

Guest Letter From The Editor: The Federal Awardee Performance and Integrity Information System (FAPIS) – What You Need to Know, Now.

by Dana Zelig, CIS Compliance Manager

If your federal contracting team has been working diligently to meet the requirements established in last year's FAPIS Federal Acquisition Regulation (FAR) Final Rule, your work will soon gain some unanticipated visibility throughout your organization. If, on the other hand, your Federal Contracting team has not yet begun to tackle compliance with FAPIS requirements, or if (gasp) you haven't heard of FAPIS yet, you have some catching up to do.



So what is FAPIS? The Past Performance Information Retrieval System (PPIRS) [1] website provides the following explanation:

The Duncan Hunter National Defense Authorization Act of 2009 [2] (Public Law 110-417) was enacted on October 14, 2008. Section 872 of this Act required the development and maintenance of an information system that contains specific information on the integrity and performance of covered Federal agency contractors and grantees. The Federal Awardee Performance and Integrity Information System (FAPIS) was developed to address these requirements. FAPIS is a distinct application that is accessed through the Past Performance Information System (PPIRS) and is available to federal acquisition professionals for their use in award and responsibility determinations. FAPIS provides users access to integrity and performance

Continued on page 2

In This Issue

- 1 Guest Letter From The Editor: The Federal Awardee Performance and Integrity Information System (FAPIS) – What You Need to Know, Now.
- 4 The Obama Administration's Ongoing Commitment to Lower Health Care Costs
- 6 Crackdown on Health Care Fraud: The Issues Arising from Significant Enforcement Tools Used in 2011 and Potential Impact on Pharmaceutical Manufacturers
- 7 Manufacturers Release #83
- 8 New 340B/OPA User Fees Detailed in the Proposed FY2012 Federal Budget
- 10 ASP to AMP Comparisons: Report Says Still on the OIG's Radar
- 11 Update Your ICF Procedures, New Rule Effective March 7, 2011
- 12 New Ideas for New Drug Development

information from the FAPIIS reporting module in the Contractor Performance Assessment Reporting System (CPARS) [3], proceedings information from the Central Contractor Registration (CCR) [4] database, and suspension/disbarment information from the Excluded Parties List system (EPLS) [5].

of fault with either a monetary fine or penalty greater than \$5,000 or reimbursement, restitution, or damages greater than \$100,000, or other acknowledgment of fault?

If Yes:

Enter information to identify the proceedings.

According to PPIRS, FAPIIS was created to track “the integrity and performance of covered federal agency contractors,” but what does this mean to you, the manufacturer? I’m glad you asked! It means that in order to enter a “New Registration” or “Renewal/Update” in the CCR database (required prior to the award of a Federal contract or blanket purchase agreement [6]), you must now complete the new “Proceedings” section, and answer Yes or No to the following three questions [7]:

The CCR User’s Guide, published on July 28, 2010, also includes this message following the final question: “Note: This information is not publicly viewable. It will only be distributed to authorized government officials.” [8] However, (PAY ATTENTION) a new Interim Rule published in the Federal Register on January 24, 2011 states that “All information posted in FAPIIS on or after April 15, 2011, except for past performance reviews, will be publicly available.” [9]

1. * Is there a Federal solicitation on which your business or organization, as represented by the DUNS number on this specific CCR record, is bidding that contains the Federal Acquisition Regulation (FAR) provision 52.209-7, or has your business or organization, as represented by the DUNS number on this specific CCR record, been awarded a Federal contract that contains FAR clause 52.209-8?
2. * Mandatory only if you answered Yes to the above question: Does your business or organization (represented by the DUNS number on this specific CCR record) have current active Federal contracts and/or grants with total value (including any exercised/unexercised options) greater than \$10,000,000?
3. * Mandatory only if you answered Yes to the above question: Within the last five years, has your business or organization (represented by the DUNS number on this specific CCR record) and/or any of its principals, in connection with the award to or performance by your business or organization of a Federal contract or grant, been the subject of a Federal or State (1) criminal proceeding resulting in a conviction or other acknowledgment of fault; (2) civil proceeding resulting in a finding of fault with a monetary fine, penalty, reimbursement, restitution, and/or damages greater than \$5,000, or other acknowledgment of fault; and/or (3) administrative proceeding resulting in a finding

You now may be asking, “Why the change in policy, from maintaining the criminal and civil payment information disclosed by manufacturers for internal government use only, to making this information publicly available?” Again, I’m glad you asked. On July 29, 2010 (ironically, only one day after the above mentioned CCR User’s Guide was published), Section 3010 of the Supplemental Appropriations Act 2010 [10] was enacted, requiring the Administrator of General Services to post all FAPIIS information, excluding past performance reviews, on a publicly available website. The January 24, 2011 FAR/FAPIIS Interim Rule explains this change as follows:

