

Guest Letter From the Editor: An Overview of CMS's Physician Fee Schedule Proposed Rule and the Impacts on Manufacturers

By: Scott Hoffman, Project Manager

In This Issue

- 1 [Guest Letter From the Editor: An Overview of CMS's Physician Fee Schedule Proposed Rule and the Impacts on Manufacturers](#)
- 3 [PHS Program Issues and Challenges From the Manufacturer Perspective](#)
- 6 [New Tricare Final Rule](#)
- 7 [Food and Drug Administration 2012 Performance Planning for Human Drugs](#)
- 10 [Recent FDA Updates in Response to OIG Report Regarding Financial Disclosure](#)

Coming this Fall...



- Improved search capabilities
- RSS Feed Support
- Breadcrumb-Trail Navigation
- State Map Interface
- CIS Integration
- Increased "Ask a Compliance Question" Capabilities

Check your Weekly PCX Newsletter for continued updates on the features and capabilities of the new PCX!

CMS recently released their Physician Fee Schedule Proposed Rule for the year 2012 (located at http://www.ofr.gov/OFRUpload/OFRData/2011-16972_PI.pdf). This document outlines how physicians will be reimbursed through the Medicare program. There are going to be some changes for the 2012 reimbursement year, specifically around how much physicians are reimbursed for certain products. The change in reimbursement is due to a shift from reimbursement at 106% of ASP to 103% of AMP¹ for certain products that meet the specified criteria outlined by CMS. This will have a direct financial impact on manufacturer sales, as physicians may decide to not purchase the product, based on the decreased reimbursement rate. Before examining the specific impacts of the current 2012 Physician Fee Schedule I think it would be beneficial to discuss some of the differences between Medicare reimbursement (based on ASP) and Medicaid reimbursement (based on AMP and in some states WAC). There are pretty substantial differences between ASP and AMP, especially considering the impact that the PPACA had on the AMP calculation last year. Both ASP and AMP are calculated and reported by manufacturers based on the products NDC number. While both are calculated and reported at the NDC level, Medicare does not use the NDC for purposes of reimbursement; it utilizes J Codes. At a high level, J Codes are issued by CMS for product classes and there are instances where multiple NDC's are reimbursed under one J Code. The J Code reimbursement rate is based on a blended rate of the ASPs for the products in the J Code as well as Relative Value Units (RVU) and other factors. I am not going to elaborate on the limitations of J Code reimbursement in this article, only describe the process at

¹ 42 CFR Parts 410, 414, 415, and 495 Page 205

an extremely high level. The last difference for purpose of this article, relates to manufacturers liability as it pertains to the reimbursement. Under Medicaid, if a manufacturer has entered into the Medicaid Drug Rebate Program, they would be responsible to pay rebates, if the State paid a physician on an outpatient basis. The State would submit an invoice to the manufacturer based on product utilization at the NDC# (Note: most states are able to crosswalk J-codes to a NDC number). In Medicare, the manufacturer has no responsibility for payments; however a manufacturer does submit a base rate when submitting the ASP price. Medicare reimburses the physician based on the established rates. Manufacturers are traditionally impacted by Medicare reimbursement through sales. If Medicare is not reimbursing the physicians at a realistic rate than they are less likely to purchase and prescribe the manufacturers product.

With that general understanding of the process, the next step is to examine how the Proposed Rule will impact the 2012 reimbursement process. The key piece of the Proposed Rule impacting reimbursement is CMS beginning to finally implement the OIG's WAMP/AMP comparisons to ASP. In the past the OIG has done studies and issued reports on the differences between WAMP/AMP and ASP, however, CMS has never substituted WAMP/AMP for purposes of physician reimbursement. In regards to WAMP, the 2012 Physician Fee Schedule Proposed Rule, WAMP will not be substituted due to the OIG reports not having sufficient information to determine whether or not the current thresholds utilized considered by CMS are inappropriate.² This is consistent with prior periods so there is no impact as it pertains to WAMP. However, CMS has a different plan for AMP.

