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Dual Pricing...The Rest of the Story

by Dave Rice, CIS Director of Federal Contracting, daverice@cis-partners.com

What is dual pricing and how can it help your company's bottom line?

The Federal Supply Schedule (FSS) contract allowsa contract holder to elect either single pricing or dual pricing. A single price company takes the lower of the FSS negotiated price and the Federal Ceiling Price (FCP), which is a calculated price

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Letter from the Editor: The 2010 Proposed Amendments to the Federal Sentencing Guidelines Help Companies Withstand Judicial Scrutiny Through Proactive Approaches to Corporate Compliance Programs

by Jamie Ghen, Esq., Director of Compliance, Ethics & Legal Affairs, jamieghen@cis-partners.com

For those of you who are unaware, the Federal Sentencing Guidelines for Organizations ("Sentencing Guidelines") allow organizations to mitigate sentences if they can demonstrate adherence to 7 elements that demonstrate an effective compliance program. The 7 elements are also the underpinning of the Office of Inspector General's (OIG's) various compliance guidelines, including the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers, issued in April 2003, and the compliance programs that the majority of pharmaceutical companies have enacted.

Undoubtedly, the Sentencing Guidelines are riddled with ambiguities that make it difficult for a company to establish a compliance program that holds up to judicial scrutiny, and corporations rarely qualify for downward departures. Downward departure(s) is a term used in criminal law to refer to departing downward from the applicable sentencing guideline range for a statutory minimum sentence. The corporate compliance tide will soon turn as the Proposed Amendments of 2010 ("2010 Amendments") directly implicate the relationship between a corporation's Chief Compliance Officer (CCO) and the board of directors, and the manner in which a corporation should respond to the discovery of criminal conduct. The 2010 Amendments concern several areas, including reporting to the board, restitution and records management. In sum, the 2010 Amendments:

1. Enhance the reporting obligations from a CCO to the board of directors in order for the compliance program to be deemed effective in all circumstances;

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2. Clarify the steps a corporation must take to meet the requirement for proper remediation in the event criminal conduct occurs;
3. Reject the proposed language that would have mentioned, for the first time, the appointment of monitors as a possible component of the remediation requirement or, separately, as a possible condition of probation for a convicted corporation; and
4. Reject language under consideration that would have given document retention policies unique prominence in the list of compliance program requirements.

Notably, for the first time, the 2010 Amendments will allow a corporation to receive a three level downward departure in sentencing for maintaining an effective compliance and ethics program, even where high level or substantial authority personnel are involved in the offense, as long as the following conditions are met:

1. The individual(s) with "operational responsibility for the compliance and ethics program" (usually the CCO) must have had "direct reporting obligations" to the governing authority (usually the board of directors) or an appropriate subgroup thereof (e.g., an audit committee of the board of directors);
2. The compliance and ethics program must have detected the offense before discovery outside of the corporation or before such discovery was reasonably likely;
3. The corporation must have promptly reported the offense to appropriate governmental authorities; and
4. No individual with "operational responsibility for the compliance and ethics program" must have participated in, condoned, or have been willfully ignorant of the offense.

A compliance officer has "direct reporting obligations" if the officer has express authority to communicate personally and promptly to the board on any matter involving criminal conduct or potential criminal conduct. Additionally, the compliance officer must communicate to the board of directors at least once a year regarding the implementation and effectiveness of the compliance and ethics program.

The 2010 Amendments also elaborate on a corporation's responsibilities after it has discovered criminal conduct. After the discovery of an offense, an effective compliance and ethics program requires that the corporation take reasonable steps to remedy the harm resulting from the criminal conduct. These steps may include: (a) providing restitution to identifiable victims; (b) self-reporting criminal conduct to relevant governmental authorities; and (c) cooperating with those governmental authorities. The list is not exhaustive.

After the discovery of criminal conduct, a corporation must assess its current compliance and ethics program and make appropriate modifications as required. I recommend, for example, that compliance programs (newly established or revisions to old) going forward have Standard Operating Procedures ("SOPs") in place where the CCO has "direct reporting obligations" to the governing authority (usually the board of directors) or an appropriate subgroup thereof (e.g., an audit committee of the board of directors). Specifically, provisions of the appropriate SOPs should be clear that the CCO has "express authority to communicate personally" and promptly to the board on any matter involving criminal conduct or potential criminal conduct. Additionally, the SOPs must require the CCO to communicate to the board of directors at least once a year regarding the implementation and effectiveness of the compliance and ethics program.

