[Instructions: This model may be used to provide affected member with direct notice of midyear changes including notice required under 42 CFR §423.120(b)(5). See also Prescription Drug Benefit Manual, Chapter 6. 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). 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.]

[Pursuant to 42 CFR §423.2267, applicable disclaimers must be included in this letter.]

**Notice of Changes to the Formulary (Drug List) or Cost Sharing that Affect Your Drug Coverage**

<Date>

<MEMBER NAME>

<Street Address>

<City, State Zip Code>

Dear <MEMBER NAME>:

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

**[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>, < 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*>*, *<* description of the change *(for example: the brand-name drug (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 [*Insert* <tier number or name>] to a higher cost-sharing tier [*Insert* <tier number or name>].]

[*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> [*Insert 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 one* <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 one:* <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>[*Insert 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>[*Insert 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 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 [Insert one <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 on our Drug List to treat your medical condition [*Insert if type of change is in preferred or tiered cost-sharing status* <that is in the same cost-sharing tier as the drug you are taking>]. These drugs include [*Plan/Part D sponsors must indicate alternative drug(s) and their respective cost-sharing tiers that are in the same therapeutic category/class as the drug subject to the formulary or cost-sharing change.*][*Insert <*name of drug(s)> <is/are>] in the same cost-sharing tier as the drug you are taking.

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. Please call <Customer/Member> Service at <phone number> (TTY/TDD users should call <TTY/TDD number>) to find out how much you will pay.

You, your prescriber, or your authorized representative may also ask for an exception. Please refer to the additional information in the “Information on Exceptions and Grievances” section of this letter.

[*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 language from Section A.2 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*][*Insert 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 removed from the Drug List; and if there is a change to the brand name drug’s cost-sharing tier or restrictions or both with the addition of the generic drug>.*] 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, and 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>] [*Insert* <name of brand namedrug>] *OR* [*Insert as applicable* <changed> <are changing> <cost-sharing> <restrictions> *<*cost sharing and restrictions> for [*Insert* <brand name drug>]because [*Insert <*name of generic drug>], a [*Insert when applicable:* <new>] generic version of [*Insert* <name of brand-name drug to be replaced with generic>], is now available. [*Insert* < *tier placement of generic drug>.*]

[*For instance,* *insert* <name of generic drug> tier<cost-sharing tier number> *or* <name for the replacement generic drug>is on [*Insert either* <the same> *OR* a <a lower cost-sharing tier than> [*Insert* <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> <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 the language in 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 either:* <that we mailed to you> *OR* <that you received electronically> andis posted on our website at [*Insert* <website address>]. Look for Chapter [*MA-PD insert* <9 of the Evidence of Coverage>][*PDP insert* <7 of the Evidence of Coverage>], “What to do if you have a problem or complaint.” You can also obtain a copy of the Evidence of Coverage if you need one by contacting us at [*Insert* <customer/member service information]. The Evidence of Coverage is also posted on our website at *<*website address*>.*
* Please call <customer/member> service at <phone number> (TTY users should call <TTY number>) for help in asking for an exception.

If you disagree with our decision to [*Insert* <remove or change the tiering structure of or restrictions applicable to> < name of drug>,] you may also file a grievance with us. Please call <customer/member> service at <phone number> (TTY users should call <TTY number>)if you want to file a grievance. You may also send your grievance to us in writing by [*Insert 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>