to purchasing entities, thus enabling Manufacturers the ability to recoup on undercharged transactions.
- Restrict dispute resolution of limited supply products to the portion allocated to PHS pricing, and allow Manufacturers to allocate a reasonable percentage of supply across government and commercial customers.
- Adopt a three-year window for restated PHS pricing.

We are anxiously awaiting HRSA’s release of its Proposed Rules for these new processes, and are interested to know your thoughts as well. Feel free to speak your mind by providing your comments below, and check back for an updated posting once the Proposed Rules are released.