The existence and adequacy of a corporation's pre-existing compliance program is a significant consideration when a prosecutor is considering whether to charge an organization. Notably, the 2010 Amendments encourage companies to be proactive through the engagement and retention of an outside professional advisor to ensure adequate assessment and implementation of any modifications to the corporation's compliance and ethics program. I strongly encourage those companies operating without a formal compliance and ethics program in place, and those companies that do have a formal compliance and ethics program in place, to retain an outside professional advisor to conduct a global risk assessment, assist with the implementation of a formal compliance and ethics program, and provide ongoing monitoring, training and comprehensive audits to ensure systematic and preventative measures are in place.

The 2010 Amendments will become effective November 1, 2010 unless Congress takes affirmative action to block them. So far, it does not look like Congress will be taking any action at all.

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[i] See http://www.ussc.gov/guidelin.htm.
[ii] http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.
[iii] See November 1, 2010 proposed Amendments to the Sentencing Guidelines.
[iv] See id.
[v] Id.
[vi] Id.
[vii] See November 1, 2010 proposed Amendments to the Sentencing Guidelines.
[viii] See id.
[ix] Id.
[x] Id.
[xi] See November 1, 2010 proposed Amendments to the Sentencing Guidelines.
[xii] See United States Attorneys' Manual, Principles of Federal Prosecution of Business Organizations, § 9-28.800 (2008).
[xiii] See November 1, 2010 proposed Amendments to the Sentencing Guidelines.

Dual Pricing, continued from page 1

and offers that price (referred to as the FSS price) to all eligible FSS entities. On the other hand, a dual price company offers the FCP to the "Big 4" (VA, DoD, IHS/PHS, and Coast Guard) and the negotiated FSS price to Other Government Agencies (OGA).

The statutory FCP calculation contains a component wherein the calculated FCP is compared to the FSS max cap (FSS price + Consumer Price Index for Urban Consumers [CPI U]) to determine the final FCP, and the final FCP is directly dependent upon the FSS max cap. In many cases, for single price companies, the FSS max cap is based on the FCP (lower of the negotiated or calculated price). In these instances, in the subsequent year calculation, the FSS max cap provides a barrier to increase the FCP. With a dual price company, the FSS max cap is typically based on the negotiated FSS price.

Now that you are totally confused……let me say this: Dual pricing is a REALLY, REALLY, REALLY good thing for pharmaceutical manufacturers. With dual pricing, your company benefits in the following ways:

- Higher FSS price
- Higher FCP
- Higher FSS sales as a result of the higher prices
- Lower TRRx refunds as a result of the spread reduction between the Non-Federal Average Manufacturer's Price (NFAMP) and FCP calculations
- Higher reference price for international sales to countries using the FSS as a reference price

In short, dual pricing can add millions of dollars to your company's bottom line.

When assessing the benefits of dual pricing over single pricing, remember that the prices allowed under the statutory calculation are theoretical prices that a company could charge to the Big 4. However, it is equally important to assess the competitive pricing environment of each therapeutic class to determine if the maximum FCP allowed will negatively or positively impact sales. I believe that companies should always position themselves to get the maximum price allowed. Prices can always be reduced on a temporary or permanent basis through a Voluntary Price Reduction or Blanket Purchase Agreement (BPA) to meet competitive pricing pressures, however it is much more difficult to increase a price.

Background

Presumably because they were single pricers when the Vereran's Healthcare Act of 1992 was enacted, most pharmaceutical companies are single pricers which creates the second price (FCP) or dual pricing option. In the mid-1990s, a few companies moved to dual pricing to address pending legislation that would allow non-FSS entities purchase capabilities at FSS prices. Some companies moved to dual pricing at that time because the mandatory 24% discount off of their calculated Annual NFAMP was much lower than the negotiated FSS price. By shifting to dual pricing, these companies were protecting themselves by forcing the non-FSS entities, who would be allowed to purchase at FSS pricing, to purchase at the higher FSS price.
Although this was a good strategy in that particular situation, it was not the right reason to change from single to dual pricing. The opportunity to recover from a "bad" FCP calculation is the most important reason to elect the dual pricing option. A "bad" FCP calculation occurs when a price penalty, caused by an increase in NFAMP that exceeds the increase in CPI-U, pushes your FCP down to an artificially low level. With single pricing, if you have a bad FCP calculation you are handcuffed at the artificially low price because the bad FCP becomes the subsequent year's FSS price, as well as the future year's maximum FSS price (FSS max cap price) in the subsequent year's calculation. With dual pricing, a bad FCP calculation only impacts sales to the Big 4 for the current year. A companycan recover in the subsequent year because the FSS max cap remains at the negotiated price, allowing the FCP to float up to that level.

