

Table 1: Crosswalk of Changes

| # | Item | Change | Rationale | Existing System Screenshot(s) | New System Screenshot(s) |
|----|--------------------------|--|--|--|---|
| 1. | ASP User Guide Structure | The previously approved user guides were written as a comprehensive guide inclusive of all steps from registration in the CMS Identity Management (IDM) portal to certification of ASP data. The proposed guides have been completely rewritten into three separate guides: one for System Registration, one for Data Submitters, and one for Data Certifiers. | Removing the one-time registration steps into a separate guide allows users the opportunity to quickly access the steps they need to complete each quarter. Separating the Data Submitter tasks from the Data Certifier tasks also allows each user to focus on their tasks at hand and not have to search for the specific items associated with their role only. | <ul style="list-style-type: none"> • No screenshots • The Registration Guide is on pages 4 through 15 of the existing user guide. • Certifier tasks are intertwined with Submitter tasks and located on pages 18, 28, 61, 65, 77, and 78. | N/A |
| 2. | System - Main Navigation | The existing system was designed with the main navigation on the left-hand side of the screen. The new system has been reorganized to have the main navigation at the top of the screen. | Based on user feedback and industry best practices, having the main navigation on the top of the screen provides a better user experience. | Medicare Part B Drug ASP User Manual Version 2.3, page 18, Figures 3-2 and 3-3. | <ul style="list-style-type: none"> • Medicare Part B ASP Module Submitter User Guide Version 0.1, page 9, Figure 8. • Medicare Part B ASP Module Certifier User Guide Version 0.1, page 10, Figure 8. |

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| 3. | System - Homepage | <p>The existing system contained a visual image of the business process flow and the steps the users would take to complete their tasks. The new system has a list of business process flow tasks assigned to each role, in chronological order, with links to related tabs in the system for those tasks, and tips for a successful data submission.</p> <p>The Reporting Summary box indicating which quarter the system is currently accepting submissions for has moved from the right-hand side of the screen to the top of the main homepage.</p> | Based on user feedback and industry best practices, adjusting the homepage to provide clearer instructions and guidance delivers a better user experience. | Medicare Part B Drug ASP User Manual Version 2.3, page 18, Figures 3-2 and 3-3. | <ul style="list-style-type: none"> Medicare Part B ASP Module Submitter User Guide Version 0.1, page 9, Figure 8. Medicare Part B ASP Module Certifier User Guide Version 0.1, page 10, Figure 8. |
| 4. | System - Manage NDC Tab | <p>The existing system was designed with a multi-select box with various NDC1/ALT ID Listings. From there, the user can assign an NDC1/ALT ID to a manufacturer.</p> <p>In the new system, this functionality has been redesigned to drop-down fields for both the NDC1/ALT ID and the Manufacturer Name. The ability to request a new NDC1/ALT ID/Manufacturer/Generic Name has also been added.</p> | The overall design and layout provide the user with a cleaner user experience, and the drop-down selection design reduces the chances of data entry errors. | Medicare Part B Drug ASP User Manual Version 2.3, pages 18 through 22, Figures 4-1 through 4-8. | Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 10 through 22, Figures 9 through 29. |

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| 5. | System - Product Data Tab | <p>The existing system was designed with the Product Data pages on the left-hand navigation, broken out into separate pages. The Add Product Data and Update Product Data field layout was scattered across the page and not easy to navigate. The Upload Product Data page did not allow for drag-and-drop functionality. The View Submitted Drugs page provided limited information to the user.</p> <p>In the new system, there are more fields (including drop-downs) for the user to populate in Add Product Data and Update Product Data, designed in a linear format that is more user-friendly. The Upload Product Data page allows the user to navigate and attach a file, as well as drag-and-drop a file to upload it. The View Drugs page provides the user with much more drug data.</p> | <p>The additional and redesigned fields in the Add & Update Product Data pages will result in cleaner, more uniform data being entered into the system, and reduce the instances of duplicate drugs being entered into the system. The view is more aesthetically pleasing and easier for the user to follow. The drag-and-drop of the upload functionality is much more user-friendly and quicker. The View Drugs page provides the user with much more information at a glance, which the user can then export via Excel for further analysis.</p> | <p>Medicare Part B Drug ASP User Manual Version 2.3, pages 34 through 50, Figures 6-1 through 6-20.</p> | <p>Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 22 through 45, Figures 30 through 51.</p> |