Similar to WAMP in previous periods, AMP has not been substituted for ASP; that is going to change for reimbursement in 2012. In the latest quarterly report from the OIG that compared ASP and AMP, the Inspector General found that they could have "reduced Medicare expenditures by \$10.3 million in the quarter alone".³ The \$10.3 million does not seem like a large amount of money, however, that calculation was only a result of 14 codes that would have been substituted as ASP exceeded AMP by the specified CMS threshold. The threshold that the OIG utilizes and that CMS has proposed is that when ASP exceeds AMP by 5%, the AMP would be substituted for ASP in the determination

of the reimbursement rate.⁴ This substitution was actually proposed for 2011 reimbursement but was never finalized as CMS decided that there was a lack of guidance due to the pending implementation of the PPACA.⁵ With the PPACA now being in place CMS has decided to go ahead and implement the AMP based reimbursement calculation when:

1. ASP exceeds AMP by the 5% threshold for "two consecutive quarters immediately prior to the current pricing quarter" or "three of the previous four quarters prior to the current pricing quarter";⁶
2. The AMP and ASP comparisons are based on the same set of NDC's (discussed in the following paragraph); and
3. The calculation of 103% of AMP is actually less than the calculation of 106% of ASP for that product.

As noted above, CMS proposed to "apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of National Drug Codes for a billing code".⁷ Based on this language and the paragraph above it would seem to imply that the AMP substitution would only be for those products where the J Code relates to only one NDC, basically and first and only in class product. CMS considers this to be "complete AMP" data and in the latest quarterly study by the OIG (referenced in the preceding paragraph) there were only 365 billing codes where this criteria was applicable.⁸ Due to CMS's history of strictly relying on J Codes for physician based reimbursement, this appears to be the beginning steps in a shift in standardizing Medicaid/Medicare reimbursement under unique NDC's.

The last component of the legislation does not consider the 5i AMP calculation introduced in the H.R. 1586 FAA Air Transportation Modernization and Safety Improvement Act. The Proposed Rule clearly defines AMP as the "average price paid by wholesalers for drugs distributed to the retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturers".⁹ Under that definition of AMP it is reasonable to assume that the AMP substitution would not be applied to products that meet the 5i criteria or are not sold through retail channels.

2 42 CFR Parts 410, 414, 415, and 495 Page 203

3 42 CFR Parts 410, 414, 415, and 495 Page 212

4 42 CFR Parts 410, 414, 415, and 495 Page 205

5 42 CFR Parts 410, 414, 415, and 495 Page 206

6 42 CFR Parts 410, 414, 415, and 495 Page 205

7 42 CFR Parts 410, 414, 415, and 495 Page 208

8 42 CFR Parts 410, 414, 415, and 495 Page 212

9 42 CFR Parts 410, 414, 415, and 495 Page 207

The Proposed Rule will most likely be published in the July 19th, 2011 Federal Register. Similar to past Proposed Rules there would be a 60 day comment window for manufacturers and others to weigh in prior to the Final Rule being published. With a suspected Final Rule for AMP expected in the immediate future it will be interesting to see the stance CMS takes on implementing the AMP substitution.



Subscribe!

You can access more articles by going to pharmacomplianceblog.com



**BE PREPARED.
BE INFORMED.
IMPLEMENT CHANGE.**

CIS keeps you informed with valuable sources of up-to-date information, commentary, insights and best practices.

**The Pharma Compliance Blog
The Healthcare Reform Beacon
Pharma Compliance Insight Webinar Series
GP Forum Discussion Group
GP Industry Events**

For more information about these and other CIS resources, visit our website at www.cis-partners.com

PHS Program Issues and Challenges From the Manufacturer Perspective

By: Chris Cobourn, Vice President of Regulatory Affairs

In recent blogs, I have spoken to some of the issues and challenges in the program, specifically from the perspective of the manufacturer. It is important for manufacturers to understand these issues and to provide substantive and clear feedback to the Agency as they progress with rule making and issuing of guidance. Given the timing of the conference this week, I would like to outline what I see as some of the topical issues that you should be thinking about. Whether or not you provide formal feedback to the Agency, I welcome input myself, or a phone call if you want to share your thoughts with me on any of these topics.

