| Currently approved version | New version with change              | Type of<br>Change | Reason for Change       | Burden<br>Change | Change<br>from 60-<br>Day |
|----------------------------|--------------------------------------|-------------------|-------------------------|------------------|---------------------------|
|                            | Expedited Appeal" and "For a         |                   |                         |                  |                           |
|                            | Standard Appeal" are reworded.       |                   |                         |                  |                           |
|                            | Sections now read as follows. "For   |                   |                         |                  |                           |
|                            | an Expedited (Fast) Appeal: You,     |                   |                         |                  |                           |
|                            | your prescriber, or your             |                   |                         |                  |                           |
|                            | representative can file an appeal by |                   |                         |                  |                           |
|                            | telephone, by fax, through the       |                   |                         |                  |                           |
|                            | plan's website, or by mail. A verbal |                   |                         |                  |                           |
|                            | request by telephone is the fastest  |                   |                         |                  |                           |
|                            | way to file an expedited (fast)      |                   |                         |                  |                           |
|                            | request. Phone:, TTY:                |                   |                         |                  |                           |
|                            | For a Standard Appeal: [Plan that    |                   |                         |                  |                           |
|                            | accepts verbal standard requests:]   |                   |                         |                  |                           |
|                            | {You, your prescriber, or your       |                   |                         |                  |                           |
|                            | representative can file an appeal by |                   | Modified to increase    |                  |                           |
|                            | telephone, by fax, through the       |                   | accessibility of plan   |                  |                           |
|                            | plan's website, or by sending a      |                   | websites allowing       |                  |                           |
| Notice-                    | letter to the mailing address listed |                   | electronic access for   |                  |                           |
| Section titled             | below.}                              |                   | beneficiaries. Modified |                  |                           |
| "How Do I                  | [Plan that does not accept verbal    |                   | to reduce confusion     |                  |                           |
| Request an                 | standard requests:] {You, your       |                   | with which type of      |                  |                           |
| Appeal?" until             | prescriber, or your representative   |                   | appeal requires which   |                  |                           |
| section titled             | can file an appeal by TTY, fax,      |                   | type of correspondance. |                  |                           |
| "What                      | through the plan's website, or by    |                   | Changes correspond      |                  |                           |
| Happens                    | sending a letter to the mailing      | Non-              | with §423.128(b)(7)(ii) |                  |                           |
| Next?"                     | address listed below.}               | substantive       | and §423.136.           | No.              | Yes.                      |

| 1                  |   |             | 1                    | -   |      |
|--------------------|---|-------------|----------------------|-----|------|
| inf                | formation required in the notice.       |             |                      |     |      |
|                    | ibsections explaining what to           |             |                      |     |      |
|                    | clude for expedited and standard        |             |                      |     |      |
|                    | ppeals are consolidated to              |             |                      |     |      |
|                    | niformly present of different ways      |             |                      |     |      |
|                    | appeal. Sections allow plans to         |             |                      |     |      |
|                    | ovide information based on              |             |                      |     |      |
|                    | hether verbal requests are              |             |                      |     |      |
|                    | ccepted for standard appeals.           |             |                      |     |      |
|                    | ection now reads as follows:            |             |                      |     |      |
|                    | Inder the section titled 'How Do I      |             |                      |     |      |
|                    | equest an Appeal?' the subsection       |             |                      |     |      |
|                    | :<br>:led 'For a Standard Appeal' gives |             |                      |     |      |
|                    | vo options. If the plan accepts         |             |                      |     |      |
|                    | erbal requests for standard             |             |                      |     |      |
|                    | ppeals, the plan must keep the          |             |                      |     |      |
|                    | formation after the brackets that       |             |                      |     |      |
| sta                | ates 'For plans that accept verbal      |             |                      |     |      |
| sta                | andard requests'. If the plan does      |             |                      |     |      |
| no                 | ot accept verbal standard               |             |                      |     |      |
| ree                | quests, the plan must keep the          |             |                      |     |      |
| se                 | ction after the brackets that           |             |                      |     |      |
| sta                | ates 'For plans that do not accept      |             |                      |     |      |
| ve                 | erbal standard requests'. Plans are     |             |                      |     |      |
| Instructions- red  | quired to enter the telephone           |             |                      |     |      |
| Section titled nu  | ımber if plan accepts verbal            |             |                      |     |      |
| "Section red       | quests, TTY number, fax number,         |             | Changed to match the |     |      |
| Titled: How Do pla | an website and physical address         |             | information          |     |      |
| I Request an tha   | at the enrollee, prescriber, or the     | Non-        | modification in the  |     |      |
| Appeal?" en        | nrollee's representative can use        | substantive | notice.              | No. | Yes. |
| In                 | the last sentence of this               |             |                      |     |      |
|                    | struction, the word "appeal" is         |             |                      |     |      |
|                    | moved from the paragraph, as            |             |                      |     |      |
|                    | ans are required to include their       |             |                      |     |      |
| l ·                | opeal website above under the           |             |                      |     |      |
|                    | ection titled "How Do I Request an      |             | Changed to match the |     |      |
|                    | ppeal?". Instead of the appeal          |             | information          |     |      |
| 1 .                |   | Non-        |                      |     |      |
| -                  | -                                       | substantive | notice.              | No. | Yes. |
| Help & More we     | ebsite, plans should include their      |             | modification in the  | No  | Yes  |