With respect to the availability of information in FAPIIS, section 872(e)(1) states, in pertinent part, that the Administrator of General Services “shall ensure that the information in the database is available to appropriate acquisition officials of Federal agencies and to such other government officials as the Administrator determines appropriate.” Section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111–212), enacted July 29, 2010, modifies section 872(e)(1) to require that the Administrator of General Services post all FAPIIS information, excluding past performance reviews, on a publicly available Web site. FAPIIS will now become the publicly available Web site. [11]

This Interim Rule was a hot topic at the 2011 Pharmaceutical Compliance Congress conference attended by CIS. Manufacturers at the conference were particularly concerned about this topic, not only because it represents yet another way that pharmaceutical industry data will be

disclosed to the public, but also because it could create a new avenue for alleging False Claims Act (FCA) violations [12]. Because the FAPIIS requirements require broad reporting of criminal and civil penalties and/or admissions of wrong doing, it is possible that any oversight or incorrect posts could lead to potential FCA allegations. In addition, it will be a one stop shop for any group or individual looking to find the “dirty laundry” of a given manufacturer.

Here comes that unanticipated visibility I mentioned... Not only will the information you submit to CCR be available to the public as of April 15, 2011, your Government Contracting team may also be under increased scrutiny by your organization's Legal and Regulatory groups because of the potential FCA implications. As a result, it will become even more important to ensure that your answers to the FAPIIS questions in CCR, and any subsequent criminal or civil liability payments you report, are current, complete, and accurate. Depending on who at your organization has been maintaining these records for the past 5+ years, this may be easier said than done. For example, the Legal Department would most likely maintain records of all liability decisions made against your company; however, record of any settlement payments made might be maintained by the Finance Department or Accounts Payable. Therefore, in order to compile a current, complete, and accurate list of all payments outlined in the “Proceedings” questions in CCR, you may need to orchestrate a collaborative effort between several groups within your organization. The bad news: this can be tedious and time consuming, so you better get started. The good news: this should now be on management's radar, so you should be able to quickly gain traction with other groups (if not, show them this article).

One other thing to prepare for (I know, I'm sorry) is that your Contracting Officer at the Department of Veterans Affairs (VA) will be responsible for amending any existing contracts you have. As documented in the January 24, 2011 Interim Rule:

Contracting officers are encouraged, to the extent feasible, to amend existing solicitations in accordance with FAR 1.108(d), in order to include the clause at FAR 52.209-9 in contracts to be awarded on or after January 24, 2011. Prior to April 15, 2011, contracting officers shall bilaterally modify existing contracts, including indefinite-delivery indefinite-quantity contracts, that contain the clause 52.209-8, Updates of Information

Regarding Responsibility Matters, if a six-month update will be due on or after April 15, 2011. The modification shall replace the clause 52.209-8 with a new clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters, Alternate I (JAN 2011). If the contracting officer is unable to negotiate this modification prior to April 15, 2011, the contracting officer shall obtain approval at least one level above the contracting officer to negotiate an alternate resolution. [13]

In conclusion, if you are a pharmaceutical manufacturer, repackager, or other entity contracting with the federal government, FAPIIS is your problem, whether you are part of the Government Contracting team responsible for gathering and reporting FAPIIS data, the Finance team providing this data to the appropriate group within your organization, or the Legal team reviewing FAPIIS submissions and implementing policies to reduce the risk of future False Claims allegations. Therefore, CIS encourages all manufacturers to read, understand, and submit comment (as appropriate) on the FAR/FAPIIS Interim Rule before March 25, 2011, see instructions below:

Submit comments identified by FAC 2005-49, FAR Case 2010-016, by any of the following methods:

- Regulations.gov: <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by inputting “FAR Case 2010-016” under the heading “Enter Keyword or ID” and selecting “Search.” Select the link “Submit a Comment” that corresponds with “FAR Case 2010-016.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “FAR Case 2010-016” on your attached document.
- Fax: (202) 501-4067.
- Mail: General Services Administration, Regulatory Secretariat (MVCB), ATTN: Hada Flowers, 1275 First Street, NE., 7th Floor, Washington, DC 20417.

Instructions: Please submit comments only and cite FAC 2005-49, FAR Case 2010-016, in all correspondence related to this case. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/

or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, at (202) 501-0650 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501-4755. Please cite FAC 2005-49, FAR Case 2010-016. [14]

If you have any questions about the information contained in this article, or about your company's FAPIIS submissions, please feel free to contact me, Clarissa Crain, Managing Director of Commercial Compliance Operations at CIS, or Jamie Ghen, CIS Director of Compliance, Ethics, and Legal Affairs.

