DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

DATE: November 1, 2018

TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Part D Communication Materials

Pursuant to 42 C.F.R. § 423.2260 and the Contract Year 2019 Medicare Communications and Marketing Guidelines (MCMG), dated September 5, 2018, formularies and the Part D Explanation of Benefits are considered communication materials (see section 100.4 for the communications requirements for these materials). The CY2019 MCMG does not provide guidance on or describe regulations applicable to these topics, which were previously included in the Medicare Marketing Guidelines (MMG).

This memo is to remind Medicare Advantage and Prescription Drug Plan sponsors that the attached guidance from the CY2018 MMG (dated July 20, 2017) still applies to all Part D communication materials. All Part D Sponsors are reminded that the applicable regulations, including 42 C.F.R. §§ 423.120 and 423.128, remain in force and this excerpt from the CY2018 MMG is the most recent guidance we have issued on those topics. Guidance addressing requirements for Part D communication materials, such as formularies and EOBs, will be incorporated into the Medicare Prescription Drug Benefit Manual in a future release.

For questions regarding this memo, please contact Lucia Patrone at Lucia.Patrone@cms.hhs.gov.

Attachment:
Part D marketing and communications guidance (formerly included in the MMG)
Excerpt from Contract Year 2018 MMG guidance published on July 20, 2017

Note: The below excerpt from the Contract Year 2018 MMG has not been updated to reflect policy changes since its most recent release in 2017. For instance, it does not reflect updates to 42 CFR §423.120(b)(5) regarding notice of mid-year formulary changes and changes to the definition of an approved month's supply. Part D sponsors must adhere to any new regulatory requirements and provisions released since publication of the 2018 MMG, including new or amended requirements implemented in the April 16, 2018 final rule (83 FR 16440). Any updates to the below information will be incorporated into the Medicare Prescription Drug Benefit Manual in a future release.

Formulary and Formulary Change Notice Requirements (formerly 60.4 in the MMG)
42 CFR 423.120(b)(5), 423.128 (b)(4), 423.2262(a), 423.2268(e)

Part D Sponsors must make available a list of drugs, known as a formulary, to enrollees at the time of enrollment and at least annually thereafter. Part D Sponsors have the option to send all enrollees either the formulary in hard copy, which may be abridged (see guidance below on the abridged formulary), or a distinct and separate notice (in hard copy) describing where enrollees can find the formulary online and how enrollees can request a hard copy formulary. This notice must be a stand-alone document (i.e., not bound with other materials) and may be included in the same mailing envelope as the Annual Notice of Change/Evidence of Coverage (ANOC/EOC). To take advantage of the option to provide a notice of online availability instead of providing a hard copy formulary, a Part D Sponsor must include in the notice the following to ensure that enrollees may access a hard copy:

- If the Part D Sponsor will not allow requests for a hard copy by email: "If you have a question about covered drugs, please call [customer service phone #] or visit [URL] to access our online formulary. If you would like a formulary mailed to you, you may call the number above, or request one at the website link provided above."
- If the Part D Sponsor will allow requests for a hard copy by email: "If you have a question about covered drugs, please call [customer service phone #] or visit [URL] to access our online formulary. If you would like a formulary mailed to you, you may call the number above, request one at the website link provided above, or email [Part D Sponsor email address]."
    - **Note:** Where applicable, Part D Sponsors who choose to provide access to an electronic versions of the provider directory (Medicare Managed Care Manual, chapter 4, section 110.2.3)/pharmacy directory and formulary may provide a single combined hard copy notice.

Regardless of the method used in making the formulary available to enrollees at the time of enrollment and annually thereafter, each Part D Sponsor must provide a comprehensive formulary on its website. See Chapter 6 of the Prescription Drug Benefit Manual for program guidance regarding formularies, change notices, and utilization management (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).

