*[Note: The below updates and replaces the model most recently posted as “Model Notice of Formulary or Cost-sharing Change\_Feb2019v508.docx” on the following website:* [*https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html*](https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html)*.]*

*Instructions: This model may be used to provide affected enrollees with direct notice of midyear changes including notice required under 42 CFR §423.120(b)(5). (See also Prescription Drug Benefit Manual, Chapter 6, Section 30.3.) Plans/Part D sponsors may adapt this language as needed for grammatical consistency, accuracy, and relevant detail (e.g., use plan name rather than “Member Services” and provide hours if desired).*

**Notice of Changes to the Formulary (Drug List) or Cost-sharing**

**that Affect Your Drug Coverage**

<Date>

<Enrollee Name>

<Street Address>

<City, State Zip Code>

Enrollee ID Number: *<Insert enrollee number>*

Dear *<insert name>*:

# This letter is to inform you of a change to our formulary.

*[Plans/Part D sponsors should insert either Section A.1 OR Section A.2 below depending on whether they intend to provide notice specific to generic substitutions (Section A.2) or other changes (Section A.1). All Plans/Part D sponsors should include Section B.]*

**[Section A.1. Notice that can be Adapted for Different Formulary Changes]**

*Plans/Part D sponsors should insert one paragraph from A.1.a through A.1.e. below in addition to the remainder of Section A.1. Paragraph A.1.a. provides general language that can be adapted for many different kinds of changes, while paragraphs A.1.b. through A.1.e. provide model language specific to several common types of changes to the Drug List. Use as applicable. Plans/Part D sponsors may also provide additional explanation of changes if desired. To report changes for which model language is not supplied, use the model language shown below as a guide.]*

[A.1.a. Notice that can be adapted for a variety of changes]

Beginning on <insert date>, <insert name of drug> <Plan/Part D sponsor must state if: the drug is being removed from the formulary or there has been a change to the drug’s preferred or tiered cost-sharing status or explain changes being made to utilization management or other restrictions>.

*[A.1.b. Notice of change in cost-sharing]*

Beginning *[insert effective date of the change]*, *[insert description of the change, for example: the brand-name drug (insert name of drug for which cost-sharing will increase) and, when relevant (for instance, for identification purposes), information about the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)* will move from Tier *xx* to a higher cost-sharing tier (Tier *xx*)*.”]*

*[A.1.c. Notice of step therapy change]*

Beginning *[insert effective date of the change]*, “step therapy” will be required for the drug *[insert name of step therapy drug and, when relevant (for instance, for identification purposes), information about the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]*. This means you will be required to try *[insert either:* a different drug first *OR* one or more other drugs first] before we will cover *[name of step therapy drug]*. This requirement encourages you to try another drug that is less costly, yet just as safe and effective as *[insert name of step therapy drug]*. If *[insert either:* this other drug does not *OR* the other drugs do not*]* work for you, the plan will then cover *[insert name of step therapy drug].*

*[A.1.d. Notice of change in quantity limit]*

Beginning *[insert effective date of the change]*, there will be a new limit on the amount of the drug *[insert name of quantity limits drug and, when relevant (for instance, for identification purposes), information about the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]* you can have: *[insert description of how the quantity will be limited].*

*[A.1.e. Notice of change in prior authorization]*

Beginning *[insert effective date of the change]*, “prior authorization” will be required for this drug: *[insert name of prior authorization drug* *and, when relevant (for instance, for identification purposes), insert information about the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)].* This means you or your prescriber need to get approval from the plan before we will agree to cover the drug for you. *[Plans/Part D sponsors may insert more explanation if desired, for example, “Your choices include asking for prior authorization in order to continue having this drug covered or changing to a different drug.”]*

*[Plans/Part D sponsors (unless providing notice of a generic substitution under A.2) should insert the remainder of Section A.1. below.]*

We are [removing or changing the tiering structure of or changing the restrictions that apply to] [insert name of drug] because [Plan/Part D sponsor must explain the reason for removal of the drug from the formulary or why there is a change to the drug’s preferred or tiered cost-sharing status or applicable restrictions.]