Changing from Single to Dual Pricing

A company can elect to change from single pricing to dual pricing at any time, although the sooner the switch, the greater the benefit. To make the switch, a company isrequired to disclose/re-disclose its Commercial Sales Practices (CSP) information. This is similar to renegotiating anFSS contract. For those who have done this, you know how time consuming and challenging it can be.However, despite the fact that it is a significant task, the increase in sales and profit far exceed the time and effort it will take to disclose/re-disclose your CSP information.

Some other considerations associated with a switch to dual pricing include maintaining two price lists, one list for Big 4 eligible entities and one list for OGA eligible entities. Companies will also have to maintain separate prices and memberships in their contract/chargeback systems. The final consideration is related to compliance and the Price Reduction Clause of 1994, which requires companies to set a tracking customer. As a single pricer, a reduction in price to the tracking customer does not impact pricing until it becomes less than the FCP. At that time, the government price is reduced on a 1:1 ratio. With dual pricing, the tracking customer ratio is established based on the negotiated price and the tracking customer price at time of award. If the tracking customer price is reduced, the ratio is applied to the tracking customer price to determine the OGA price. There is no impact on the Big 4 price. Once the tracking customer price falls below the FCP, the FCP is reduced at a 1:1 ratio as with single pricing. Although this requires a change in the thought process for tracking customer purposes, it again, is a small change

compared to the additional money that can be garnished as a result of dual pricing.

If you have questions about the benefits of dual pricing, or about how to make the switch, email me at daverice@cis-partners.com.

Make your change today!

A Few Lessons Learned – The Process of Preparing a Client's First State Reports

By Judy Fox, Director, Commercial Compliance
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CIS has been retained by several pharmaceutical manufacturers to assist with their annual state reporting and compliance declaration processes. One such client is going through the reporting process for the first time and contracted with CIS to assist because the company's compliance department was limited in resources and felt that meeting the state reporting deadlines would be a challenge. I thought I would share some of the lessons learned by the client, and some of the hurdles that CIS had to overcome in order to provide accurate and compliant reports. While the process was painful at times, in the endit allowed our client to identify compliance gaps and implement corrective actions to make future reporting more efficient and cost effective.

Vendor Management

The first state report we faced was West Virginia. West Virginia requirements include calculating the marketing expenses aggregated for the state based on the state's population1. The fact that West Virginia offers the methodology for calculating the expenses made it easy; pulling the data from the vendor was another story. When the key stakeholders (in this case the product managers) were notified that marketing and advertising costs were needed, panic set in. To simplify the process, CIS provided the vendor with a template for the data that CIS was required to collect and use for analysis. After several conference calls (okay, arguments) with the vendor, it was agreed that the dollars reported had to be separated with regard to promotional and non-promotional items. To facilitate the vendor data collection process moving forward, CIS had to clarify to the vendor that it was the responsibility of our client's legal department to decide how the state laws would be interpreted. While we were discussing the templates for the advertising expenses, the vendor asked an interesting question, "Do you want us to provide you with all of the speaker fees we paid out last year on behalf of the manufacturer?" We found the question

interesting because the manufacturer had reported to us that they did not conduct any promotional speaker programs. It turns out that they did have promotional speaker programs all managed by the vendor.

Lesson Number One: Vendor Compliance requirements should be clearly defined through contractual arrangements and business rules. Vendors should never be permitted to interpret state or federal laws on behalf of a manufacturer.

Lesson Number Two: Vendor-managed programs must be approved and monitored. Any programs that involve interactions with Healthcare Practitioners (HCPs) including fees, meals, entertainment and travel and expense reimbursement have to be clearly defined to follow both state requirements and company policy.