Resources:

- 1 <http://www.ppirs.gov/fapiis.html>
- 2 http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h5658pcs.txt.pdf
- 3 <http://www.cpars.csd.disa.mil/cparsmain.htm>
- 4 <https://www.bpn.gov/ccr/>
- 5 <https://www.epls.gov/>
- 6 <https://www.bpn.gov/ccr/CCRPol.aspx>
- 7 <https://www.bpn.gov/ccr/doc/CCRUsersGuide.pdf>
- 8 <https://www.bpn.gov/ccr/doc/CCRUsersGuide.pdf>
- 9 <http://edocket.access.gpo.gov/2011/pdf/2011-1323.pdf>
- 10 <http://www.govtrack.us/congress/bill.xpd?bill=h111-4899>
- 11 <http://edocket.access.gpo.gov/2011/pdf/2011-1323.pdf>
- 12 <http://www.taf.org/federalca.htm>
- 13 <http://edocket.access.gpo.gov/2011/pdf/2011-1323.pdf>
- 14 <http://edocket.access.gpo.gov/2011/pdf/2011-1323.pdf>

The Obama Administration's Ongoing Commitment to Lower Health Care Costs

by Chrissy Spicer, Director, Commercial Consulting Services

On February 14, 2011, the Obama Administration released the 2012 fiscal budget, which demonstrated the Administration's continued focus on initiatives for realizing cost savings on pharmaceuticals. In alignment with the overarching goal to lower health care costs, the budget proposes the following:

1. A proposal to decrease the number of years drug makers could exclusively market brand-name biologic drugs from 12 years to 7.
2. The budget discusses plans to end the "Pay for Delay" programs.
3. Obama's budget proposes additional fees to be paid for by the industry related to FDA activities, such as the review of new generic drug applications as well as fees to cover re-inspections and safety fees [1].

Its seven-year proposal "strikes a balance between promoting affordable access to medication while at the same time encouraging innovation to develop needed therapies," the White House said in budget documents; however, with a divided congress, the proposals are expected to face tough scrutiny [2].

While the generic pharmaceutical manufacturers have been tenacious in promoting the reduction of time periods of patent exclusivity, the Biotechnology Industry Organization indicated "that reducing exclusivity to 7 years would prevent biotech firms from recouping their investments [3]. Without being able to recoup the cost to further invest in innovation, the thought is that this proposal could disincentive biotechnology manufacturers to develop new products. While the previously mentioned proposal is more obvious with the split in opinion, the proposal to end "Pay-for-Delay" initiatives would have an adverse impact on both branded and generic pharmaceutical manufacturers.

According to the FTC's January 2010 Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions pay-for delay initiatives have been summarized as:

Brand-name pharmaceutical companies can delay generic competition that lower prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain

period of time. These so-called “pay-for-delay” agreements have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies [4].

Within a year of the publication of the study, Obama’s Administration has proposed to end these programs overtime agreeing with the argument that these programs delay and harm access to consumers from these much needed products [5].

Lastly, the industry could face more than \$250 million in new fees that are included in the Food and Drug Administration budget as another initiative proposed for improving the quality of pharmaceuticals delivered to consumers. The fees paid by the industry “would be used to review applications for generic drugs, improve inspections of food facilities and cover the costs of re-inspecting drug manufacturing plants [6].”

The proposal of new initiatives demonstrates the Administration’s ongoing commitment to reduce health care costs while improving quality and access for consumers. Although manufacturers can expect the initiatives to be heavily scrutinized by the divided congress, the savings extracted from changes resulting from health care reform last year will not be the last of the ongoing effort to reduce health care costs.

Resources:

[1] <http://www.reuters.com/article/2011/02/14/us-usa-budget-healthcare-idUSTRE71D3WD20110214>

[2] <http://www.reuters.com/article/2011/02/14/us-usa-budget-healthcare-idUSTRE71D3XD20110214>

[3] <http://www.reuters.com/article/2011/02/14/us-usa-budget-healthcare-idUSTRE71D3WD20110214>

[4] <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>

[5] <http://www.reuters.com/article/2011/02/14/us-usa-budget-healthcare-idUSTRE71D3WD20110214>

[6] <http://online.wsj.com/article/SB10001424052748704107204575039123049251324.html>



