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<u>Change</u>
Revised date from "08" to "29"
Revised date from "08" to "29"
replaced "Create Assumption" with "Reasonable Assumptions"
replaced "Upload Assumption File" with Other Assumptions (Optional)
replaced "3.4.1" with "3.5.1"
replaced "3.4.2" with "3.5.2"
replaced "3.4.3" with "3.5.3"
replaced "3.4.4" with "3.5.4"
replaced "Drug manufacturers can submit comments regarding their certifications to CMS. Manufacturers may submit these comments for either the current or prior reporting periods" with "Drug manufacturers can submit comments regarding their certifications to CMS via the Assumptions tab. Each quarter, manufacturers will submit these comments for the current reporting period, or they may submit assumptions for any previous quarters they are restating and resubmitting."
deleted "Follow these steps to submit certification assumptions to CMS: 1. From the Medicare Part B Average Sales Price homepage, click the Assumptions tab. The Assumptions page opens, and defaults to the current quarter and year. Refer to Figure 23."
deleted figure 23 and text under figure "Figure 23: Assumptions" and "Note: Click the Reporting Period (required) tab in the top left to scroll through previous quarters. Use the drop-down menu to navigate to a previous quarter starting with the most recent quarter. Note: Click the Export to Excel box to download all products under the Assumptions tab."
replaced "Create Assumption" with "Reasonable Assumptions"
added "Note: Certifiers cannot finalize the certification process until the Reasonable Assumptions Form is complete. If a drug manufacturer does not have additional information for the required response fields, please enter "N/A"." and "1. From the Medicare Part B Average Sales Price homepage, click the Assumptions tab. The Assumptions page opens, and defaults to the current quarter and year. Select the appropriate reporting period before clicking the Reasonable Assumptions (Required) tab . Refer to Figure 23."
added Figure 23 and text under figure "Figure 23: Assumptions" and "Note: Click the Reporting Period (Rrequired) tab in the top left to scroll through previous quarters."
replaced "1. Click the Create Assumption or Upload Assumption File button. The Create Assumption or Upload Assumption File window displays. The Module automatically defaults to the Reporting Period selected on the Assumptions default page with a Manufacturer Name (required) drop-down menu and empty Short Description and Text for Assumption file fields. Refer to Figure 24." to "2. Click the Reasonable Create Assumptions Form button. The Reasonable Assumption Form window displays. The Module automatically defaults to the Reporting Period selected on the Assumptions default page with a Manufacturer Name (required) drop-down menu and empty required response fields . Refer to Figure 24."
replaced figure 24 with a new figure 24 and replaced text "Figure 24: Assumptions - Create Assumption or Upload Assumption File" with "Figure 24: Reasonable Assumptions Form"

added text "4. Click "View All" to view all the required response fields. Refer to Figure 25.

- Bona Fide Service Fees
- Bundled Sales
- Price Concessions and Discounts
- Reporting of Products with Zero, Negative, or False Positive ASPs
- Sales Excluded from Best Price
- Sales to U.S. Territories
- Time Value of Money
- Free Goods Not Contingent on a Purchase Requirement
- Value-Based Purchasing Agreements
- Sales to 340B Covered Entities
- Returned Goods
- Billing Corrections"

added figure 25, text under figure 25 "Figure 25: "View All" Required Response Fields", and a note under the figure "Note: For drug manufacturers with contractual agreements, please enter comments in the Reasonable Assumptions form and complete the Bona Fide Service Fee Certification. Refer to Section 3.4 for instructions."

added text "5. Complete all the required fields. Enter NA if reasonable assumptions are not available for a particular field.

Note: Each required field allows for 1,000 characters of text to provide a summary of the assumption. If a response exceeds the character limit, submit or upload the additional verbiage on the Other Assumptions tab. Refer to Section 3.3.2 - Other Assumptions (Optional) for instructions."

added text "6. Click the Save Form button located at the bottom of the form. Refer to Figure 26."

added figure 26 and text "Figure 26: Save Reasonable Assumptions Form" under figure"

added text under figure 26 "A message displays confirming you have successfully created your Reasonable Assumptions. The Module lists saved forms under Added Forms. Refer to Figure 27"

replaced figure 25 with figure 27 and updated text under figure "Figure 27: New Assumption Successfully Saved"

added text "7. To make any necessary revisions before submitting, click the Edit button." and "8. If the submission does not require additional revisions, click the Submit button. A message displays confirming you have successfully submitted your Reasonable Assumptions. Refer to Figure 28."

added figure 28 and text under figure "Figure 28: Reasonable Assumptions Successfully Submitted"

added new text "3.3.2 Other Assumptions (Optional)

This section provides instructions on how drug manufacturers can submit comments regarding their certifications to CMS via Create Assumptions or Upload Assumptions.