Healthcare Practitioner's Location and License Identification

As CIS progressed through the state reports CIS became concerned about how to handle the Massachusetts requirements which include HCP license identification. First, CIS had to get through Minnesota's state reporting requirements which turned out to be a good "practice run". CIS contacted the Minnesota Board of Pharmacy for clarification on its requirements, and CIS was instructed to report all HCPs who actively practiced in MN, regardless of the percentage of their practice. For example, if an HCP's primary practice is in North Dakota, but the HCP has a small practice in MN, then the HCP has to be reported2. CIS' client's HCP data was not provided in a manner that would allow CIS to obtain this information, so a list of all targeted HCPs in any of Minnesota's neighboring states were compiled and CIS consultants physically looked up each HCP to determine whether he or she had a MN state license. Once HCPs with multiple licenses were identified, CIS verified that they actively practiced in MN. Those expenses were audited for compliance, and any HCPs with fees or honorarium paid were included in the MN state report.

Lesson Number Three: A Customer Master List of all HCPs and their active licenses is extremely important to ensure that all reportable data is captured. In addition, lack of knowledge regarding HCP state licensure status put the company at risk for MN spending limitations non-compliance.

As we moved through the year and the Massachusetts deadline loomed ahead, CIS knew that it had to strategize a methodology to ensure a compliant report. The most challenging part of Massachusetts requirement pertains to any HCP with an active MA license must be reported to the state regardless of where the HCP is located3. The client captured expenses based on the location of the sales representatives and not on the HCP, so becoming compliant involved several steps. First, all expenses for the reportable period were manually pulled by the client. The expenses were audited by CIS consultants to make sure compliance requirements were based on event locations and dollar value. Any dollar amounts that fell within the reportable limits were pulled, and the state licenses for the HCPs involved were researched. All in all, it was a daunting task considering there were thousands of events, attendees listed as "Dr. Smith and staff," and no standardized method for recording information. Members of the field sales force had to be contacted to clarify event locations, attendee names and the purpose of the event.

Lesson Number Four: The Customer Master List of all HCPs must be used to establish a standardized method for collecting expense data and specifying mandatory expense reporting information.

Internal Understanding and Communication

During the process of scrubbing and auditing data, there were several occasions in which CIS had to reach out to members of the field sales force and their managers. CIS often responded to questions regarding what was perceived as CIS' interpretation of state laws. CIS often had to clarify that it was acting on behalf of the manufacturer's own legal counsel with regard to any interpretations of state law. Notably, not everyone was operating under the process, and there was no universal understanding about the impact that state laws have on the entire sales force. On more than one occasion, managers had taken it upon themselves to communicate state requirements to their sales teams. The message was not always incorrect, it just was not always approved by the client's legal and compliance departments and as a result, there were multiple interpretations of a law.

Lesson Number Five: A lack of communications protocol opened up an opportunity for employees and vendors to interpret requirements. These multiple interpretations resulted in reportable data being collected and reported in several different ways.

Compliance is of the utmost importance for this client. However, the lack of specific controls made the client's reporting process inefficient and the data at times questionable. CIS' work on this portion of a multi-level project allowed the client to strengthen its state reporting process, identify non-compliance issues and eliminate existing gaps. CIS educated key stakeholders in the nuances of the various state reporting requirements, identified

activities that would benefit from certain process changes, and assisted the legal and compliance departments in revising policies to reflect the corporate response to specific state requirements. In all, the project will allow the client to create a more efficient, economical and compliance process that was more efficient,

economical and compliant as long as the lessons learned are put into practical application.

For some solutions to the challenges in incorporating the requirements of Healthcare Reform into your existing state compliance and reporting process, join one of CIS' upcoming events:

CIS will be speaking on "Lessons Learned" at CBI's 4th Annual Forum on Tracking State Laws and Aggregate Spend, August 16-18. http://www.cbinet.com/

Sources:

1. CHAPTER 5A. DEPARTMENT OF ADMINISTRATION. ARTICLE 3C. PHARMACEUTICAL AVAILABILITY AND AFFORDABILITY ACT OF 2004. §§5A-3C-1 to 5A-3C-17. Repealed. Acts, 2009 Reg. Sess., Ch. 10. http://www.legis.state.wv.us/WVCODE/Code.cfm?chap=05a&art=3
2. 2009 Minnesota Statutes: 151.461 GIFTS TO PRACTITIONERS PROHIBITED. https://www.revisor.mn.gov/statutes/?id=151.461
3. PART I. ADMINISTRATION OF THE GOVERNMENT. TITLE XVI. PUBLIC HEALTH CHAPTER 111N. PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT Chapter 111N: Section 6. Disclosure of data relating to provision of economic benefits valuing fifty dollars or greater [Text of section added by 2008, 305, Sec. 14 effective January 1, 2009. See 2008, 305, Sec.6 2.] http://www.mass.gov/legis/laws/mgl/111n-6.htm