CalcPartner™

**MANAGING GOVERNMENT
PRICING CALCULATIONS**

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

ClaimsPartner™

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

Crackdown on Health Care Fraud: The Issues Arising from Significant Enforcement Tools Used in 2011 and Potential Impact on Pharmaceutical Manufacturers

by Rick Moore, Senior Associate

In January, 2011, U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius and U.S. Associate Attorney General Thomas J. Perrelli announced a Health Care Fraud and Abuse Control Program (HCFAC) Report [1] showing that the government's health care fraud prevention and enforcement efforts recovered more than \$4 billion in taxpayer dollars in Fiscal Year (FY) 2010. "Our aggressive pursuit of health care fraud has resulted in the largest recovery of taxpayer dollars in the history of the Justice Department," said Perrelli.[2] In addition to these criminal enforcement successes, in 2010 a record \$2.5 billion in recoveries were obtained in civil health care matters brought under the False Claims Act (FCA), the most lucrative year in the history of the Department of Justice (DOJ). The Justice Department hasn't stopped there. On February 15th the Justice Department and HHS announced that twenty people, including three doctors, were charged in Florida for various health care fraud, kickback and money laundering charges related to their alleged participation in a fraud scheme, which involved approximately \$200 million in Medicare billing for purported mental health services. According to court documents, the defendants who worked with and for American Therapeutic Corporation (ATC) and Medlink Professional Management Group Inc. participated in a scheme to defraud Medicare by submitting false claims for mental health services, administered at ATC facilities, which were either medically unnecessary or not provided at all. The indictment also alleges that various defendants paid kickbacks to patient brokers, as well as owners and operators of halfway houses and assisted living facilities, in exchange for delivering patients to ATC facilities.[3]

The cases are being investigated by the FBI and HHS Office of Inspector General (OIG). The cases were brought as part of the Medicare Fraud Strike Force, supervised by the Criminal Division's Fraud Section and the U.S. Attorney's Office for the Southern District of Florida. Since their inception in March 2007, Strike Force operations in seven districts have obtained indictments of more than

850 individuals who have, collectively, falsely billed the Medicare program for approximately \$2.1 billion.[4]

The Centers for Medicare and Medicaid Services (CMS), working in conjunction with the OIG, are taking steps to increase accountability and decrease the presence of fraudulent providers. The Affordable Care Act (ACA) provides additional tools and resources to help fight fraud that will help boost these efforts, including an additional \$350 million for HCFAC activities. HHS also announced new rules authorized by the ACA through the ("Final Rule") [5] which will include new provider screening and enforcement measures to help keep 'bad actors' out of Medicare, Medicaid and Children's Health Insurance Program (CHIP). The Final Rule also contains important authority to suspend payments when a credible allegation of fraud is being investigated. The administration is already using tools authorized by the ACA, including enhanced screening and enrollment requirements, increased data sharing across government agencies, expanded overpayment recovery efforts, and greater oversight of private insurance abuses. [6]

Specifically, the Final Rule mentioned above, which CMS published on February 2, 2011 created a vigorous screening process for new and existing Medicare, Medicaid and CHIP providers and suppliers; giving CMS authority to temporarily stop enrollment of new providers and suppliers; expanding the ability of CMS and States to temporarily suspend payments to providers and suppliers; establishing requirements for States to terminate providers from the Medicaid and CHIP programs; and adding several other enrollment-related provisions. Generally, the new rules are effective March 25, 2011.

There are several issues arising from the heightened levels of enforcement and CMS' use of new tools to force health care organizations out of federal health care programs. One is the broad and largely undefined requirement that a "credible allegation of fraud" must exist. In the Final Rule, CMS defines credible allegation of fraud as:

An allegation of fraud from any source, including but not limited to the following: (1) fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. [7]

The Final Rule also lowers the threshold level of evidence necessary to suspend payments; where the

existing regulations require “receipt of reliable evidence,” the Final Rule requires only a “credible allegation.”

CMS notes that while it will consult with the OIG, as it is statutorily required to do, it retains ultimate authority over whether to impose payment suspension upon a provider or supplier. With the adoption of the Final Rule, CMS will also have a considerable amount of discretion whether to impose, or continue, a payment suspension on a provider. As reflected in the comments to the proposed rule, providers have legitimate reason to raise concern over lack of adequate due process, particularly since an 18-month suspension could easily put a provider out of business.[8]

Another issue arising from the heightened level of enforcement is the substantial barrier to entry for new and expanded health care organizations. Entry is now subject to rigorous screening, as well as possible moratoria on enrollment of particular types of health care organizations, as well as enrollment in certain geographic regions. The Final Rule allows CMS to impose such temporary moratoria in 6-month increments:

- (1) where CMS, based on its review of existing data, identifies a trend that appears to be associated with a high risk of fraud, waste, or abuse;
- (2) where a State has imposed a moratorium on enrollment in a particular geographic area, or on a particular type of provider or supplier, or both; or
- (3) where CMS, in consultation with the OIG or DOJ or both, and with the approval of the CMS Administrator, identifies a particular geographic area or a particular provider or supplier type, or both, as having significant potential for fraud, waste, or abuse in the Medicare or Medicaid program.[9]

These barriers to entry present a problem to the creation of new and expanded health care organizations that are supposed to serve newly covered individuals and meet other objectives of health reform. The result of these barriers will ultimately lead to greater limitation on health care access, which is the opposite of the purpose of the ACA. Providers will need to ensure they have a robust compliance program to prevent and detect potential fraud. The compliance program should include a policy and process for questionable actions to be anonymously reported through a corporate fraud hotline. Additionally,

providers should consider internal audits and data mining to increase efforts to prevent and detect potential fraud. Pharmaceutical Manufacturers could be disappointed in Medicare, Medicaid and CHIP expected sales as a result of these changes. The suspension of payments, and the barriers to entry or expansion for providers and suppliers may result in fewer providers, which in turn could create a restraint on health care access for covered individuals.