Patient Definition & What Constitutes an “Eligible Patient” Under the PHS Program

<http://www.pharmacomplianceblog.com/blog/?p=3437>)

- For all practical purposes, manufacturers manage eligibility at the entity level, validating chargebacks against membership as listed on the Office of Pharmacy Affairs (OPA) website, and they have very limited visibility to the patient that the entity is serving. Manufacturers do see situations, however, where a majority of purchases by an institution go through the PHS clinic, and it has been made clear by some entities that they feel that purchases for almost any individual who comes through the clinic is an eligible patient, including even staff of the institution. The area of “patient definition” under the program has been a gray area for years. Health Resources and Services Administration (HRSA) did provide some clarification in 2007, but that did not fully resolve the issue, and the 2007 proposal has been withdrawn, so we are back to the 1996 Federal Register guidance. Most manufacturers believe that there should be some provisions around the patient/individual being serviced by the entity in a way that meets the mission of the program.

Purchasing of “Inpatient Products” Through the PHS Program

- Some manufacturers have products that are primarily used in an inpatient setting, such as heart transplant medication. They clearly understand that these products are covered under the 340B

agreement, and absolutely know that there are legitimate outpatient purchases for these products under the program. At the same time they also see purchasing activity where some institutions that have both inpatient GPO contracts and outpatient PHS eligibility purchase a large percentage of products off the PHS agreement. Manufacturers have struggled with what options they have to dispute this activity, or to ask for supporting information, and when they should make the OPA aware of potentially ineligible purchasing activity.

blog/?p=2531)

- A credit and rebill process can be put in place for many purposes, and is usually facilitated by the wholesaler. There are many operational and compliance issues with credit and rebills, and manufacturers should be aware of policies that wholesalers may put in place around the process. In my view, a manufacturer should understand the nature of the request, and only approve the request if it is for legitimate purposes, or else they may be giving retroactive PHS pricing to an entity that is not eligible for that pricing.

Audit Provisions, and Dispute Resolution

- Relevant to the prior 2 points, as well as other areas of potential disputes, manufacturers would like some clarity on what rights they have to dispute or audit entities where they believe there has been questionable or illegal purchasing activity. Performing audits can also be costly and time consuming for both the manufacturer and the entity. Therefore, manufacturers are hoping that upcoming dispute resolution guidance will help provide clarification in this area, and provide an efficient and reasonable process for both the manufacturer and the entity
- I believe that the Agency will work with manufacturers to develop a practical scope for an audit, and manufacturers can and should work with the Agency to evaluate audits where appropriate.
- We hope that in future dispute resolution rule making, that a reasonable and practical process can be put in place, for both the manufacturers and the entities, that allows for an efficient and fair dispute resolution . (<http://www.pharmacomplianceblog.com/blog/?p=2539>)

Some Children's Hospitals Still Seeking Retroactive Rebates
<http://www.pharmacomplianceblog.com/blog/?p=811>

- Guidance in February of 2010 allowed for Children's Hospitals to seek retroactive pricing under the PHS program. Specific criteria was established, and very few hospitals were eligible for the retroactive pricing. If manufacturers continue to receive requests, they should make sure that the entities understand the criteria. There could be other compliance risks, and possible Medicaid Best Price violations if a manufacturer gives retroactive PHS pricing to an entity that is not eligible for it.

Medicaid Restatements, Best Price (BP) True-ups and the Retroactive PHS Price Impact

- The PHS price is derived directly from the manufacturer's submitted Medicaid Average Manufacturer Price (AMP) and calculated Unit Rebate Amount (URA). CMS has published guidance for Medicaid restatements within a 12 quarter window. Restatements can come about by identification of data or methodology errors, and manufacturers routinely update pricing appropriately. Manufacturers also report quarterly Best Price (BP) based upon an estimated BP or a maximum-achievable BP, as BP is required 30 days after the end of a quarter and actual rebate data is not yet available. Manufacturers routinely "true-up" their reported BP when actual data is available, this results in a change to the calculated URA, and therefore a change in the PHS price. Where there has been no official guidance by OPA on the changes of historical PHS prices due to a change in the Medicaid calculations, it has been communicated by the Agency and understood

The Proposed PHS User Fee

<http://www.pharmacomplianceblog.com/blog/?p=3836>

- The Agency has proposed a nominal user fee, which would be added to the PHS price, collected by the manufacturer and then sent to the Agency. The fee is seen as critical to support the Agency in managing the program and promulgating rules, and they seek industry input on the operational aspects of the proposed fee.