ASP to AMP Comparison and the ASP Proposed Rule: It's Time to Pay Closer Attention...

by Jackie O'Connor, CIS Compliance Associate
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An integral component of the proposed ASP rule (summarized in blog, Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B and CY 2011) is the ASP to AMP comparison. I would like to comment specifically on this area, as it has been brewing for some time. While the ASP to AMP comparison has been a focus of the OIG, it has been under the radar for most manufacturers, and CMS has not taken specific action on the OIG's findings until recently.

Since January 2005, Medicare Part B has paid for most covered drugs using a reimbursement methodology based on Average Sales Price (ASP) [1]. In a continual effort to ensure the appropriate amount is being reimbursed, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) has been conducting studies comparing the Average Sales Price (ASP) to the Widely Available Market Price (WAMP) and Average Manufacturing Price (AMP). For the past five years, this applicable threshold for comparison has remained at 5% for both WAMP and AMP. The consistency was based on the fact that data was too limited to support an adjustment of the established threshold [2]. If the ASP exceeds the percentage threshold, the ASP would be disregarded and substituted with the lesser value of the widely available market price for the drug or biological (if any), or 103% of the average manufacturer price [3].

The proposed rules for Medicare Part B, effective 2011, were recently released on Tuesday, July 13th and are open for manufacturer's comments. The proposed rules incorporate updates to the current procedures based on the findings of past studies.

The comparison of ASP to WAMP has not been affected – the threshold of 5% has been deemed appropriate and has been proposed for 2011 [4].

However, there have been proposed changes for the ASP/AMP comparison. For 2011, CMS is proposing to substitute AMP when the comparisons of ASP and AMP exceed the threshold of 5% for two consecutive quarters or three of the previous four quarters. The OIG is concerned that only looking at one specific quarter does not allocate for temporary fluctuations and underlying marketing trends [5]. In addition, CMS is proposing a substitution of 103% of AMP for 106% of ASP, however this should be limited to only those drugs with ASP and AMP comparisons based on the same set of NDCs [6]. This verifies the pricing data collected is accurate and complete for comparison purposes.

Additional reasoning for ASP/AMP comparison changes can be found in the Inspector General's report: "Comparison of Average Sales Prices and Average Manufacturer Prices: An Overview of 2008". Some factors include:

In 2008, ASPs for 80 Healthcare Common Procedure Coding System (HCPCS) codes exceeded AMPs by at least 5%in one or more quarters.

- Manufacturers identified several reasons why ASPs for certain drugs consistently exceeded AMPs, including:
- AMPs are a weighted average across multiple package sizes;
  - Different types of sales are included in ASPs and AMPs;
  - Pricing arrangements among different categories of purchasers;
  - Errors in the calculation of AMPs.
  - Missing and unavailable AMP data in 2008 prevented OIG from conducting thorough drug-pricing comparisons [7].

It is evident through the amount of research performed by the OIG and CMS that the Medicare Part B reimbursement issue will not be easy to resolve. As they continue to look deeper into the issue, it is important and essential that manufacturers are compliant with the AMP and ASP reporting requirements.

Sources:

[1] http://oig.hhs.gov/oei/reports/oei-03-09-00350.pdf
[2] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40156
[3] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40156
[4] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40156
[5] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40156
[6] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40156
[7] http://oig.hhs.gov/oei/reports/oei-03-09-00350.pdf

Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B and CY 2011

Courtesy of Jackie O'Connor (jacquelineoconnor@cis-partners.com) and Erika Scholl (erikascholl@cis-partners.com), CIS Compliance Associates

Federal Register/Vol. 43, No. 133/Tuesday, July 13, 2010
Department of Health and Human Services
Centers for Medicare & Medicaid Services

