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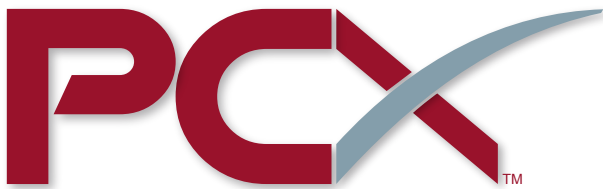
Guest Letter From the Editor: A Tale of Two AMPs

By: Chris Cobourn, VP, Regulatory Affairs

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As our wait continues into the summer for the anticipated AMP rule (<http://www.pharmacomplianceblog.com/blog/?p=3821>), we are more than curious about a few key things, including when the rule will hit and what it will be.

To the question of when the rule will hit, the word on the street continues to be the end of August. We continue to get some mixed signals on whether it will be a “Interim Final Interim Rule” that will be effective in October, or whether it will be a Proposed Rule. I have also included in past blogs the discussion of it being an Interim Final rule, but the OMB site actually has it listed now as a Proposed Rule, which should mean that we will have sufficient time for the comment period prior to implementation. As for timing, in speaking with Larri Short from Arent Fox, she suggests that we look at an August 26th date, in that it is the last Friday of the month, and is CMS’ final opportunity to get it out before September (if you want to hear Larri’s thoughts on the matter, please join our GP Forum call this Wednesday with Larri as our guest speaker; you can email me for more information).

The compelling question continues to be WHAT the AMP rule will be. I look for it to fall into one of two categories. It will either be fairly close to what we have been doing since the PPACA changes in October with the Retail Community Pharmacy, or RCP, AMP, focusing primarily on COT inclusion and exclusion changes, or it will be a more radical change reversing our traditional view of the gross to net AMP, starting with gross sales and removing excluded class of trade and moving to what is being called the “build up” methodology, using some data source, such as 867 type data, and calculating AMP based upon transactions that

can be defined as RCP. The manufacturing community is pretty vocal in our hope that CMS stays with the traditional overall method, and on how extremely difficult it would be to change to the buildup method. It is questionable whether we could even get the data to be able to do it. We recognize that the retail industry is a very strong proponent of the buildup method, and has made this known to CMS. When the retail industry successfully got an injunction on the 2007 AMP Final Rule, it was based on their view that AMP should be based upon the concept of the net cost to retail community pharmacies, and they have extended this logic to the view of basing AMP on a build up methodology.

So, the biggest question is which of the 2 AMPs we will see. Our hope is that that the AMP is pretty much in line with what we have been doing since October, and that the detailed changes will be overall fairly manageable in the time given to implement the new AMP.

There are, of course, other major questions. Some of the key being the following:

- Bona Fide Service Fees clarification, reconciling the new PPACA language with the still in effect 2007 Final Rule Bona Fide Fee for Service criteria
- 5i clarification, with definition of “generally sold to retail” as well as more definition on included and excluded classes of trade, especially excluded transactions involving government entities
- Clarification on Line Extensions (which may be one of the more complicated and challenging components)
- The effective date of the new AMP rule, and whether there will be any retroactive application of the rule back to October 2010
- Whether manufacturers will have the opportunity to restate Base AMP using the new AMP rules

Proposed Rule for Medicare Contains ASP Changes

By: Don Russell, Director Government & Commercial Operations

CMS released the 2012 Medicare Physician Fee Schedule (MPFS) Proposed Rule on July 19, 2011. Among the 176 pages in the Federal Register that CMS-1524-P entails, there are several pages of interest to manufacturers of Medicare Part B ASP reportable products. Comments are due to CMS by August 30, 2011 at 5 PM to assure consideration. The ASP provisions are found on pages 42828-42833, 42921, and 42947. In general, the proposed rule proposes:

- To retain the AMP to ASP comparison threshold of 5% for 2012.
- To apply the price substitution of 103% of AMP for 106% of ASP when ASP exceeds 105% of AMP under certain circumstances. Specifically, a price substitution of AMP for ASP will be made only when the ASP exceeds the AMP by 5 percent in the two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the quarter in which the price substitution would be applied.
- If the substitution price is to be used, it will be utilized 3 quarters after the calculation quarter (one quarter delay from the normal effective quarter of the ASP+6% price). The substitution price will not be used if 103% of AMP exceeds the calculated 106% of ASP price calculated for the quarter of the proposed substitution. This is in order to avoid a situation in which the Secretary would inadvertently raise the Medicare payment limit through this price substitution policy.¹
- The definition of Unit was changed to account for products with variable amounts of active ingredients. The proposed definition is: “Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by an NDC varies.”² CMS plans to

¹ Federal Register Vol. 76, No. 138 / Tuesday July 19, 2011 / Proposed Rules, page 42832

² Federal Register Vol. 76, No. 138 / Tuesday July 19, 2011 / Proposed Rules, page 42947

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maintain a list of “HCPCS codes for which ASP reporting is done in units of measure other than an NDC.” The current proposed codes and proposed reporting units are found on page 42833.