Part D Sponsors must ensure that each formulary marketed for a specific plan is consistent with the HPMS formulary file approved by CMS for that plan:

- Each covered drug must be displayed at the correct cost-sharing tier and with the approved utilization management edits (i.e., prior authorization, step therapy or quantity limits)
- The formulary drug category and class must be consistent
- The applicable HPMS approved formulary file submission ID number, which is the HPMS formulary submission ID number of the approved formulary that is being marketed, and version number must be included
- Indicate when the document and search tool (if available) was last updated by including the phrase, "Updated MM/YYYY" or "No changes made since MM/YYYY"

Any drug adjudicated as a formulary drug at the point of sale must be included in the Part D Sponsors' marketing materials. This applies to drugs that exist on the approved HPMS formulary as well as drugs covered as Part D formulary enhancements to the approved formulary. Generally, these drugs are expected to relate to newly approved brand or generic drugs (including new formulations and strengths) that do not currently reside on the Formulary Reference File (FRF), but that would likely be added during subsequent FRF updates. These marketed formulary drug enhancements must be added to the HPMS formulary once the drugs are represented on the FRF. A Part D Sponsor may market enhancements (such as adding a newly available drug to the formulary), but not negative changes, to its formulary prior to receiving CMS approval.

For more details, see Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.3 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).

In the event that a marketing discrepancy is identified, the Part D Sponsor must continue to cover the drug(s) at the more favorable cost share or with less restrictive utilization management for the affected enrollee (as defined in 42 CFR 423.100) through the end of the contract year.

Abridged Formulary (formerly 60.4.1 in the MMG)
42 CFR 423.128, 423.2262(c), 423.2268(e)

In addition to the comprehensive formulary on the Part D Sponsors website, Part D Sponsors may choose to make abridged formularies available. The abridged formulary document, at minimum, must include the following:

- Sponsor Name on cover page
- "<Year> Formulary (List of Covered Drugs)" on cover page
- "PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN" on cover page
- Advise enrollees that the document includes a partial list of drugs; that enrollees can visit the website or call the plan for a complete list of covered drugs
- Contact information on both the front and back cover pages
- The following statement: "Note to existing enrollees: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take."
- The definition of a formulary as compared to an abridged formulary (42 CFR 423.4 defines "formulary" as "the entire list of Part D drugs covered by a Part D plan.")

- An explanation of how to use the Part D Sponsor's formulary document
- The following statement: "<Part D Plan Sponsor Name> covers both brand name drugs and generic drugs. A generic drug is approved by the FDA as having the same active ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs."
- A statement describing the general utilization management procedures
- The date the formulary was last updated and describe how to obtain updated formulary information
- A statement that if a drug is not on the formulary, enrollees may contact the Part D Sponsor to obtain a list of alternatives or to apply for exceptions to coverage rules
- An explanation of how to obtain an exception to the Part D Sponsor's formulary, utilization management tools or tiered cost sharing
- A description of the drug transition policy
- A statement that enrollees may contact the Part D Sponsor for additional information or questions on the formulary
- A chart (the CMS-approved formulary) of covered drugs organized by therapeutic category that includes at least two covered drugs for each therapeutic class. Exceptions to this include when only one drug exists in the category or class or in the case where two drugs exist in the category or class, and one is clinically superior to the other. The category or class names must be the same as those found on the CMS-approved Part D formulary.
    - **Note:** While Part D Sponsors must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D Sponsors have the option to include the therapeutic classes as subheadings within the abridged formulary, as this level of detail may be confusing for enrollees. The row of the chart must include at least the three items described below.
- Drug Name: We suggest capitalizing brand name drugs (e.g., LIPITOR), and listing generic drugs in lowercase italics, (e.g., penicillin). Part D Sponsors may include the generic name of a drug next to the brand name of the drug. The abridged formulary may only consist of drugs included on the CMS approved HPMS formulary. Formulary drug enhancements described in section 60.4 may not be included in the abridged formulary document.
- Tier Placement: Part D Sponsors that provide different levels of coverage for drugs depending on their tier should include a column indicating the drug's tier placement and the corresponding tier label description (e.g., Generic or Preferred Brand) from the approved PBP. Part D Sponsors may also choose to include a column providing the co-payment or co-insurance amount for each tier.
- Utilization Management (UM): Part D Sponsors must indicate any applicable UM tools (e.g., prior authorization, step therapy, and quantity limit restrictions) for the drug. A description of the indicator used to describe the UM tools must be provided somewhere within the document (e.g., in footnotes). For example, a Part D Sponsor may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.
    - **Note:** Every enrollee must be able to tell by examining the complete formulary whether a specific drug is covered—including those drugs that have varying dosage forms or strengths at different formulary statuses, tier placements, and/or utilization management procedures (e.g., prior authorization, step therapy, quantity limit, or other restrictions). If there are differences in formulary status, tier placement, quantity limit, prior authorization, step therapy, or other restrictions for a drug based