The Credit and Rebill process

(<http://www.pharmacomplianceblog.com/>)

that manufacturers who identify that the revised PHS price is lower than the originally calculated PHS price should pay or credit the difference back to the individual entities. Additionally, if the manufacturer determines that with the new price they undercharged the entity they cannot recover the difference. The paying or crediting of price differences to the entities has been a heavy operational burden to the manufacturers, as they have to identify each individual purchase and entity and process credits, often minor in nature.

The Medicaid Base AMP Dilemma Under the PPACA Creates a Scenario for Penny Pricing Under the PHS Program

- Under the Patient Protection and Affordable Care Act, AMP was redefined to the Retail Community Pharmacy Class of Trade or the Alternative 5i AMP. This has resulted in higher AMPs for most branded manufacturers. A manufacturer's quarterly Unit Rebate Amount compares each quarter's AMP to the manufacturer's initial, or Base, AMP and establishes a penalty if the price difference indicates that the manufacturer has raised prices more rapidly than the rate of inflation (based upon the published CPI-U). As the new AMPs under the PPACA are higher than the original AMPs under the older methodology definition, it is creating an artificial CPI-U penalty. For some manufacturers, the Unit Rebate Amount became the AMP (as the URA cannot exceed AMP). This results in the PHS price being calculated at zero, AMP minus AMP, resulting in "penny pricing" for the PHS price.

Products With Limited Supply

- There are some manufacturers that have products with limited supply. These may be related to the manufacturing process, or that the products are blood derivatives. Manufacturers have worked with the Agency to develop policies to try to ensure fair and equitable access to the product to commercial and government (Medicaid, VA and PHS) markets by allocating product levels across the markets. The OPA has been very willing to work with manufacturers to develop fair and reasonable policies.

Clarification on Requirement for Manufacturers to Submit Pricing to the OPA

- It is my understanding that the "pricing database" will be operational and required at some point in the future. Manufacturers currently submit PHS pricing information to wholesalers, and would like to understand the pricing submission process and how the information will be made available to entities.

340B Identifier, and Difficulty Matching to Manufacturer Systems

- It is very difficult for manufacturers to coordinate their contracting system data with the OPA membership list. The OPA membership list uses the 340B identifier, which does not match to the DEA or HIN number normally used by manufacturers and by wholesalers to identify customers for purchasing under contracts. Additionally, the nomenclature of entity names often does not match the name that may be in a manufacturer's system. Mismatches on abbreviations, etc., make it difficult to match the entities by name. This is further complicated by trying to match a specific 340B eligible entity within an institution that has multiple sites, addresses and DEA numbers. The matching of manufacturer's contracting systems to the OPA database is very manual and time consuming.

Bill To/Ship To Matching - Can a Manufacturer Deny a Chargeback if the Two Do Not Match

- Manufacturers deny chargebacks to an entity that does not have a Bill To and Ship To match to the entity as listed in the OPA database. Some entities may not have their information up to date in the OPA database. So they may actually be eligible, but the manufacturers are unable to verify their eligibility and therefore deny the chargebacks.

The Proposed Orphan Rule

<http://www.pharmacomplianceblog.com/blog/?p=3804>

- On May 19, 2011, the HRSA published a proposed rule regarding the exclusion of orphan drugs for certain covered entities under the 340B Program. The proposed rule would limit the orphan drug exclusion to only the indications for which the product received orphan drug status. As the indication for which a drug was prescribed is not available to manufacturers through chargeback

submissions, it would be up to the covered entity to determine whether the product was prescribed for an orphan indication (in which case they would not be able to buy the product at the 340B price) or a non-orphan indication (where they could).

Evaluating the Impact of Medicaid Managed Care Rebates on 340B Service Providers

<http://www.pharmacomplianceblog.com/blog/?p=3839>

- A significant change in the PPACA is the extension of Medicaid rebates to Managed Care Organizations (MCOs) that provide prescription drug services for Medicaid patients. A key area of recent interest we are hearing is the effect the requirement for such rebates will have on contractual and reimbursement arrangements between MCOs and 340B service providers.

New Tricare Final Rule

By: Lisa C. McNair, Senior Manager

TRICARE has issued a new final rule which allows a TRICARE retail network pharmacy to be an authorized provider for the administration of covered vaccines in the retail pharmacy setting. The final rule is effective August 12, 2011.

