

AMP Guidance:

AMP-Related Provisions and Best Practices in Government Reporting without Clear Guidance





Webinar Tips

- The audio for today's webinar is available via either the internet or telephone conference line
- Type questions into the Question box
- Information will be available after the webinar at www.cis-partners.com



Disclaimer

- This presentation is being made by specific presenters, and reflects their industry experience on the topics at hand.
- The information expressed in this presentation does not necessarily reflect the advice of CIS.
- This presentation does not constitute legal advice.

Additional Resources

For more information about our upcoming complimentary webinars, or to download previously recorded webinars, go to

cis-partners.com/resources/webinars.html

Keep up with the latest industry developments with the Pharma Compliance Blog and monthly GP Forum

[pharmacomplianceblog.com/blog/
cis-partners.com/resources/gpforum.html](http://pharmacomplianceblog.com/blog/cis-partners.com/resources/gpforum.html)

Check out the Healthcare Reform Beacon for a printer-friendly compilation of CIS insights

cis-partners.com/resources/cisnewsletters.html

How prepared do you feel about the upcoming AMP rules?

Poll Results (single answer required):

Completely confident our processes and systems are ready.	5%
Somewhat confident our processes and systems are ready.	30%
Hesitant because so little is set in stone.	32%
Concerned because we don't know what to expect.	24%
Very concerned that we won't be able to handle the change.	8%

Today's Speakers



Chris Cobourn
Commercial
Compliance



Amy VanDeCar
Commercial
Compliance



By attending this complimentary webinar, you will have a better understanding of the current status of AMP guidance, and what to expect with future rule making:

- What kind of rule will it be, and how might it be implemented?
 - A proposed rule?
 - An interim final rule?
- What are the key timing considerations?
 - Once announced, when may the rule go into effect?
 - What should we do in the meantime?
- What key policy or methodology questions might the new rule address?

Pharmaceutical Manufacturers are required to be in adherence with the legislative language of the Patient Protection and Affordable Care Act (PPACA) related to Medicaid Drug Rebate Program participation and the definition of Average Manufacturer Price (AMP), yet we do not have regulations to define AMP according to the PPACA language. While we await substantive, regulatory guidance, we are in a “sub-regulatory environment” and must make reasonable assumptions.

- PPACA legislation mandated AMP changes were effective October 2010.
 - Established two approaches to AMP: RCP AMP and Alternative “5i” AMP
 - Largely reflected focus of retail industry from injunction, making Retail Community Pharmacies the basis for AMP
 - See NACDS letter to CMS dated July 20, 2010
- Portions of the DRA Final Rule of 2007 (which had been under an injunction) were withdrawn
 - Section 504 withdrawn
 - Other sections still in effect (i.e., bona fide service fee definition)
- The common view of the current environment is that we are in a “sub-regulatory environment.” Manufacturers consider their current AMP (since October 2010) to be an interim AMP
- CMS is in a rule-making process, and we await a proposed rule
 - In a related side note, the OPA is also in a rule-making process

What to look for when the rule comes out

- Proposed or interim, and what is the effective date?
- Top down (gross-to-net) or build up?
 1. Top down assumes unidentified wholesale sales are to retail
 2. Build up only counts specifically identifiable retail sales
 3. Retail pharmacies have advocated “build up” approach in litigation and lobbying
 4. Operational implications
 1. Requirement for, availability, and validity of wholesaler sales-out data?
 2. Major programming revisions
 5. CIS observations
 1. Build up approach could be scary
 2. It would be difficult to reconcile data to the general ledger or account for the validity of the data used
 3. It would be inconsistent with ASP, the PHS program statutory AMP, and Non-FAMP
- Ability to restate Base AMP?
- Retroactivity to October 2010?

Key Timing Considerations

- If it is a proposed rule, how long is the comment period and what is the likely actual effective date of the eventual Final Rule
 - What to do in the mean time with your current “Interim AMP”
- If it is an Interim Final rule, what is the effective date
 - How encompassing are the changes, what do you need to do to implement it on time



Current “word on the street”

- When may the proposed rule be published?