on its differing dosage forms or strengths, the formulary must clearly identify how it will treat the different formulations of that same drug.

- An index listing drugs in alphabetical order that directs the reader to the page containing complete information for that drug (e.g., name, tier placement, and utilization management strategy)
- A symbol or abbreviation, as well as an explanation, to identify any utilization management restrictions, drugs that are available via mail-order, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only)
- Part D Sponsors may not include OTC drugs in the formulary table, but are expected to provide a separate list or table of the drug. The abridged formulary may only consist of drugs included on the CMS approved HPMS formulary. Formulary drug enhancements described in section 60.4 may not be included in the abridged formulary document.

Comprehensive Formulary (formerly 60.4.2 in the MMG)
42 CFR 423.4, 423.120, 423.128(c)(1)(v)

The comprehensive formulary must include the same information provided within the abridged formulary document, except that the comprehensive formulary must include the entire list of drugs covered by the Part D Sponsor (for instance, drugs covered as an enhancement) and would not inform beneficiaries that they can obtain a comprehensive formulary by contacting the Part D Sponsor. Drugs adjudicated at the point of sale as formulary drugs that are not found on the CMS approved HPMS formulary must be included in the comprehensive formulary. This may include drugs that are not found on the CMS approved HPMS formulary as described above.

Changes to Printed and Posted Formularies (formerly 60.4.3 in the MMG)
42 CFR 423.120(b), 423.128(a)-(c)(d)(2)(ii)

Part D Sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any applicable formulary changes. Part D Sponsors may make any necessary formulary changes via errata sheets mailed to affected enrollees. While Part D Sponsors retain the flexibility to utilize other processes for notifying enrollees of non-maintenance changes to their printed formularies, CMS expects Part D Sponsors to send out errata sheets with formulary changes no less than monthly to the extent that any negative non-maintenance formulary changes have occurred. Consistent with formulary errata sheets and hard copy notifications, website updates for non-maintenance negative formulary changes must also be made no less than monthly to the extent that negative formulary changes have occurred. Errata sheets must include a statement explaining that the plan will continue to cover the drugs in question for enrollees taking the drug at the time of change for the remainder of the plan year as long as the drug continues to be medically necessary and prescribed by the enrollee's physician and was not removed for safety reasons. Refer to the Medicare Prescription Drug Benefit Manual, Chapter 6, sections 30.3.3.3 and 30.3.4.1. This requirement does not extend to mid-year maintenance changes defined in section 30.3.3.2 of the Medicare Prescription Drug Benefit Manual (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf). Changes to previously printed formularies as a result of negative changes or enhancements may be

made at the time of the next printing. This is not a substitute for the required advanced 60 days' notice to enrollees affected by negative changes.

Other Formulary Documents (formerly 60.4.4 in the MMG)
42 CFR 423.128(b)(4)

In addition to comprehensive and abridged formularies, Part D Sponsors may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them and include the disclaimer. Refer to Appendix 5 for the appropriate disclaimer.