Previously, vaccines were only covered as a TRICARE medical benefit unless administered by a pharmacist in a pharmacy under the interim final rule issued in December 2009, published at 74 FR 65436. The interim final rule provided coverage of seasonal flu vaccines, H1N1 flu vaccines and pneumonia vaccines. With the implementation of this final rule, TRICARE is including vaccines under the pharmacy benefit when provided at a TRICARE retail network pharmacy, as long as the pharmacy is functioning in the scope of their state laws. Along with being cost-effective, this change will allow the ease of processing claims and reimbursement for services. Vaccines available to TRICARE beneficiaries are those authorized as preventative care under the TRICARE basic program benefits at 32 CFR 199.4 and for Prime enrollees at 32 CFR 199.18 (immunizations for beneficiaries age six (6) and older; immunization recommended by the Center for Disease Control and Prevention (CDC); and immunizations required for dependents of active duty personnel who are traveling outside the United States as a result of an assignment and the travel is being performed under orders issued by a Uniformed Service). Information on recommended vaccinations is located at <http://www.cdc.gov/vaccines> or <http://www.tricare.mil/pharmacy>.

The recently released final rule amends:

- §199.6 – TRICARE-authorized providers (d)(3) to read: “Pharmacies. Pharmacies must meet the applicable requirements of state law in the state in which the pharmacy is located. In addition to being subject to the policies and procedures for authorized providers established by this section, additional policies and procedures may be established for authorized pharmacies under § 199.21 of this part implementing the Pharmacy Benefits Program.”
- Revises §199.21(h) to read, “Obtaining pharmacy

CalcPartner™

**MANAGING GOVERNMENT
PRICING CALCULATIONS**

CIS.

**Your Government Programs
Calculations and Claims Partner.**

ClaimsPartner™

**THE HASSLE-FREE WAY
TO MANAGE INVOICES**

services under the retail network pharmacy benefits program.”

- Adds new paragraphs (h)(4) and (i)(2)(ii)(D) to §199.21:
 - (4) Availability of vaccines/immunizations. A retail network pharmacy may be an authorized provider under the Pharmacy Benefit Program when functioning within the scope of its state laws to provide authorized vaccines/immunizations to an eligible beneficiary. The Pharmacy Benefits Program will cover the vaccine and its administration by the retail network pharmacy, including administration by pharmacists who meet the applicable requirements of state law to administer the vaccine. A TRICARE authorized vaccine/immunization includes only vaccines/immunizations authorized as preventative care under the basic program benefits of §199.4 of this part, as well as such care authorized for Prime enrollees under the uniform HMO benefit of §199.18. For Prime enrollees under the uniform HMO benefit, a referral is not required under paragraph (n)(2) of §199.18 for preventative care vaccines/immunizations received from a retail network pharmacy that is a TRICARE authorized provider. Any additional policies, instructions, procedures, and guidelines appropriate for implementation of this benefit may be issued by the TMA Director.
 - (i)(2)(ii)(D) – \$0.00 co-payment for vaccines/immunizations authorized as preventative care for eligible beneficiaries.

<http://www.gpo.gov/fdsys/pkg/FR-2011-07-13/html/2011-17516.htm>



Food and Drug Administration 2012 Performance Planning for Human Drugs

By: Erica Brooks, Senior Compliance Manager

The 2012 Budget talks are dominating our states and federal governments. As we prepare to move into the next year, balanced budgets are causing our leaders to truly debate the issue of debt. Within the proposed federal budget, the Department of Health and Human Services have released the proposed budget for the Food and Drug Administration 2012 fiscal year.¹ Under the Food and Drug Administration, the proposed 2012 Budget is just about 4.4 billion dollars. This is an increase from 2010 of about 1.1 billion dollars.

The following information summarizes the FDA budgets for fiscal years 2010, 2011, and 2012.