**What you and your prescriber can do.**

Depending on the type of change, there may be different options to consider. For example:

You may be able to use another drug to treat your medical condition that *<is on our formulary or is in the same drug tier as <insert drug name>>.* These drugs include *<plan must indicate alternative drug(s) that are in the same therapeutic category/class or in the same cost-sharing tier.>* You, your prescriber, or your authorized representative may also ask for an exception. See below.

This list can help your prescriber to find a covered drug that might work for you and have fewer restrictions or a lower cost. You should ask your prescriber if one of these drugs is right for you. The amount you will pay for *[insert name of alternative drug(s)]*, depends on which drug payment stage you are in when you fill the prescription. To find out how much you will pay, please call us at *[insert plan name]* Member Services at *<insert toll-free number>*.

*[Plans/Part D sponsors providing notice under Section A.1 should not include Section A.2 below and rather continue with language found in Section B. Plans/Part D sponsors providing notice of generic substitutions should not include Section A.1 but rather insert Section A.2 below and Section B.]*

***[Section A.2. Notice of Generic Substitutions]***

*[The below language, with appropriate modifications, can be used to provide notice of immediate generic substitutions by plans/Part D sponsors meeting the requirements under 42 CFR 423.120(b)(5)(iv), as well as other generic changes, as long as the notice is provided to the enrollee within required timeframes.]*

Beginning *[insert effective date of the change]*, the brand-name drug *[insert name of brand-name drug to be replaced with generic version and, when relevant (for instance, for identification purposes), information about the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)] [insert either: “*will be” *OR “*was”*]* *[state if brand name drug is being substituted or if there is a change to the brand name drug’s cost-sharing tier or restrictions with the addition of the generic drug. For instance,]* removed from our Drug List. We *[insert either: “*will add” *OR “*added”*]* a new generic version of *[insert name of brand-name drug to be replaced with generic]* to the Drug List (it is called *[insert name of replacement generic drug and, when relevant (for instance, for identification purposes), information about the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)])*.

We are *[insert either: “*replacing” *OR* “replaced” *[name of brand name drug]* *OR [insert as applicable:* “changed” *OR “*are changing” “cost-sharing” *OR* "restrictions” for *[insert brand name drug]* because *[insert name of generic drug],* a *[insert if applicable “*new*”]* generic version of *[insert name of brand-name drug to be replaced with generic],* is now available. *[Indicate tier placement of generic drug. For instance,* *“[Insert name of generic drug]* (tier *[insert cost-sharing tier number or name for the replacement generic drug]*)is on *[insert either:* “the same” *OR* a “lower” cost-sharing tier than *[name of brand name drug],* the drug it *[insert either:* “is replacing” *OR* “replaced”*] [insert if generic drug is on a lower cost-sharing tier:* (tier *[insert cost-sharing tier number or name for the brand name drug that is being replaced]*).

***[Section B. Information on Exceptions and Grievances]***

*[Regardless of whether they have provided notice under Section A.1 or A.2, all plans/Part D sponsors should insert the remainder of this model:]*

You, your prescriber, or your appointed representative can also ask the plan to make an exception for you. This means asking us to agree that the change in coverage or cost-sharing tier of a drug does not apply to you or asking for a drug that isn’t on our Drug List.

* Your prescriber will need to tell us why making an exception is medically necessary for you.
* To learn how to ask for an exception, see the Evidence of Coverage *[insert as applicable:]* that we sent to you *OR [insert if plan/Part D sponsor meets the conditions and is relying on notification of electronic availability under Medicare Communications and Marketing Guidelines, Section 100.2.1:]* which is posted on our website at *<insert website address>*. Look for Chapter *[MA-PD insert:* Chapter 9*] [PDP insert:* Chapter 7*]*, “What to do if you have a problem or complaint.” (You can obtain a copy of the Evidence of Coverage if you need one by contacting us at *[insert appropriate information]*. The Evidence of Coverage is also posted on our website at *<insert website address>.*)
* Or, you can call us at *<insert toll-free number>* for help in asking for an exception.

If you disagree with our decision to *<remove or change the tiering structure of or restrictions applicable to> <insert name of drug>*, you may also file a grievance with us. Please call us at *<toll-free number>* if you want to file a grievance. You may also send your grievance to us in writing by *<describe the process for filing a written grievance, and refer the enrollee to the appropriate section(s) in the EOC for more information>*.

# Thank you.

<Plan/Part D sponsor name>