Overall Summary: This proposed rule addresses proposed changes to the physician fee schedule and other Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice and the relative value of services. It also addresses, implements or discusses certain provisions of both the Patient Protection and Affordable Care Act (PPACA) and the Medicare Improvements for Patients and Providers Act of 2008. In addition, this proposed rule discusses payments under the Ambulance Fee Schedule, Clinical Laboratory Fee Schedule, payments to End Stage Renal Disease (ESRD) facilities, and payments for Part B drugs. Finally, the proposed rule includes a discussion regarding the Chiropractic Services Demonstration program, the Competitive Bidding Program for Durable Medical Equipment and Provider and Supplier Enrollment Issues associated with Air Ambulances.[1]

Section VI. Other Provisions of the Proposed Regulation Effects on Medicare Part B, Average Sales Price (ASP)

Summary: CMS published its proposed ruling summaries for areas related to Medicare Part B. First, to minimize the possibility of ASP payment limitation fluctuations due to missing data, CMS is proposing a "carry over" ASP for NDCs missing manufacturer ASP and/or WAC data. Second, a proposal hto clearly state regulations with regards to payment of drugs/biological which include intentional overfill was made. Third, CMS is proposing 2011 threshold percentages for WAMP comparisons (to remain at 5%) and AMP substitutions (policy substitute of 103% of AMP for 106% of ASP when ASP exceeds AMP by 5% or more). CMS also took this opportunity to provide clarification on partial quarter ASP data. No proposals were submitted for comment on this topic. Comments must be received by 5 p.m. on August 24, 2010 to be considered. Comments can be submitted electronically at http://www.regulations.gov (follow instructions for "submitting a comment") or via mail to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1503-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please see the blog article, Medicare Part B Proposed Ruling Summary, for a more detailed outline of the proposed ruling.

Current State and Proposed Rules
Part B Drug Payment: Average Sales Price (ASP) Issues
Note: ASP Methodology is authorized under section 303 (c) of the MMA which amends Title XVIII of the Act.

1. "Carry Over" ASP

Although uncommon, recent instances of delays in ASP reporting could have lead to significant ASP payment limit fluctuations for highly utilized Healthcare Common Procedure Coding System (HCPCS, pronounced "hick-picks") codes.

- The greatest potential impact occurring from data for high volume drug products within an HCPCS code that is represented by a limited number of NDCs has not been reported and cannot be included in the ASP volume weighted calculations.
- HCPCS is a coding system created by the American Medical Association (AMA) and the Center for Medicare and Medicaid Services (CMS), a division of the Health and Human Services, to ensure that claims made by healthcare professionals are processed orderly and consistently. The HCPCS is divided into two subsystems: Level I and Level II. Level I is comprised of Physicians Current Procedural Terminology (CPT) and contains the codes to bill insurance companies for any in-patient or office visit where treatment or supplies is used in the medical facility. Level II contains alpha-numeric codes to bill for services not provided in a physician's office.[2]

Proposed Rules: To minimize the possibility of ASP payment limitation fluctuations due to missing data, CMS proposes to "carry over the previously reported manufacturer ASP for NDCs when missing manufacturer ASP and/or WAC data could cause significant changes or fluctuations in ASP payment limits."[3]

Ex: Recently reported ASP prices for products on the market would be carried over to next quarter if: (1) entire manufacturer submission was not received;(2) Manufacturer ASP price data for specific NDC's was not reported; or(3) only WAC data was reported. Notably, NDCs with zero sales or NDCs no longer manufactured are not subjected to this process.

CMS proposes to only apply carryover in cases where missing data results in a 10% or greater change in an ASP payment limit compared to the previous quarter. (Note: CMS is specifically requesting comments on the 10% proposal.)

- In an effort to represent actual market trends, CMS proposes that "the manufacturer ASP payment amounts for individuals NDCs that are carried over be adjusted by the weighted average of the change in the manufacturer ASP for NDCs reported during both the most recent quarter and the current quarter."[4] This includes both single source and multiple source drugs, however CMS is concerned that including single source drugs could create incentive for non-reporting in certain situations. (Note: CMS specifically requesting comments on this option.)
- Proposed change is intended to more accurately represent prices in the marketplace if ASP data for a particular drug is missing.
- Proposed change will not prevent CMS and OIG from collecting penalties for ASP reporting violations.

2. Partial Quarter ASP Data

Opportunity to Clarify: CMS is taking this opportunity to describe their policy regarding how reported data is used in the calculation of ASP payment limits during first quarter sales (for both single and multiple source drugs).