Program ¹	FY 2010 Enacted ²	FY 2010 Adjusted Enacted	FY 2010 Actual	FY 2011 Continuing Resolution	FY 2012 PB request	+/- FY 2010 Adjusted Enacted
Budget Authority	\$2,363,786	\$2,361,786	\$2,369,396	\$2,361,786	\$2,743,965	\$382,179
User Fees	\$922,280	\$922,280	\$748,265	\$1,011,175	\$1,616,316	\$694,036
Total	\$3,286,066	\$3,284,066	\$3,117,661	\$3,372,961	\$4,360,281	\$1,076,215
FTE	12,335	12,335	12,381	12,381	14,436	2,101

¹ FY 2010, FY 2011 and FY 2012 do not include an estimated 77 reimbursable, 51 PEPPAR, 6 HCFAC and 11 IDDA FTE and the associated funds. FY 2010 Actuals do not include \$1.3 million for CRADA.
² The FY 2010 Enacted column displays the FDA appropriation provided in P.L. 111-80 plus the \$2 million Gulf Spill one time supplemental provided in P.L. 111-212. The \$2 million is not included in the FY 2010 Adjusted Enacted column.

Along with the 2012 Budget, the 2012 performance planning results were published in the FY 2012 Online Performance Appendix for Human Health Services. Within the document is the Food and Drug Administration- FY 2012 Online performance Appendix. The objectives align with the FDA Strategic Priorities 2011-2015 document. Within the Appendix, the different sectors of the FDA present the details of their plan. The different sectors include: Food, Human Drug, Biologics, Animal Drugs and Feed, Medical Devices and Radiological Health, National Center for Toxicological Research, Office of Regulatory Affairs, Tobacco, and the Headquarters and Office of the Commissioner Performance Details. For the Human Drug Performance Details, the agency outlined nine objectives for 2012. See below a summary taken from the Appendix of the objectives.²

1. Percentage of Standard NDAs/BLAs and Priority NDAs/BLAs within 10 months.

This performance goal focuses primarily on improving the effectiveness and efficiency with which the FDA processes

new drug and biologics licensing applications. CDER exceeded the review performance goal for standard reviews for the FY 2009 cohort by reviewing 92% of standard NDAs/BLAs within 10 months. CDER did not meet the review performance goal for priority reviews for the FY 2009 cohort. Longer CDER priority review times for FY 2009 reflect the impact of several factors. To ensure a rapid and compliant process CDER is continuing to examine the expanded review process requirements, while training the significant number of newly-hired staff to enable them to achieve review expertise as rapidly as possible.

2. The total number of actions taken on abbreviated new drug applications in a fiscal year.

Generics play an important and increasing role in providing safe, effective, and affordable drugs to the American public and thereby in controlling health care expenditures. The target for FY 2009 and FY 2010 was 1,900 actions; the FY 2011 target is 2,000 actions, the FY 2012 target is to maintain 2,000 actions.

In FY 2010 CDER's generic program took 2,079 actions – exceeding the target measure by 179 actions.

3. Improve the safe use of drugs by patients and health care providers by reviewing safety labeling changes required under FDAAA within the timeframes established by FDAAA.

CDER is implementing a policy of more transparency in ensuring patients and physicians have the most up-to-date and complete information necessary to make treatment decisions. In FY 2010, CDER reviewed 94% of safety labeling change supplements within the timeframe

specified by FDAAA.

4. The Unit Cost associated with turning a submitted Adverse Event Report into a verified record in the database.

The collection and analysis of data by FDA staff must occur throughout the entire life cycle of the product to identify unexpected safety risks associated with the use of a human drug that could not have been predicted by clinical trials and biostatistical analysis. Reports of these unexpected safety problems, called adverse events, are captured in the Adverse Event Reporting System (AERS), a critical component of FDA's post-marketing safety surveillance systems for all drug and therapeutic biologic products. The targets for FY 2012 and FY 2011 have been reduced to \$10 per report.

In FY 2003, the cost per report was \$21.91 per report. In FY 2008, the actual cost per report was \$10.59 per report. In FY 2009 the cost per report rose slightly to \$10.79 per report but was still below the target of \$12 per report. In FY 2010, the cost per report was reduced to \$7.35. The overall savings to FDA from electronic submission continues to increase due the increasing numbers of received reports.

5. The percent of manufacturer submitted expedited adverse event reports received electronically compared to all expedited adverse event reports received from industry.

Drug manufacturers are required to submit to FDA reports of adverse events they receive related to their products. Currently, manufacturers may submit these reports to CDER by mail, fax, or electronically through CDER's MedWatch portal. As electronic reporting streamlines CDER processes, saves time and money, and ensures quicker reporting, CDER is committed to increasing the proportion of reports submitted electronically. CDER's target for FY 2010 of 80% of all manufacturing reports submitted electronically was exceeded by 7%. The FY 2011 and FY 2012 targets are set at 90%.