#### 3.3.2.1 Create Assumptions

Follow these steps to submit certification assumptions CMS:

From the Medicare Part B Average Sales Price homepage, click the Assumptions tab. The Module automatically defaults to the Reasonable Assumptions (Required) Tab. Click the Other Assumptions (Optional) tab. Refer to Figure 29."

added figure 29 and text under figure "Figure 29: Create Other Assumptions"

added text "Note: Click the Reporting Period (required) tab in the top left to view previous quarters. Use the drop-down menu to navigate to select the appropriate quarter.

2. The Module automatically defaults to the Create Assumption radio button with a Manufacturer Name (required) drop-down menu and empty Short Description and Text for Assumption file (required) fields. Refer to Figure 29.

3. From the Manufacturer Name (required) drop-down menu, click the -Select- drop-down menu to expand the list and select the manufacturer name.

4. Complete the Short Description and Text for Assumption file fields.

Note: The Short Description field is optional and allows 500 characters of text to provide a summary of the complete assumption you are submitting to CMS. The Text for Assumption file field is required and allows for 1,000 characters to provide as much detail as possible related to the selected period's financial submission.

5. Click the Save Form button.

A message displays confirming you have successfully created your Assumption. Refer to Figure 30."

added figure 30 and text under figure "Figure 30: Other Assumptions Saved Successfully"
replaced "3.3.2" with "3.3.2.2"
replaced "1. Click the Create Assumption or Upload Assumption File tab." with "1. Click the Other Assumptions (Optional) file tab."
replaced "A Manufacturer Name (required) drop-down menu and empty File Description field display. Refer to Figure 26." with ""A Manufacturer Name (required) drop-down menu and empty File Description (required) field display. Refer to Figure 31."
replaced figure 31 with a new figure and revised text under 31 to say "Figure 31: Upload Assumptions"
deleted text "As you select your manufacturer name, additional fields display on the screen. Refer to Figure 27."
deleted figure 27 and text under figure
deleted text "Note: Click the Show More tab to display all Supported File Formats available in the Module for you to use in your Assumption File upload."
deleted text "refer to Figure 28"
deleted figure 28 and text under figure "Figure 28: Upload Assumption File - Uploading Files From Desktop"
deleted text "A download bar displays as your file uploads"
replaced "Figure 29" with Figure 34"
added two figures
replaced text "29" with "34"
<p>added text "3.4 Bona Fide Service Fee Certification</p> <p>Follow these steps to submit a Bona Fide Service Fee Certification to CMS:</p> <ol style="list-style-type: none"> <li>1. From the Medicare Part B Average Sales Price homepage, click the Bona Fide Service Fee Certification tab. The Bona Fide Service Fee Certification page opens and defaults to the current quarter and year. Refer to Figure 35.</li> <li>2. The Module automatically defaults to the current reporting period. Select the accurate reporting period before proceeding.</li> <li>3. Select the Manufacturer Name in the drop-down menu.</li> <li>4. Download, complete, and sign the Bona Fide Service Fee Certification Form.</li> </ol> <p>The fields to complete are as follows:</p> <p>Section 1: Enter all drug and manufacturer information associated with the bona fide service fee</p> <ul style="list-style-type: none"> <li>• Drug Name(s):</li> <li>• HCPCS code(s):</li> <li>• Manufacturer name:</li> <li>• Manufacturer address:</li> </ul> <p>Section 2: Recipient of BFSF information</p> <ul style="list-style-type: none"> <li>• Name and title of certifying individual:</li> <li>• Organization or entity name:</li> <li>• Organization or entity address:</li> <li>• Bona fide service:</li> <li>• Bona fide service fee amount (if the fee varies based on certain metrics, describe the conditions of the fee and how it is determined):</li> </ul> <p>Section 3.: Certification Statement</p> <ul style="list-style-type: none"> <li>• I certify that the fee is not passed on in whole or in part to an affiliate, client, or customer of an entity.</li> <li>• Manufacturer Signature:</li> <li>• Fee Recipient Signature:</li> </ul> <ol style="list-style-type: none"> <li>5. Save the completed form to your computer. Upload the form once completed.</li> </ol>
added figure 35 and text under figure "Figure 35: Bona Fide Service Fee Certification Submission"
replaced "3.4" with "3.5"
replaced "30" with "36"

replaced "31" with "37"
replaced "32" with "38"
replaced "33" with "39"
replaced "3.4.1" with "3.5.1"
replaced "34" with "40"
replaced "35" with "41"
replaced "3.4.2" with "3.5.2"
replaced "36" with 42"
replaced "37" with "figure 43"
replaced "3.4.3" with "3.5.3"
replaced "38" with "44"
replaced "39" with "45"
replaced "40" with "46"
replaced "3.4.4" with "3.5.4"
replaced "41" with 47"

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