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| 6. | System - Financial Data Tab | <p>As part of the financial data submission process, the existing system asks users for the Number of Cap Units Excluded; the title of this field has been changed in the new system to Average Wholesale Price.</p> <p>In addition, new functionality has been added to the Upload Financial Data screens, allowing users to see and access previously uploaded data files. The new system provides additional details regarding errors found in uploaded data to allow users to resolve data submission issues more easily.</p> <p>The Upload Financial Data page allows the user to navigate and attach a file, as well as drag-and-drop a file to upload it.</p> | <p>The new system provides a more user-friendly screen for submitting financial data from manufacturers, including the ability to expand/hide line items to see additional product related data, enhanced status reporting, and easier navigation between pages of product data. The new system provides additional inline help text and improved data entry error alerts and warnings to assist users with financial data submission. The new system also provides separate views for Certified and Uncertified financial data, providing users with the ability to see previously submitted and certified financial data.</p> <p>The CAP Units field was removed because the CAP program was not implemented so this data is not needed. The Average Wholesale Price was added because this data is needed to calculate payment limits for drug products paid at AWP by statute.</p> | Medicare Part B Drug ASP User Manual Version 2.3, pages 51 through 58, Figures 7-1 through 7-13. | Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 45 through 58, Figures 53 through 66. |

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| 7. | System - Financial Data Tab - Restatements | <p>The existing system includes Restatements as a separate tab. The Restate Financial Data or Add for Prior Quarters tasks have been moved to drop-down items under the Financial Data Tab in the new system.</p> <p>As part of the financial data submission process, the existing system asks users for the Number of Cap Units Excluded; the title of this field has been changed in the new system to Average Wholesale Price.</p> <p>The Upload Restate Financial Data page allows the user to navigate and attach a file, as well as drag-and-drop a file to upload it.</p> | <p>The Restatements functionality was moved to drop-down items under the Financial Data Tab based on user and CMS internal team feedback to minimize confusion across data submitters and to align all financial data activities under one area of the new system.</p> <p>The CAP Units field was removed because the CAP program was not implemented so this data is not needed. The Average Wholesale Price was added because this data is needed to calculate payment limits for drug products paid at AWP by statute.</p> | <p>Medicare Part B Drug ASP User Manual Version 2.3, pages 68 through 76, Figures 11-1 through 11-14.</p> | <p>Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 58 through 65, Figures 67 through 78.</p> |
| 8. | System - Compliance Summary Tab | <p>The Compliance Summary in both the existing and new systems contain the same information providing the user with access to all their drug products and their respective status in the data submission process. The new system has this information reorganized by status on horizontal tabs versus the drop-down accordion style in the existing system.</p> <p>The newest feature in this section is the ability for users to Export the Compliance Summary to Excel. This feature is available for each status in the data submission process.</p> | <p>The newly reorganized structure provides the ability to easily sort through the user's drug products and take appropriate actions based on the drug's status. Adding the Export to Excel functionality allows users to export data for internal reporting and data gathering purposes.</p> | <p>Submitter - Medicare Part B Drug ASP User Manual Version 2.3, pages 23 through 28, Figures 5-1 through 5-10.</p> <p>Certifier - Medicare Part B Drug ASP User Manual Version 2.3, pages 28 through 33, Figures 5-11 through 5-18.</p> | <p>Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 66 through 77, Figures 79 through 90.</p> <p>Medicare Part B ASP Module Certifier User Guide Version 0.1, pages 13 through 23, Figures 13 through 22.</p> |

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| 9. | System - Generate One-Time Password (OTP) Tab | The existing functionality and new functionality are largely the same, with the exception that the new functionality provides the user with a Copy button to copy the OTP. | The ability to copy the OTP is more user-friendly and eliminates the chances of mistyping the OTP when it gets passed from the Submitter to the Certifier. | Medicare Part B Drug ASP User Manual Version 2.3, pages 59 through 61, Figures 8-1 through 9-3. | Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 77 through 88, Figures 91 through 94. |
| 10. | System - OTP Verification | In the existing system, users are asked to enter the OTP provided by their data submitter. In the new system, users are asked to provide the Manufacturer Name as well as the OTP provided by the data submitter. | The Manufacturer Name field was added to the OTP Verification to confirm that the information is correct at the one-time establishment of the relationship between the manufacturer and the data certifier. | Medicare Part B Drug ASP User Manual Version 2.3, pages 77 through 78, Figures 12-1 through 12-4. | Medicare Part B ASP Module Certifier User Guide Version 0.1, pages 11 through 13, Figures 9 through 12. |
| 11. | System - Assumptions Tab | The existing functionality and new functionality are largely the same, with the new system moving the Manufacturer Name drop-down and Text for Assumption field into a pop-up box, rather than having them directly on the landing page with multiple tabs. The pop-up box also added a field for Short Description. The Assumptions landing page also provides the user with the ability to export a list of assumptions to an Excel file for further analysis. | The new system shows all existing Assumption files on the landing page, rather than requiring the user to click on a separate tab to see them. The upload functionality allows the user to drag-and-drop an Assumption file as well, which helps to streamline the user experience. | Medicare Part B Drug ASP User Manual Version 2.3, pages 62 through 67, Figures 10-1 through 10-14. | <ul style="list-style-type: none"> Medicare Part B ASP Module Submitter User Guide Version 0.1, pages 88 through 94, Figures 95 through 101. Medicare Part B ASP Module Certifier User Guide Version 0.1, pages 23 through 29, Figures 23 through 29. |