- ASP Reporting will change effective January 1, 2012 (for the Q4 2011 submission in January). The ASP Reporting Template (Addendum A) will be revised including:
 - o The NDC column will be divided into NDC1, NDC2, NDC3 (Labeler, Product, Package)
 - o A new field for Alternate ID will be added to identify products without an NDC
 - o A macro will be added to validate the data entered. The proposed rule does not list any specifics of what the macro will validate beyond stating: “We have also added a macro to the Addendum A template that will allow manufacturers to validate the format of their data prior to submission. This will help verify that data are complete and submitted to CMS in the correct format, thereby minimizing time and resources spent on identifying mistakes or errors.”³ Note that use of the validation macro does not preclude or supersede manufacturer’s responsibility to provide accurate and timely ASP data!

The additional reporting burden for a manufacturer is estimated at 2 additional hours per response. Based on the proposal, if you have a system solution to create Addendum A, changes will be necessary before the fourth quarter 2011 submission can be filed by the January 30th due date. Mark your calendar to schedule for system changes accordingly! If you have comments, please respond to CMS before August 30th.

Clarifications and Modifications to IRS Branded Drug Fee as a Part of Temporary and Proposed Regulations Being Issued

By: Erika Scholl, Senior Associate

On August 15, the IRS issued new temporary regulations, effective August 18, in regards to governing the branded prescription drug fee. As a part of the Patient Protection and Affordable Care Act (section 9008) and amended by section 1404 of the Health Care and Education Reconciliation Act of 2010, regulations were enacted affecting certain branded prescription drug companies. Accompanying the proposed rules is a notice of proposed rulemaking which lays out procedures for commenting, due by November 16, 2011 (note that comments on the paperwork/information collection aspect of the proposals are due by October 17).

It is important to note that the temporary regulations remain generally consistent with the IRS guidance; however, there were a few modifications that were made in response to the public’s comments. For more information on the original releases, see Kathy Castoro’s blogs entitled [IRS Industry Fee Dispute STOP!! Hold the Press!! June 1, 2011 Deadline](#) (May 19, 2011), [IRS Industry Fee Dispute – Another Point to Ponder](#) (May 19, 2011), and [UPDATE on the IRS Industry Fee for Branded Prescription Drug](#) (May 31, 2011). Below you will find a summary of clarifications and modifications made to the IRS guidance:

- I. Information Requested From Covered Entities: The temporary regulation confirmed that the submission of Form 8497 is voluntary and that errors in the form can be addressed through the dispute resolution process provided under Rev. Proc. 2011-24. Although commentators requested that CMS provide all rebate data, CMS has stated that until they can provide all relevant data, covered entities will have the opportunity to report data as a part of the Form 8947.
- II. Information Provided by Agencies: The temporary regulations provide revised descriptions of the methodologies used by Agencies to report branded prescription drug sales, as well as some error

3 Federal Register Vol. 76, No. 138 / Tuesday July 19, 2011 / Proposed Rules, page 42832

reports submitted as part of the dispute resolution process based on commentator's questions that were raised. Page 51247 of the Federal Register Vol. 76, No 160 details the specific methodology descriptions that have been clarified.

Additionally, CMS addressed comments in regards to sales data. First, as to whether Medicare Part B is capturing complete data with respect to drugs that are not directly correlated with a specific HCPCS Code, CMS is continuing to work with the data available to capture these drugs. Second, as to whether Medicaid sales data was reporting secondary payers, therefore potentially duplicating reporting, CMS revised the Medicaid methodology to exclude non-Medicaid payments, with the temporary regulations including a description of this revised methodology.

III. Fee Calculation Including Adjustment: The temporary regulations clarify that the fee will be calculated by the IRS for a covered entity based on the branded drug sales and rebate data for each NDC reported by the Agencies. Each NDC will be assigned to the covered entity that owns the drug as of December 31 of the sales year. Although the DOD and VA are expected to have complete data for the calendar year immediately preceding the fee year, CMS is not expected to have comparable data. **Therefore, the temporary regulations clarify that the second calendar year will be used to calculate the fee.** Because the second year will be used, the annual fee due every year after 2011 will include an adjustment amount for the previous year. The previous proposal provided guidance to compute an adjustment separately, but the temporary regulations modify this guidance to include the adjustment as a part of the calculation.

IV. Notice of Preliminary Fee Calculation: The temporary regulations remain consistent with the proposed regulations in regards to IRS notification of preliminary payment. A date by which the IRS will send notification will be communicated each year. For 2011, the notices were sent by May 16.

V. Dispute Resolution Process: The temporary regulations remain consistent in regards to the

dispute resolution process. Contrary to several comments, the IRS will not allow error reports to be submitted after notification of final fee determination has been sent.

VI. Notification and Payment of Fee: The temporary regulations clarify that covered entities will be sent their final fee calculation no later than August 31st of each year (for 2011, notification will be sent by August 24th), and payment is due by EFT no later than September 30th.