The percentage of all reports submitted electronically (not limited to industry reports) grew from 33% in FY 2006 to 87% in FY 2010.

6. Number of people for whom FDA is able to evaluate product safety through multiple miniature Sentinel pilots.

The goal of the Sentinel Initiative is to create a national, integrated, electronic system (the Sentinel System) for

JOIN CIS FOR OUR MONTHLY



PROGRESSIVE THINKING FOR GOVERNMENT
PROGRAMS AND FEDERAL CONTRACTS
PROFESSIONALS

CONTACT US AT INFO@CIS-PARTNERS.COM
FOR MORE INFORMATION

monitoring medical product safety. The Initiative, which will be developed and implemented in stages, will ultimately enable FDA to leverage the capabilities of multiple, large databases (e.g., electronic health record systems, medical claims databases) to augment the Agency's existing safety monitoring capability. In FY 2010, miniature Sentinel pilots enabled FDA to reach 60 million patients. With the addition of a collaborative project with Federal partners, expectations are to be able to reach 70 million people by late FY 2011, and maintain that level of access in FY 2012.

7. Number of safety analyses that are conducted using Medicare and Medicaid data through the SafeRx Project.

The SafeRx project is using Medicare and Medicaid data to perform in-depth safety analyses. Analyses involve many types of active surveillance and epidemiology methodologies, which may last many months.

8. Number of foreign and domestic high-risk human drug inspections.

FDA is continuing to develop a more quantitative risk model to help predict where FDA's inspections are most likely to achieve the greatest public health impact. The Risk-Based Site Selection Model provides a risk score for each facility, which is a function of four component risk factors – Product, Process, Facility, and Knowledge. For FY 2010, the target was increased to 700 to reflect the FY 2009 Appropriations. In FY 2011, the target is being increased by 50 inspections for a new target of 750 inspections. In FY 2012, the target is being maintained at the FY 2011 level. FDA exceeded the FY 2010 goal of 700 by inspecting 705 high-risk foreign and domestic drug manufacturers.

9. Percentage of television advertisements requiring submission reviewed within 45 days.

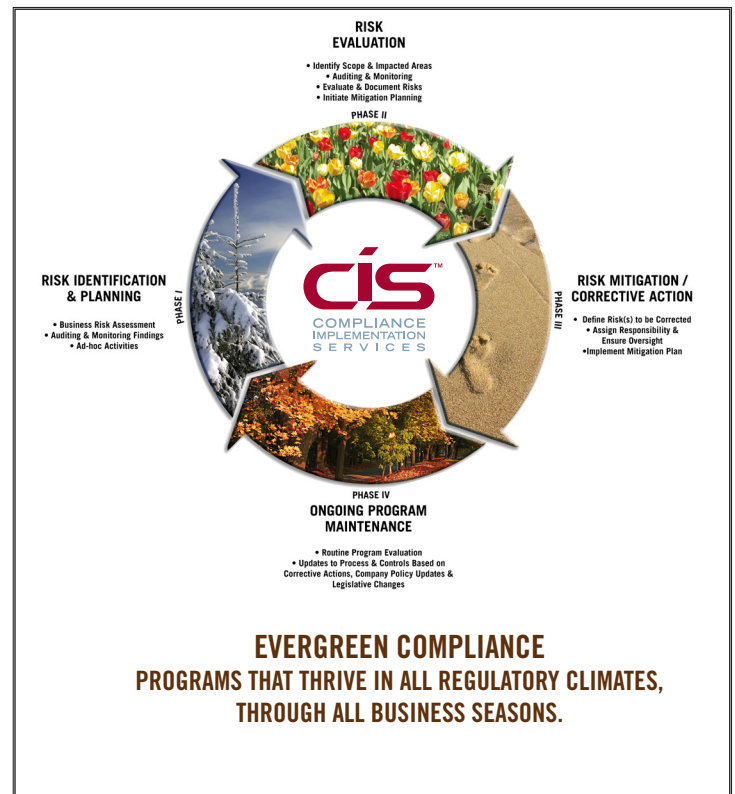
Under the Food and Drug Amendments Act of 2007 (FDAAA) FDA gained authority to require submission of television advertising for review 45 days before dissemination in order to protect the well-being of consumers and ensure advertising information remains consistent with prescribing information for the product under review. The FY 2010 target of issuing draft guidance and establishing the baseline was not met as the draft guidance is still undergoing review. The target for FY 2011 is to issue the draft guidance to industry on the program and receive submissions for pre-review. The FY 2012 target is 30% of reviews of TV ads completed within 45 days for advertising identified as meeting the high-risk criteria.