Provision of Notice to Enrollees Regarding Formulary Changes (formerly 60.4.5 in the MMG)
42 CFR 423.120(b)(5)

Part D Sponsors must provide at least sixty (60) days' notice or a 60-day supply with notice to affected enrollees before removing a Part D drug from the Part D Sponsor's formulary (e.g., adding prior authorization, quantity limits, step therapy or other restrictions on a drug), or moving a drug to a higher cost-sharing tier. A sixty (60) day notice must be provided in writing unless a beneficiary has affirmatively elected to receive electronic notice. Part D Sponsors should refer to Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.3.4.1 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).
If a Part D Sponsor does not provide 60 days advance written notice to an affected enrollee, the Part D Sponsor must provide a 60-day fill of the prescription under the same terms as previously allowed, with written notice of the change, unless the drug is deemed unsafe by the FDA or removed from the market.

Provision of Notice to Other Entities Regarding Formulary Changes (formerly 60.4.6 in the MMG)
42 CFR 423.120(b)(5)

Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D Sponsor must provide at least sixty (60) days' notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective. Part D Sponsors should refer to Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.3.4.2 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).

Online Formulary, Utilization Management (UM), and Notice Requirements (formerly 100.4 in the MMG)
42 CFR 423.128(d)(2)(ii)

The online formulary must be the Part D Sponsor's comprehensive formulary and the Part D Sponsors must provide a definition of a comprehensive formulary. It must display all information contained within the HPMS approved formulary files and meet all the requirements of the model

comprehensive formulary.

The online formulary must be downloadable. Part D Sponsors may also provide an online formulary search tool, but the search tool should not substitute for the downloadable formulary.

The downloadable formulary, any search tools, and utilization management documents must:

- Be updated at least once per month to the extent that changes have occurred; and
- Indicate when the document and search tool (if available) was last updated by including the phrase, "Updated MM/YYYY" or "No changes made since MM/YYYY."

Part D Sponsors can refer to the April 29, 2016 memo entitled "Part D Formulary Frequently Asked Questions" and the January 19, 2016 HPMS memo titled "CY 2016 Formulary Information" to clarify questions for formulary and UM criteria changes. If a search tool is provided, it must be searchable by drug name. When search results indicate a drug is not covered, it must provide an explanation or a link to an explanation of how to obtain an exception to the Part D sponsor's formulary, utilization management tools, or (if applicable) tiered cost sharing.

Part D Sponsors may include formulary and non-formulary alternatives; however, the formulary alternatives must be clearly marked as formulary drugs without the need for further navigation. Each search result that appears in the search tool is expected to:

- Indicate whether a drug is covered, its tier placement, and any applicable utilization management requirements. If quantity limit restrictions apply, the quantity limit amount and days' supply need to be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria must be included.
- Include the following statement for drugs with a Part B versus Part D administrative prior authorization requirement: "This drug may be covered under Medicare Part B or Part D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination."
- When the online formulary search tool results indicate a drug is not covered, explain or link to an explanation of how to obtain an exception to the Part D sponsor's formulary, utilization management tools or tiered cost sharing both by an introductory screen and when search results indicate a drug is not covered.
- Provide an indicator to identify mail-order availability, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).

Utilization management documents (detailing the criteria needed to satisfy the prior authorization and/or step therapy requirements) and the transition policy document are reviewed and approved as part of the HPMS formulary review process and not the HPMS marketing process. See the Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.2.7 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).

Part D Sponsors may post online the notice of formulary changes, provided that it:

- Includes all changes associated with removing or changing a Part D drug or adding authorization, quantity limits, step therapy, changing the cost sharing status, or any other restrictions on a drug

- Meets all requirements for written notice specified in the Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.3.4 (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf). This information must be maintained on the website until the next annual mailing of the updated formulary.