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| 12. | System - FAQs | <p>Both the existing and new systems have a page for Frequently Asked Questions (FAQs). The new system's FAQs have been updated to reflect the most current FAQs regarding the system and steps within the system and not policy or program guidance. This content will be refreshed regularly to provide more accurate helpful information.</p> <p>The Help Desk information was added to the FAQ page.</p> <p>In addition, the new system links to a newly created FAQ document which answers many questions about the process and related policies.</p> | <p>The system/technical related questions have been separated from policy and process related questions, allowing users to find answers about the system quickly and easily. The technical questions and respective answers are now included directly within the system and users are provided a direct link to a separate FAQ document with answers to frequently asked process and policy related questions.</p> | N/A | N/A |

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| 13. | System - Drug Certification | <p>In the new system, the Title for the Certifying Data For field has been changed to Reporting Period.</p> <p>Users are asked to self-select whether they are a Direct Employee of the manufacturer or a Contractor, and to verify and confirm the manufacturer's address and certifier's contact information. Users are provided the ability to edit the manufacturer's address or certifier's contact information if needed.</p> <p>The new system provides separate views for Drug Data Pending Certification and All Submitted Drugs in the reported period via tabs rather than a drop-down.</p> <p>In the existing system, users can click a checkbox to certify an individual line item. In the new system, this has been changed to a button.</p> | <p>The new system provides a more user-friendly screen for certifying submitted drug and financial data, including the ability to expand/hide line items to see additional product related data, enhanced status reporting, and easier navigation between pages of data.</p> <p>The selection of Direct Employee or Contractor as part of the Drug Certification process allows the resulting screen to be tailored to the certifier type. Users are asked for a one-time verification of manufacturer and certifier contact information to mitigate data entry and data quality errors.</p> | Medicare Part B Drug ASP User Manual Version 2.3, page 61, Figures 9-1 through 9-3. | Medicare Part B ASP Module Certifier User Guide Version 0.1, pages 29 through 39, Figures 30 through 41. |
| 14. | System - Hover-over Tips | <p>The new system has hover-over tip functionality. The hover-over tip is a callout that appears in certain parts of the data collection workflow containing helpful hints about or definitions of less intuitive fields or terminology.</p> | <p>This was done to help users navigate the system more easily and provide additional on-screen guidance for better data collection and user experience.</p> | N/A | N/A |

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| 15. | Product Data Template | The field for Expiration Date of Last Lot Sold was removed. Five new fields were added to the product data template: Alternate ID Website URL, Unit for Volume per Item, Package Type, Unit for Strength, and First Marketing Date. Instructions were added to the Excel version. | The field for Expiration Date of Last Lot Sold will be entered directly into the Update Product Data tab of the ASP data collection system. The Alternate ID Website URL was added so that manufacturers of skin products could input their website URL. We use this data to verify skin product data. The unit for Volume per item (drop-down) and Unit for Strength (valid values listed in the worksheet tab of the product data template) were added so that the reporting of the units is uniform. The package type was added so that we can identify single use versus multiple-use vials/dosages to apply the drug wastage provision. The first marketing data was added so that we can correctly assign the benchmark quarter and CPI-U for the rebatable drug provision. | N/A | N/A |

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| 16. | Financial Data Template | <p>Three fields were removed from the financial data template: Generic Name, Brand Name, and Number of CAP units. Four fields were added: Average Wholesale Price (AWP), NDC1, NDC2 and NDC3.</p> <p>Instructions and samples are included in the Excel version.</p> | <p>The CAP Units field was removed because the CAP program was not implemented so this data is not needed. The Average Wholesale Price was added because this data is needed to calculate payment limits for drug products paid at AWP by statute. NDC1, NDC2 and NDC3 data is being requested to identify the product instead of using the brand name and generic name to identify the product. This is consistent with how drugs are identified on the product data template.</p> | N/A | N/A |