- Section 1847A(c)(4) of the Act explains that during an initial period where there is insufficient data to compute ASP, the Secretary may determine the amount payable based on WAC.
- It has been CMS' policy to price new single source drugs at WAC for first quarter (unless date of the first sale is on the first day of the quarter) and add new multiple source drugs (and product line extensions of single source drugs) to the ASP calculation for a quarter as soon as products are reported.

3. Determining the Payment Amount of Drugs and Biological Including Intentional Overfill

Proposed Rule: CMS proposes to update regulation42 CFR 414 (J) to state that "Medicare ASP payment limits are based on the amount of product in the vial or container as reflected on the FDA-approved label."[5]

- CMS also proposes to update regulations to clearly state "payment for amounts of free product, or product in excess of the amount reflected on the FDA approved label, will not be made under Medicare."[6]
- Manufacturers, at times and by design, include small amounts of "intentional overfill" to compensate for loss of product when a dose is prepared and administered properly. For example, Ex: A drug is intended to be delivered at 0.5 mg dose. The vial is labeled 0.5 mg but actually contains 1.5 mg of product. The additional 1.0 mg is included to ensure a full 0.5 mg dose is administered to the patient.
- ASP calculations are based on reported information from the manufacturer.
- When a provider purchases a vial or container of product, they are purchasing an amount of drug defined by the product packaging or label.
- Overfill is included without charge to the provider and therefore may not be billed to Medicare.
- Claims that do not represent a cost to the providers are not reimbursable and may be subject to CMS and OIG scrutiny.

4. WAMP/AMP

Current State Summary:

- The Inspector General of HHS shall compare the ASP (for drugs and biological) with: The Widely Available Market Price (WAMP), and The Average Manufacturer Price (AMP). [8]
- Based on previous Acts, the Secretary may disregard the ASP for a drug or biological that exceeds the WAMP or the AMP for such drug or biological by the applicable threshold percentage of 5%. [9]
- If the OIG finds that the ASP for a drug or biological is found to have exceeded the WAMP or AMP by 5%, effective as of the next quarter, the ASP will be substituted for the amount of payment, the lesser of: WAMP for the drug or biological (if any); 103% of the AMP. [10]

Proposed Rules:

- **WAMP Threshold Percentage:** For CY 2011, when making comparisons to the WAMP, CMS proposes the applicable threshold percentage to remain at 5%.
- **AMP Threshold Percentage:** For CY 2011, regarding AMP substitution, CMS proposes to apply the applicable percentage subject to a certain adjustment so that comparisons of ASP to AMP will only be made when the ASP exceeds the AMP by 5% in two consecutive quarters immediately prior to the current pricing quarter, or three of the previous four quarters immediately prior to the current quarter. CMS is concerned that comparisons of a single quarter's ASP to AMP will not adequately account for temporary fluctuations and underlying market trends. Moreover, applying this threshold percentage adjusted to reflect data from multiple quarters will account for continuing differences between ASP and AMP, and allow for better identification of those drugs that consistently

trigger the substitution threshold.
- CMS also proposes to apply the applicable AMP threshold percentage only for those situations where AMP and ASP comparisons are based on the same set of NDCs for a billing code (that is, "complete" AMP data).
- AMP Price Substitution: CMS proposes a policy to substitute 103% of AMP for 106% of ASP where the applicable percentage has been satisfied for a number of calendar quarters. CMS acknowledges the limitation of the preliminary injunction on its ability to publicly disclose AMP data and until that injunction is modified, the price substitution policy will not be implemented.[10]

Comment Submission Instructions

Comment Submission Deadline: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 24, 2010.

Comment Submission: When commenting, please refer to file code CMS-1503-P.
You may submit comments in one of four ways (please choose only one of the ways listed).

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions for "submitting a comment."

2. By regular mail. You may mail written comments to the following address only:
Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1503-P, P.O. Box 8013, Baltimore, MD 21244-8013. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1503-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC–Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD–Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with a staff member. Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.[11]

Sources:

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[2] The National Assistive Technology Advocacy Project, http://www.nls.org/av/FAQ's%20HCPCS.pdf, Page 1, (Last visited July 8, 2010).
[3] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40153
[4] http://edocket.access.gpo.gov/2010/pdf/2010-15900.pdf; Page 40153
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