VII. Tax Treatment of Fee: The temporary regulations confirm that the fee is considered an excise tax for purposes of subtitle F of the Internal Revenue Code.

As a reminder, these are clarifications and modifications to the proposed rule. It is important to review the proposed regulations in their entirety to understand how they relate to your company.

References

1. Federal Register Vol 76, No. 160 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-18/pdf/2011-21011.pdf>
2. Hogan Lovells Pharmaceutical and Biotechnology Alert, August 18, 2011 - <http://www.hoganlovells.com/irs-issues-temporary-and-proposed-regulations-for-branded-prescription-drug-fee-08-18-2011/>

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Health Care Merger and Acquisition Update

By: Mike Rowland, Senior Associate

One of the common business themes in the 21st century has been mergers and acquisitions. We have seen it occur in all types of companies and locations in the global economy. Some notable examples include AOL and Time Warner in the communications, Royal Dutch and Shell in oil and gas, and Inbev and Anheuser-Busch in the beverage space. The pharmaceutical industry has seen its fair share of M&A activity as well, most notably with Pfizer and Wyeth in 2009, and Glaxo Wellcome and Smith Kline Beecham in 2000.


The reasons behind this type of activity can range from the influx of new revenue and sales of an acquired product, favorable tax advantages, or cost savings to the consumer through synergies or economies of scale.

Last month, two of the largest pharmaceutical benefit managers, Express Scripts and Medco Health Services decided to join forces in a deal valued at \$29 billion. This would be the eighth merger for Express Scripts, which has said that every single deal has resulted in lower costs for consumers.¹ Government regulators still have to approve the change, which is expected to be completed early next year.

PBMs primary purpose is to manage prescription drug programs for large organizations, unions, or other entities. The two companies believe that this will result in ultimately lower costs for the consumer. The PBM model can produce great savings for individuals, primarily in the mail order area. This is where many of the cheaper generic versions of blockbuster drugs can be obtained once the initial patent has expired. This can also result in lower co-pays for the non-branded drugs as well. This is subject to individual preference however, as some people prefer to interact with a pharmacist and therefore would not be able to take advantage of the mail order option.

While the hope from the consumer standpoint would be to keep costs to a minimum while still maintaining service levels, it will still take time to determine whether this merger will be a benefit or detriment. Many have

¹ NPR Health Blog, August 17, 2011



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argued that the consolidation of Big Pharma has led to a diminished investment in R&D, and that it could ultimately hurt the patient or customer.² This much remains clear: There appears to be no slowdown in sight for M&A activity in the health care domain, so expect to continue to see headlines in the near future as business opportunities arise.

² Nature Reviews Drug Discovery, August 1, 2011

Agreement between FDA and Generic Drug Industry to Benefit Industry and Consumers

By: Suma Kallurkar, Senior Manager

The Food and Drug Administration (FDA) has worked out an agreement with generic drug manufacturers that will allow for greater inspections of foreign manufacturing plants and lead to speedier approvals of generic drugs. This is a highly important agreement in that it will help achieve greater oversight of foreign-manufactured active ingredients for drugs. A majority of active ingredients for generic drugs that are sold in the U.S. are manufactured outside of the U.S., largely in plants in China and India. Until now the FDA has struggled with being able to adequately inspect such manufacturing facilities abroad.

The agreement, which is in the process of being completed and expected to be finalized within weeks, calls for generic drug companies to collectively pay \$299 million in annual fees that will be used for conducting inspections of foreign manufacturing plants every 2 years. This would match the frequency with which domestic plants are currently inspected. It has taken decades to work out such an agreement. The generic drug industry has suffered in recent years from occurrences of tainted medicines. The FDA has not been able to obtain adequate funding from Congress for the review of generic drug applications, let alone inspections of manufacturing plants abroad. The fees from this agreement will dramatically change the situation by allowing the FDA to not only conduct the needed inspections, but to also increase its resources to review generic drug applications, and hopefully decrease approval times significantly.

The agreement will go to Congress early next year and is expected to be approved. Many benefits are expected from this agreement. The reduced approval times will allow for less expensive medicines to be available to consumers more quickly. Most importantly, the routine inspection of foreign manufacturing facilities, many of which have never been inspected, will result in safer generic drugs for consumers. It also expected that the agreement will aid in keeping jobs in the generic drug industry in the U.S. By establishing standards for foreign manufacturing plants that align with standards for U.S. plants, generic manufacturers will be less inclined to move manufacturing operations overseas. All in

all this is a deal which will significantly benefit the generic drug industry and consumers alike.

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1. The New York Times - <http://www.nytimes.com/2011/08/13/science/13drug.html?pagewanted=1&sq=generics&st=cse&cp=3>
2. The New York Times - <http://www.nytimes.com/2011/08/18/opinion/a-deal-to-get-cheaper-and-safer-drugs.html?scp=2&sq=generics&st=cse>
3. Medical News Today - <http://www.medicalnewstoday.com/articles/232838.php>

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