

Question 1: What do you think the likelihood of being able to restate base AMP?

The precedent for doing so was established with the DRA. We are hopeful that manufacturers will have the opportunity to calculate HCR baseline AMPs. There are clear and dramatic differences in AMP with the new RCP AMP as well as the Alt 5i AMP. CMS is aware of these differences and of the impact it is having on the calculated URA.

Question 2: What kind of system changes do you anticipate being required to accommodate this type of change?

[Assuming that this is in the context of using 867 data] At a minimum, manufacturers' GP systems would have to be configured to accommodate this additional data source (loading, storing, mapping how the wholesalers' data corresponds to the fields used to calculate pricing), and to tie the wholesalers' customer specifications to the manufacturer's customer master and class of trade schema. Additional factors would be setting up validations on the data, establishing rules for what to do with redacted data (i.e., the lines for customers who won't allow the wholesalers to identify them in the data), and coding the logic of how the 867 data would relate to the existing data sources. If the rule focuses more on COT definitions and clarifications but maintains the gross to net approach, we would not anticipate as significant a system impact.

Question 3: Does the Grassley/Kohl letter of October 3, 2011 impact the situations discussed in this webinar?

The Grassley/Kohl letter of October 3rd was focused on the need for regulations around the Sunshine Act, so the specific topic was a bit different. However, the letter's call for guidance is very relevant to the situation with AMP.

Question 4: If guidance allows restatement of Base AMP, do you believe that restatement will be allowed for one code and not another? For example, data available for a code and not for another because the second code was a purchased product.

Yes, I would expect so, based again on the precedent from the DRA.

Question 5: You mentioned that definition specialty pharmacies may vary by product. Can you provide more detail on this? Why would it vary based on product?

Class of trade tends to be very company specific, with manufacturers using different categories and definitions, depending on their business model and product line. “Specialty pharmacy” is a good example of a category where the definitions do vary widely. I’ve seen manufacturers use the term to mean pharmacies that handle specialty products, often requiring special storage or handling, typically distributing these products through the mail. On the other hand, I’ve seen companies use the term to mean brick and mortar pharmacies with compounding services. We think that a good approach is to start by your definition of RCP, and then evaluate whether your Specialty Pharmacy COTs fit in to that definition.

Question 6: In what ways did PPACA broaden the wholesaler definition?

PPACA defined wholesaler as “a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.” This new definition has prompted many manufacturers to reassess their relationships with other manufacturers and with repackagers/relabelers.

Question 7: How is capturing authorized generic data from another manufacturer different than capturing data from another manufacturer when a product is sold? I believe that there is already guidance and processes that would mirror authorized generic data.

When a manufacturer purchases a product from another manufacturer it is common to have a period of time where there is inventory owned and sold by the acquiring manufacturer, but it is still under the divesting manufacturer's labeler code until the inventory is sold off and the acquiring manufacturer has product in the market under their labeler code. In this situation, the product under the divesting manufacturer's labeler code is still covered under their Medicaid Drug Rebate Program agreement. It is common for the acquiring and divesting companies agree on a process for reporting the divesting company's AMP and BP values. This often means the acquiring company calculating the AMP and BP values, as it is their product and they have the transactional sales data, and providing this to the divesting company to report to CMS. We see this is a very different scenario than an AG company providing transactional level sales data to the branded company for inclusion in their AMP calculations.

Question 8: Wouldn't the data for restating AMP be readily available from pricing services (i.e., Wolters-Kluwer)?

The data from the pricing services typically does not have sufficient detail to perform the recalculations. The data also cannot be reconciled to the manufacturer's general ledger, making it difficult or impossible to say that the data is complete and accurate.

Question 9: Can you please explain the purpose for including the "S" tab in the DRAFT AMP FUL guidance? Additionally, any insight into the methodology applied to the formulation of the "5i" tab.

My impression from reviewing the file is that CMS attempted to put all of the products listed in DDR into one of the tabs. So, the "S" tab is intended to account for the single source products that are not part of the calculation of the FULs. As for the methodology applied to the formulation of the "5i" tab, we will forward the question along to CMS and follow up with their response.