- Basic CIS approach to interim AMP methodology
 - As consultants, not providing legal interpretation of the limited language in the PPACA
 - Keep changes as simple as possible, focusing upon class of trade
 - Try to be consistent with standard industry practices and assumptions
 - Be consistent with 2007 AMP rule, unless directed specifically otherwise
 - Where interpretation is required, work with counsel on reasonable assumptions
- Two potential outcomes for AMP guidance
 1. Fairly consistent with the changes that went into effect in October, but with clarification in RCP and alternative AMP
 2. A major shift with a build up AMP methodology

Policy and Methodology Challenges



- The RCP Class of Trade
 1. Brick and mortar, serving the general public
 2. What about specialty pharmacies?
- Inclusion of Authorized Generic sales in AMP given the broadened definition of wholesaler



- Determining what is an Alternative 5i AMP drug, and the qualifier of “not generally sold to retail”
 1. Must be in one of “I” classes
 1. Injected
 2. Implanted
 3. Infused
 4. Inhaled
 5. Instilled
 2. Must be “not generally dispensed at retail”
 1. Quantitative
 2. Qualitative
 3. What about non-5i, non-retail?
- Alternative 5i AMP COT

- Line Extensions
 1. Line extension of an S/I drug that is an oral solid dosage form
 2. Line extension is a “new formulation..., such as an extended release formulation”
 3. “Formulation” potentially broadly construed
 4. Some open questions
 - Must both original and new formulation be oral solids?
 - New strength as new formulation?
 - Effect of different indication?
 - What if one of the products is OTC?

- Bona Fide Service Fees clarification, reconciling the new PPACA language with the still in effect 2007 DRA Final Rule Bona Fide Fee for Service criteria
 1. Bona fide service fees excluded from AMP calculations
 2. Distribution service fees, inventory management fees, stocking allowances, and administrative service fees may qualify as bona fide service fees
 - “(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);”

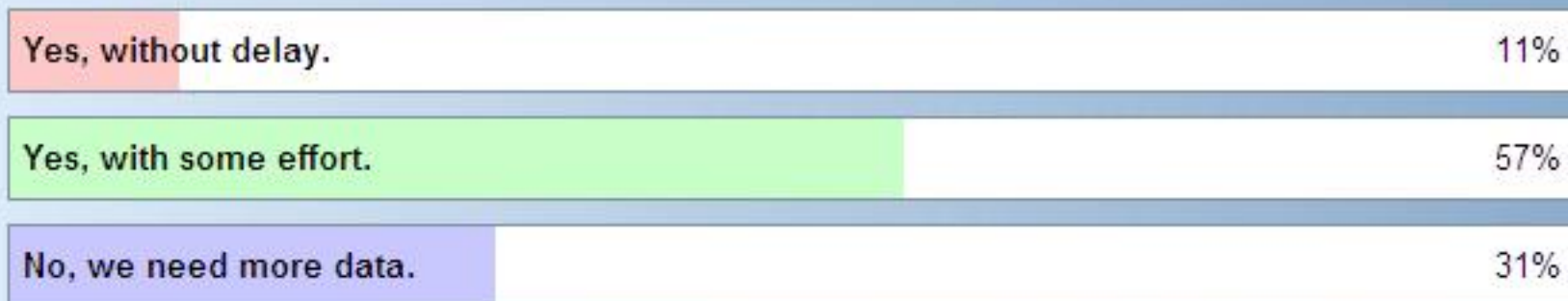
- Impact of higher RCP AMPs on the PHS Price
 - High base AMP comparison creates high penalty and max URA of AMP
 - AMP minus URA for PHS price creates penny pricing
- Remember the May 9th 2007 Jimmy Mitchell letter
 - A separate PHS AMP is a possibility

- AMP for use for FUL
 1. FULs required where there are three equivalent products
 2. 175% of weighted average AMP of equivalent products
 3. Publication of weighted average AMP
 - Implications of publishing AMP on commercial pricing
- Draft AMP FUL Guide published September 21st, 2011
 - This is not a proposed rule; it is a draft guide, but comments are being accepted
 - Learn more on the Pharma Compliance Blog:
(pharmacomplianceblog.com/blog/)
- CIS observation
 - Remember that these draft FULs are based on the interim AMP methodologies, and may change with the publication of the rule

Poll

If you were given the ability to restate base AMP under a new AMP rule, would you have the data to be able to do it?

Poll Results (single answer required):



Questions?

- What do you think the likelihood of being able to restate base AMP?
- What kind of system changes do you anticipate being required to accommodate this type of change?



Contact Us



Chris Cobourn
ChrisCobourn
@cis-partners.com



Amy VanDeCar
AmyVanDeCar
@cis-partners.com



Thank you

Thanks for Attending



cis-partners.com
info@cis-partners.com

PharmaComplianceBlog.com
cis-pcx.com

Compliance Implementation Services

1400 N Providence Rd.
Building II, Suite 3005
Media, PA 19063
484.445.7207

3005 Carrington Mill Blvd.
Suite 580
Morrisville, NC 27560
919.463.1990

1350 Old Bayshore Hwy.
Suite 730
Burlingame, CA 94010
650.227.2400