Resources:

- [1] oig.hhs.gov/publications/hcfac.asp
- [2] <http://www.hhs.gov/news/press/2011pres/01/20110124a.html>
- [3] <http://www.justice.gov/opa/pr/2011/February/11-crm-186.html>
- [4] <http://www.justice.gov/opa/pr/2011/February/11-crm-186.html>
- [5] 76 Fed. Reg. 5,862-5,971 (Feb. 2, 2011)
- [6] <http://www.justice.gov/opa/pr/2011/February/11-crm-186.html>
- [7] 76 Fed. Reg. at 5961, amending 42 C.F.R. 405.370(a)
- [8] <http://www.ebglaw.com/showclientalert.aspx?Show=13994>
- [9] <http://www.ebglaw.com/showclientalert.aspx?Show=13994>
- [10] <http://www.ebglaw.com/showclientalert.aspx?Show=13994>

Manufacturers Release #83

by Scott Hoffman, Project Manager

Published February 9, 2011 to PharmaComplianceBlog.com

On February 3, 2011, the Centers for Medicare & Medicaid Services (CMS) issued Manufacturer Release No. 83 which detailed smoothing for the Average Manufacturer Price (AMP) calculation. CMS stated that the smoothing utilized by manufacturers in the calculation of AMP should mirror the smoothing that is applied to the calculation of Average Sale Price (ASP) under Medicare Part B. This means that lagged price concessions for a 12-month period should be divided by the AMP eligible sales for that period to determine the price concession percentage that should be applied to the current periods AMP eligible sales.

To illustrate:

June Monthly AMP Eligible Sales = \$100,000

12 Month AMP Eligible Sales = \$1,000,000

12 Month Lagged Price Concessions = \$50,000

*Lagged Price Concession Percentage
= (\$50,000/\$1,000,000) or 5%*

June Price Concessions = (\$100,000 x 5%) or \$5,000

June AMP Sales = (\$100,000 - \$5,000) or \$95,000

June AMP Units = 10,000

June AMP = (\$95,000/10,000) or \$9.500000

Upon reading this release, my first takeaway is the fact that it specifically references lagged price concessions. I personally define a lagged price concession as any discount or rebate that is realized after the sale of the drug not including customary prompt pay discounts. Using this definition, the Release implies that smoothing should only be done to rebates and chargebacks and not to ineligible sales. It is important to note that this has been a much discussed question since the 2007 AMP Final Rule; and subsequent to that rule, there is little guidance that I am aware of that speaks directly to extending smoothing logic to excluded sales (although it is briefly touched upon in one FAQ that was posted). We are aware that there were manufacturers who did and continue to smooth excluded sales, and may have sought legal guidance on the topic.

My second takeaway surrounds the lack of specification of Retail (“RCP”) AMP versus Alternative (“5i”) AMP. Under the Patient Protection and Affordable Care Act (PPACA) and the Air Transportation Modernization and Safety Improvement Act, manufacturers were introduced to the fact that there would need to be two possible AMPs calculated post October 2010 based on the drug profile. The Release states that 12 month AMP eligible sales should be the denominator of the price concession percentage calculation, however, it does not tell the manufacturer whether those 12 month sales should reflect the new Class of Trade (COT) inclusions/exclusions that were created by the introduction of the RCP and 5i AMP calculations. For the 12 months, should the manufacturer use their pre-PPACA COT inclusions/exclusions for the months prior to October 2010 while applying their post-PPACA COT inclusions/exclusions after October 2010? Should they retroactively apply their post-PPACA COT inclusions/exclusions to the entire 12 months? This is an area not addressed in the legislative level language, and may not be addressed until regulations are published. For this reason, it is imperative for manufacturers to maintain clear documentation of their methodologies

and apply consistent procedures across their calculations.

Specifically to this Release, manufacturers should document what they are considering to be a price concession, how they are deriving their 12 month AMP eligible sales, as well as how they are treating COT for purposes of inclusions and exclusions from the AMP calculation.

