

# Negotiation Data Elements and Drug Price Negotiation Process Information Collection Request (ICR) for Initial Price Applicability Year 2027

## Crosswalk of Changes Between the 30-Day and Final Documents\*

| Location of Edits                                     | Summary of Changes<br>(Included for 30-day Comment Period)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Type of Change | Explanation of Changes                                                                                   | Burden Change<br>(Yes/No) |
|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|----------------------------------------------------------------------------------------------------------|---------------------------|
| Supporting Statement                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                |                                                                                                          |                           |
| Background, Outside Consultation and Burden Estimates | <ul style="list-style-type: none"> <li>Included discussion of final revisions</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Modify         | Technical Updates                                                                                        | No                        |
| Information Collection Request (ICR) Forms            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                |                                                                                                          |                           |
| ICR Form – Negotiation Data Elements                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                |                                                                                                          |                           |
| Section C                                             | <ul style="list-style-type: none"> <li>Revised instructions for Questions 1, 2b, 3d, 4c, and 5a regarding adjustments for inflation and cost of capital</li> <li>Revised instructions for Questions 1, 2a, 3a, 4a, and 5c regarding adjustments for inflation and cost of capital</li> </ul>                                                                                                                                                                                                                                                                                                                           | Modify         | Revisions made in response to comments received from the ICR 30-Day Comment Period                       | No                        |
| Question 27                                           | <ul style="list-style-type: none"> <li>Instructions revised to clarify that respondent should list the applicable question numbers and also indicate which question the response applies to within the free text field</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                      | Modify         | Technical Updates                                                                                        | No                        |
| Section I                                             | <ul style="list-style-type: none"> <li>Added clarifying instructions to Question 28 regarding the applicability of the options and sub-question regarding manufacturer affiliation for a Primary Manufacturer</li> <li>Added clarification to instructions for patient- and caregiver-focused questions that respondents should address their experience related to the selected drug and its therapeutic alternatives</li> <li>Revised title of Question 45 to include “Additional”</li> <li>Revised instructions for Question 61 to specify that respondents will select, not click, applicable questions</li> </ul> | Modify         | Technical Updates and revisions made in response to comments received from the ICR 30-Day Comment Period | No                        |
| Question 62                                           | <ul style="list-style-type: none"> <li>Instructions revised to clarify that respondent should list the applicable question numbers and indicate which question the response applies to within the free text field</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                           | Modify         | Technical Updates                                                                                        | No                        |
| ICR Form – Drug Price Negotiation Process             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                |                                                                                                          |                           |
| Question 1                                            | <ul style="list-style-type: none"> <li>Revised “counteroffer price” to “proposal for the MFP”</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Modify         | Technical Update                                                                                         | No                        |

\*Question numbering matches final document.