|                             | THE paragraph beginning with with                                     | I           |                           |     |      |
|-----------------------------|---|-------------|---------------------------|-----|------|
|                             | PD" has been rewritten to include                                     |             |                           |     |      |
|                             | instructions for Part B step therapy                                  |             |                           |     |      |
|                             | requirements. The paragraph now                                       |             |                           |     |      |
|                             | reads as follows: "Where the plan                                     |             |                           |     |      |
|                             | processes a Part D coverage   |             |                           |     |      |
|                             | determination but determines that                                     |             |                           |     |      |
|                             | the requested drug is covered   |             |                           |     |      |
|                             | under Part A or Part B, insert the                                    |             |                           |     |      |
|                             | following additional text: 'This                                      |             |                           |     |      |
| Instructions-               | request was denied under your   |             |                           |     |      |
| In section                  | Medicare Part D benefit; however,                                     |             |                           |     |      |
| referencing                 | coverage/payment for the  |             |                           |     |      |
| "Additional                 | requested drug(s) has been  |             |                           |     |      |
| Instructions                | approved under Medicare Part A/B                                      |             |                           |     |      |
|                             |   |             |                           |     |      |
| for Drugs not covered under | {include an explanation of the conditions of approval in a            |             |                           |     |      |
| Part D when                 | readable and understandable   |             |                           |     |      |
|                             |   |             |                           |     |      |
| the plan has determined     | format}. If you think Medicare Part D should cover this drug for you, |             |                           |     |      |
| that the drug               | you may appeal.' If the plan  |             |                           |     |      |
|                             |   |             |                           |     |      |
| is or ma be                 | determines that the requested   |             |                           |     |      |
|                             | drug is typically covered under Part                                  |             |                           |     |      |
|                             | B and instead processes a Part C                                      |             |                           |     |      |
| A or Part B:",              | organization determination, the                                       |             |                           |     |      |
| after .                     | plan must send the Integrated   |             | Added to reflect new      |     |      |
| paragraph                   | Denial Notice (CMS-10003) if  |             | 2019 regulations          |     |      |
|                             | coverage is denied under Part B                                       |             | concerning Part B step    |     |      |
| "MA-PD"                     | (e.g., Part B drug step therapy                                       | Substantive | therapy §422.136(a).      | No. | No.  |
|                             |   |             |                           |     |      |
|                             |   |             |                           |     |      |
|                             | The paragraph beginning with "The                                     |             |                           |     |      |
|                             | Part D" has been edited for clarity                                   |             | This paragraph change is  |     |      |
|                             | regarding the appropriate language                                    |             | to streamline the         |     |      |
|                             | version of the notice. The  |             | instruction on using the  |     |      |
|                             | paragraph now reads "The Part D                                       |             | appropriate version of    |     |      |
| Instructions-               | Denial Notice is available in English                                 |             | the notice (English or    |     |      |
| The second                  | and Spanish. Part D plan sponsors                                     |             | Spanish). This edit aims  |     |      |
| paragraph                   | should choose the version of the                                      |             | to focus on               |     |      |
| I                           | notice that will be readable and                                      | Non-        | readability/understanda   |     |      |
| "The Part D"                | understandable to the beneficiary."                                   | substantive | bility for beneficiaries. | No  | Yes. |
|                             | The sentence in the beginning that                                    |             | ·                         |     |      |
|                             | notifies beneficiaries if their right                                 |             |                           |     |      |
|                             | to appeal the denial now reads  |             |                           |     |      |
|                             | "you can call one of the numbers                                      |             | This change reflects that |     |      |
|                             | listed on the third page under"                                       |             | the phone numbers         |     |      |
| Notice-                     | instead of "you can call one of                                       |             | referenced in the notice  |     |      |
| Header titled               | the numbers listed on the last page                                   | Non-        | are on the third page,    |     |      |
| "Important"                 | under"  | substantive | not the last page.        | No  | Yes. |
| important                   | unuer   | Substantive | not the last page.        | 140 | 103. |

| Notice- In the |                                     |             |                     |    |      |
|----------------|-------------------------------------|-------------|---------------------|----|------|
| section titled |                                     |             |                     |    |      |
| "Important     |                                     |             |                     |    |      |
| Information    |                                     |             |                     |    |      |
| about your     |                                     |             |                     |    |      |
| Appeal         |                                     |             |                     |    |      |
| Rights", the   | The sentence saying "If your appeal |             |                     |    |      |
| subsection     | is for payment of a drug you've     |             |                     |    |      |
| titled         | already received, we'll give you a  |             |                     |    |      |
| "Standard (7   | written decision within 14 days."   | Non-        | Request from public |    |      |
| days)"         | was added back to the notice.       | substantive | comments.           | No | Yes. |