One final comment, and general topic that Chris Cobourn at CIS has blogged about on several occasions, is the timing on AMP regulations, and whether CMS will put out additional “sub-regulatory guidance” such as letters to manufacturers, to address specific areas in the mean time. That is an area that we all will have to track closely, as we will now have the PPACA legislative language as guidance, various release letters, and ultimately regulations. You should ensure that you keep very good track of the authoritative guidance that you rely on (another great reason to subscribe to the PCX).

The actual release can be found at http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp

New 340B/OPA User Fees Detailed in the Proposed FY2012 Federal Budget

by Danny Umar, Senior Associate

Published Feb. 18, 2011 to PharmaComplianceBlog.com

President Barack Obama’s proposed FY2012 Federal Budget released this Monday was met with a mix of partial approval and outright anger by the media and government. [1] The national debt is over \$14.1 trillion. The estimated FY2011 budget deficit is over \$1.6 trillion. The estimated FY2012 budget deficit is still over \$1.1 trillion. You don’t have to dig much further than the summary tables to get frustrated with the proposed budget, but you might want to take a closer look at the HRSA federal funding detail to find out about a new 340B/OPA user fee proposed for FY2012. [2]

HRSA’s user fee is a 340B cost recovery system based on the VA’s administration of pharmaceuticals on the FSS, which operates with similar cost recovery fees (IFFs). For manufacturers, implementation of the fee will include reporting 340B sales and establishment of the fee as a percentage of 340B drug purchases (read: IT system updates). Though detailed reporting requirements will be unclear until regulations are published, we know that the fee will be embedded since HRSA

has explicitly stated that it is in addition to 340B pricing. [3]

Establishment of the user fees can be expected with an update to the agreement between the Secretary and participating manufacturers with the following requirements:

- (1) to establish a cost recovery fee from participating 340B covered entities to pay for the total operating cost of the 340B Drug Pricing Program;
- (2) to give the Secretary discretion to require manufacturers to collect the fee at the time of sale of a covered outpatient drug to a 340B covered entity and remit that fee to the Secretary;
- (3) the fee initially will be 0.1 percent of the total 340B drug purchase paid by participating 340B covered entities to a manufacturer solely for drugs purchased by covered entities for 340B Drugs;
- (4) to incorporate the requirement that manufacturers report their calculated ceiling price with a supplemental report of the total amount obtained by the manufacturer for each covered outpatient drug sold to a covered entity (exclusive of non-discriminatory bona-fide service or administrative fees) and any additional information determined by Secretary necessary to administer the 340B Program; and
- (5) manufacturers would deposit the cost recovery fee into a no year account established by the Secretary for use by the Secretary and designees in paying the total costs of the 340B Drug Pricing Program. [3]

If the fee is included in the approved budget, manufacturers should assume that participating manufacturers would have to sign a new Pharmaceutical Pricing Agreement that complies with the current law, or no longer be compliant with the requirements of 340B.

So why the fee? Budget cuts and growth. HRSA's discretionary budget authority decreased \$0.7B to \$6.8B, down from actual spending of \$7.5B in FY2010. This decrease, among others within DHHS, will be used to pay for offsetting initiatives such as the NIH's National Center for Advancing Translational Sciences (discussed in Yasmeen Muhammad's article about spurring drug development earlier this week). [2]

However, the cuts have not deterred HRSA from expanding their oversight of the 340B program. In their Justification of Estimates for Appropriations Committees, HRSA claims that they have "not been able to fully implement the program integrity recommendations of the OIG or statutory requirements." The cost recovery fee would be used to a) fully administer the 340B program and b) allow HRSA to better monitor compliance among both manufacturers and covered entities. Specifically, funds will go towards the OPA Information Systems, tech support, a new administrative dispute resolution process, and compliance & oversight. HRSA seeks to develop a systematic method of monitoring manufacturer or covered entity compliance with 340B (deficiencies noted in the OIG reports from 2005 and 2006) and imposing civil monetary penalties on manufacturers up to \$5,000 per instance of overcharging a covered entity knowingly and intentionally.

HRSA also acknowledges that participating 340B entities receive a significant benefit and want to shift the burden of the program administration to the beneficiaries from the taxpayers (exclusively). The new user fees should not be effective until 2012, though we will not know an effective date until the regulations are published (if the fees are included in the approved budget). [3]

We'll keep our ears perked – as should you – for details on the new fee and will provide updates as they become available.

Resources:

[1] http://voices.washingtonpost.com/federal-eye/2011/02/federal_budget_2012_lawmakers.html

[2] <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2012/assets/budget.pdf>

[3] <http://www.hrsa.gov/about/budget/budgetjustification2012.pdf>

ASP to AMP Comparisons: Report Says Still on the OIG's Radar

by Erica Scholl, Senior Associate

On Monday, February 14, 2011, the Office of Inspector General (OIG) issued their Memorandum Report: Comparison of Second-Quarter 2010 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for Fourth Quarter 2010, OEI-03-11-00030. The review, in accordance with statutory mandate, compares the average sales prices (ASP) and the average manufacturer prices (AMP) for Medicare Part B prescription drugs. The OIG seeks to identify ASPs that exceed AMP by a specified threshold (currently 5%).