In 2012, the Human Drug sector of the FDA has decided to keep their objectives to the targets set forth in 2011. The overall proposed budget for the FDA has increased from 2010 by 1.1 million. The proposed objectives are in line with the strategic plan. For industry professionals who are beginning 2012 planning, the FDA initiative can serve as supplemental information of where focus should be placed. Although 2012 mirrors, 2011 this was increased monitoring from 2010. As budget talks continued, we will need to stay informed on if they will have any influenced objectives set forth by the FDA.

References:

Fda.gov and hhs.gov:

1. Department of Health and Human Services ;Food and Drug Administration FY 2012 Budget
2. Department of Health and Human Services ;Food and Drug Administration; FY 2012 Online Performance Appendix.
3. FDA Strategic Priorities 2011-2015



Recent FDA Updates in Response to OIG Report Regarding Financial Disclosure

By: Kristin Williams, Compliance Associate

In January 2009, the Office of Inspector General (OIG) issued a report, OEI-05-07-00730, entitled, “The Food and Drug Administration’s Oversight of Clinical Investigators’ Financial Information.” In this report, the OIG cited several critical findings regarding FDA review of investigator financial disclosure information that led to FDA’s decision to update its current guidance on financial disclosure by clinical investigators and increase its inspection activity of Financial Disclosure information. A new draft guidance, “Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators” was released by the FDA in May 2011¹ and the updated BIMO 7348.810 Compliance Program Guidance Manual was implemented March 11, 2011.² The new draft guidance is intended to supersede the guidance released in March 2001, which was strictly for industry.

The OIG reviewed financial disclosure information for all approved marketing applications from 2007, and discovered that FDA has not had thorough oversight of financial disclosure information for investigators. In fact, according to the report, the “FDA did not document a review of any financial information for 31 percent of marketing applications.”³ However, deficient applications were still gaining approval as it was reported that, “42 percent of FDA-approved marketing applications were missing financial information.”³ In addition, 20 percent of applications in which investigators disclosed financial interests, the sponsor nor FDA took any actions to ensure that potential bias was minimized.³

The OIG raised an important issue related to FDA’s review of the financial disclosure documentation. FDA could not determine whether a sponsor submitted all financial information for all clinical investigators involved in each covered trial, because sponsors did not provide a complete

list of all clinical investigators and sub-investigators to reference.³ The new draft guidance addresses this issue by outlining how FDA reviewers should document a complete list of clinical investigators for each covered trial and specific instructions for what sponsors should provide. The updates reveal a shift in process by FDA to implement 21 CFR part 54 and enforce increasing quality standards.

The OIG findings and recommendations triggered FDA to emphasize the review of financial disclosure information, which is a highlight of the new draft guidance.¹ The new guidance incorporates FDA steps for documentation of Financial Disclosure reviews and the actions taken when issues arise.¹ The Question and Answer portion in the draft guidance discusses what the agency considers “due diligence” of the sponsor in gathering this information from investigators.¹ In response to the OIG report and the increased expectation of “due diligence”, FDA has also added a section in BIMO 7348.810 CPGM outlining the increased inspection procedures for Financial Disclosure information.

FDA’s response shows a higher agency standard when it comes to reviewing financial disclosure information in marketing applications and during inspections. This in turn means FDA will hold sponsors to the same or higher standards.

CRPartner™
Compliance and Reporting
Obligation Relief

- 1 FDA DRAFT Guidance for Clinical Investigators, Industry, and FDA Staff – Financial Disclosure by Clinical Investigators. May 2011.
- 2 BIMO 7348.810 FDA Compliance Program Guidance Manual. March 11, 2011.
- 3 OIG Report OEI-05-07-00730, “The Food and Drug Administration’s Oversight of Clinical Investigators’ Financial Information.” January 2009.