CROSSWALK DOCUMENT FOR CMS 10110

<table>
<tr><th>CHANGE</th><th>RATIONALE</th></tr>
<tr><td>Font formats for the two data collection forms (Addendum A and Addendum B) were enlarged and changed to a sans serif font.</td><td>To comply with Section 508 best practices.</td></tr>
<tr><td>Page margins were adjusted so the forms will continue to appear on one page</td><td>To accommodate larger font size while keeping to a one page format.</td></tr>
<tr><td>Supporting document details were updated to reflect more accurate estimates of burden and the number of respondents.
The number of respondents was increased to 180 from 120.
The number of hours for each response was increased by 3 hours to recognize the requirement to report 4 additional data elements.
The respondent costs were increased to better reflect estimated costs in addition to customary business expenses.
The agency’s cost to collect the data was increased to $200,000 from $110,000 to more accurately reflect additional labor and resources used for this project.</td><td>CMS revised the burden and reporting estimates based on available feedback from respondents.</td></tr>
<tr><td>Added 3 data elements to Addendum A to identify the FDA approval for the drug product.<table><tr><th>FDA Application Number</th><th>FDA Final Pre-Marketing Approval Date</th><th>FDA Approval Type</th></tr></table></td><td>To appropriately determine payment amounts under Section 1847A of the Social Security Act, CMS must identify and associate the FDA approval number of a product with the applicable ASP data. The FDA approval number at the drug product level is not available to CMS from an existing source. Therefore, CMS must collect these data directly from manufacturers.</td></tr>
<tr><td>Added a data field to facilitate reporting of a change in descriptive data since the last response.

Descriptive Data Corrected</td><td>Respondents have requested a method for identifying when descriptive data previously reported is being corrected. Corrected data must be clearly identified for CMS so that appropriate modifications to the payment amount calculations may be made to ensure accurate program payments.</td></tr>
</table>