As a brief background, Medicare Part B, which accounted for over \$11 billion in 2009 spend, pays for most covered drugs (other than certain drugs including some vaccines and blood products) using a reimbursement methodology based on ASP. Manufacturers that participate in the Part B program are required to submit ASP (as well as National Drug Code (NDC) and sales volume) on a quarterly basis. Section 1847A(d)(2)(B) of the Social Security Act mandates the comparison of ASP to AMP by the OIG. If it is determined by the OIG that ASP exceeds AMP by a predetermined threshold, the Act states that ASP may be disregarded by the Secretary of Health and Human Services when determining reimbursement amounts.

The price comparison performed was examining drugs that exceeded the current 5% threshold between ASP and AMP. This was based on manufacturers who submitted complete or partial AMP information in the 2nd quarter of 2010. There were 350 drug codes that submitted complete AMP information for the quarter, 106 drug codes with partial information submitted and 54 drug companies with no corresponding AMP information provided. Of the 350 with complete information, ten codes exceeded the 5% threshold. Of the 106 with partial information, 15 exceeded the percentage threshold.

According to the Social Security Act, if a drug exceeds 5% threshold, the Secretary may disregard the ASP of the reported drug. In this case, the payment is to be substituted with the lesser of the widely available market price or 103% of AMP. Based on this calculation, the OIG estimated the amount of expenditure that Medicare could have reduced

if the 103% of AMP had been used instead of ASP. For the ten codes with complete AMP information, it was estimated that there was a potential for a \$713,000 reduction in 4th quarter alone. As well, it was noted that six of these ten codes were also in excess of 5% in previous quarters. If these reimbursement amounts had been based on the 103% of AMP instead of ASP, another potential reduction of \$610,000 of expenditures would have been realized. For the 15 codes that had an excess of 5% while reporting partial AMP information, there was a potential of \$239,000 reduction being realized in the 4th quarter of 2010. Additionally, \$11,000 could have been realized in previous quarters as 10 of the 15 codes exceeded the 5% threshold in quarters prior.

Although the OIG did not offer any additional recommendations as a part of this findings report, they have released reports in the past with recommendations based on their findings. In the December 2008 and February 2010 Comparison of Average Sales Price and Average Manufacturer Prices Reviews, the OIG recommended that the Centers for Medicare & Medicaid Services (CMS) “develop a process to adjust payment amounts based on the results of OIG’s pricing comparisons” as well as “subsequently lower[ing] Medicare reimbursement amounts for drugs with ASPs that meet the 5-percent threshold specified in Section 1847A(d)(3) of the Act.” [2] At the time, CMS concurred with the recommendation to develop a process for adjusting payments based on the OIG findings however they did not “specifically concur with [the] recommendation to lower Medicare reimbursement for drugs that meet the 5-percent threshold” [3] citing the complexity of substituting payments and the importance of proceeding cautiously. Finally, CMS agreed to continue its efforts to ensure that required AMP information is reported timely. They supported adequate enforcement action against those that fail to comply, without stating specifically what these actions entail.

Although the OIG did not submit any new recommendations, nor has CMS declared that they will be lowering Medicare reimbursements, the report makes it clear that ASP to AMP comparison is still very much on the radar of the OIG. With the potential effects on pricing and subsequently utilization, this is something that manufacturers must continue to be aware of. We recommend that manufacturers that do have a large variance between their ASP to AMP values be aware of the reasons for the variance should they be called upon to answer questions from CMS or OIG in the future.

Resources:

[1] Section 1847A(d)(2)(B) http://www.ssa.gov/OP_Home/ssact/title18/1847A.htm

[2] Comparison of Average Sales Prices and Average Manufacturers Prices: An Overview of 2007, OEI-03-09-00350, <http://oig.hhs.gov/oei/reports/oei-03-08-00450.pdf>

[3] Comparison of Average Sales Prices and Average Manufacturers Prices: An Overview of 2007, OEI-03-09-00350, <http://oig.hhs.gov/oei/reports/oei-03-08-00450.pdf>

Update Your ICF Procedures, New Rule Effective March 7, 2011

by Billy Grimme, Clinical Compliance Specialist

The recent implementation of Food and Drug Administration Amendments Act (FDAAA) 2007 mandated a change to 21 Code of Federal Regulations (CFR) part 50 for the inclusion of the following statement into clinical trial informed consent forms, “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.” In conjunction with its final rule, effective March 7, 2011, Food and Drug Administration (FDA) has stated that the expected benefits of this change are:

- “[An] increase [in] the transparency of clinical trials by increasing participant and patient awareness of the existence of the clinical trials databank and those trials that are registered in the databank.”¹
- “By helping to create a system of checks and balances through which participants, patients, and health care providers are encouraged to check whatever information about a trial of interest is registered in the databank, it also would provide greater accountability of clinical investigators for outcomes and adverse events, thereby raising confidence in the validity of the research process.”¹
- “Last of all it would encourage physicians and patients to obtain more information in order to make more educated treatment decisions.”¹

In the effort to provide more transparency and accountability within clinical trials, a few implications for the clinical trial sponsor have become evident:

- “It is likely to increase the scrutiny of information posted on ClinicalTrials.gov, including the description of the protocol and enrollment status, by patients who are considering enrollment as well as Institutional Review Boards.”²
- “It may increase the use of ClinicalTrials.gov by patient subjects and other parties for the later examination of clinical trial results, including adverse events, and promote expectations for timely access to results on this public website.”²
- “The characterization of the disclosure as a basic element of human subject’s protection may increase scrutiny by the public and enforcement agencies regarding the consistency and accuracy of posted data in comparison with other disclosures by sponsors or investigators regarding clinical trials.”²

A few proactive steps taken by the sponsor can ensure compliance with the update. First, the sponsor should ensure that a procedure is in place for registration and disclosure of information on ClinicalTrials.gov. Second, sponsors should review their current procedures to update their informed consent form writing requirements or templates. Third, the sponsor should ensure that all applicable staff are trained and aware of the change. Lastly, the sponsor should establish a plan to communicate the informed consent process change to their clinical study investigators and ensure that sites are adequately informing their patients of the new information. As this new regulation takes effect, March 7, 2011, sponsors should begin the process of updating procedures for the compliance date of March 7, 2012. Implementing these regulatory updates can be cumbersome for some small to mid-size companies. CIS is ready to assist in this GCP-related regulatory change, and offers services to ensure compliance with the most current regulatory requirements.

Resources:

[1] Federal Register volume 76, section 270; http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?dbname=2011_register&page=270&position=all

[2] <http://www.kslaw.com/imageserver/KSPublic/Library/publication/ca012510b.pdf>

New Ideas for New Drug Development

by Yasmeen Muhammad, Senior Consultant

Over the past several years, the number of new drugs introduced to the market has steadily declined. “The Food and Drug Administration has approved fewer and fewer new compounds every year since 1995.” Several factors that have contributed to the decline include time, cost and tough regulations. It can take more than ten years for a drug company to research and develop a new drug and the cost of doing so is now more than a billion dollars. Many drug companies find it more feasible to further develop drugs that are already on the market because they are less risky and approved more easily. This is an advantage for drug companies because it allows them to utilize time and money on other business opportunities. However, this comes as a huge disadvantage to the consumer because the lack of drug innovation leaves many illnesses untreated.

The Obama administration has become increasingly concerned about this issue. As a means to create new drugs to bring to market, the Federal government is starting a new drug development center. The center will be a part of the National Institutes of Health (NIH). The goal of the new center is to begin research for potential new drugs in hopes that drug companies will invest and move the products to market. The research will entail drug discovery research and possibly animal testing and human trials. The new center, which will be called The National Center for Advancing Translational Sciences, is projected to open in October of this year.

The government wants to assist the private sector in the development of new drugs rather than take over or compete with the drug industry. However, experts are on both sides of the fence when it comes to the idea of the government getting involved in drug discovery. Some experts see it as a good idea. Others are more skeptical and have little faith in the NIH to do a good job at drug discovery. There are also concerns about the federal budget. In 2009 alone, industry spent about 45 billion dollars for the research of new drugs. However, the funding to start the new center will cost only one billion dollars.

Drug companies are starting to make changes to the way they do research and development in order to help increase the number of new drugs introduced to the market. According to Tufts Center for the Study of Drug Development (CSDD), companies are looking to use the following techniques to address the issue:

- More reliance on translational science to help identify the right disease targets for new molecules
- Partnering with external service providers to share risks, reduce cycle times, lower costs and improve resource management
- Greater use of sophisticated portfolio management techniques

With efforts being made by the federal government and drug companies, consumers are likely to see an increase in new drug development in the coming years. This is a positive step for the US economy, as well as the competitiveness of US drug companies.

Resources:

[1] <http://www.popsoci.com/science/article/2011-01/feds-open-new-drug-research-center-effort-spur-pharmaceutical-industry?page=#comments>

[2] <http://www.nytimes.com/2011/01/23/health/policy/23drug.html?pagewanted=2&r=2&hp>

[3] http://csdd.tufts.edu/news/complete_story/pr_outlook_2011