Instructions:

* This model may be used to provide affected enrollees with direct notice of changes to an approved formulary as required under 42 CFR § 423.120(f)(4). Part D sponsors may use all or part of the language in this model, modify the language as needed, or create their own language, provided they comply with all relevant regulatory requirements.
* Part D sponsors should insert either Section A.1 or Section A.2 below depending on whether they are providing notice specific to immediate substitutions (Section A.2) or other changes (Section A.1). Sections B, C (with one exception as noted for market withdrawals), D, and E should always be included.
* Effective dates of change: Regulations at 42 CFR §§ 423.120(e) and 423.100, subparagraphs (1) and (2) of the definition of maintenance changes, require Part D sponsors making an immediate substitution or substitution that is a maintenance change, respectively either 30 or 90 days, to remove or otherwise apply a negative formulary change to a brand name drug or reference product after the date that they add its replacement. The effective date of the change, as used in this notice, is the date of the negative formulary change. The notice also provides options to note whether a replacement drug has been or will be added.
* Coinsurance tiers: As described in relevant instructions throughout, if a change described in this notice involves tiers with coinsurance-based cost sharing, plans should remind enrollees they can call the plan or use the plan’s Real-Time Benefit Tool for cost information as of the moment of the search.
* Terminology: Instructions for Part D sponsors use terms found in CMS regulations which may differ from the terms used in beneficiary-facing language.
* This notice must comply with all relevant requirements under 42 CFR § 423.2267.

**Notice of Changes to the Formulary (Drug List) that Affect Your Drug Coverage OR COST SHARING**

<Date>

<ENROLLEE NAME>

<Street Address>

<City, State Zip Code>

Dear <ENROLLEE NAME>:

**[Section A. Notice of Formulary Changes]**

This notice is to inform you of a change we [insert either: <made> OR <are making>]to our formulary (Drug List) that affects a drug you are taking.

*[Part D sponsors providing notice of changes other than immediate substitutions should insert one paragraph from A.1.a through A.1.f. below for each change. Paragraphs A.1.a. through A.1.f. provide model language specific to several common types of changes to the formulary which should be used and adapted as applicable to the specific type of change. Paragraph A.1.f. provides general language that can be adapted for a variety of changes. Part D sponsors may also provide additional explanation of changes if desired.]*

**[Section A.1 Notice of Changes Other than Immediate Substitutions]**

*[****A.1.a.*** *Advance notice of substitutions under the definition of maintenance changes at § 423.100 subparagraphs (1) and (2) (that is, generic or biosimilar substitutions that are not immediate substitutions)]*

**[Insert <name of drug> subject to change; plans may also include information about the strength or form in which the drugs is dispensed (e.g., tablets, injectable, etc.)]**

**Future Drug Substitution**

Beginning on *[insert effective date of the change which is date of the negative formulary change to the drug originally on the formulary]*, the *[insert <*brand name drug> *OR* <original biological product>*] [insert name of drug to be replaced or subject to a negative formulary change]* will be *[insert as applicable <*removed from our Drug List> *OR [insert either or both of the following: <*moved to a higher cost-sharing tier*> OR <*subject to> *[insert either:* *<*new> *OR <*more restrictive*>] [insert as appropriate* <prior authorization (PA)> *OR*, <step therapy (ST)> *OR* <quantity limit (QL)> requirements*.]* We *[insert either: <*have added*> OR <*will add> a *[insert if applicable: <*new>*] [insert either: <*generic version> *OR <*biosimilar> *OR* <unbranded biological product>*]* of *[insert name of drug to be replaced]* to the Drug List. It is called *[insert name of drug added to formulary]*. We are making this change because *[insert name of drug added to formulary],* a *[insert if applicable <*new>*] <*generic version> *OR* <biosimilar> *OR* <unbranded biological product >*]* of *[insert name of drug to be replaced or subject to negative formulary change],* is now being added to our Drug List. *[Indicate tier placement of drug added to formulary. (For instance,* *“[Insert name of drug added to formulary]* is on tier *[insert cost-sharing tier number or tier name],* which is *[insert either:* <the same> *OR*  <a lower>*]* cost-sharing tier *[insert if applicable <*than>*]* that of *[insert name of drug to be replaced or subject to negative formulary change],* the drug you have been taking, and has *[insert either* <the same> *OR* <fewer>*]* restrictions. *[Plan has the option to provide more information on restriction changes, such as describing the extent to which there are fewer restrictions.]*

*[Insert when making a substitution of or applying negative formulary changes to a reference product:* If any of the above drug type terms are new to you and you need help understanding them, please see our Evidence of Coverage, Chapter *[MA-PD insert <*5*>] [PDP insert <*3*>],* Section 3.1, “The Drug List tells which Part D drugs are covered.”*]*

[For any change involving any drug currently on or that will be moved to a cost-sharing tier with coinsurance, insert the following: For information on how the change to our Drug List may change the amount you pay out of pocket, call [<member services> or insert term plan prefers] use the contact information provided at the end of this document. You can also use our Real Time Benefit Tool [insert <direct website link>] to look up costs of drugs on the Drug List as of the moment of the search.] [Part D sponsors may insert as applicable, “This change will result in savings for you.” OR “Your costs will remain the same.”]

*[****A.1.b.*** *Advance notice that drug is moving to a higher cost-sharing tier]*

**[Insert <name of drug> subject to change; plans may also include the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]**

**Higher cost-sharing tier**

Beginning [insert <effective date of the change>, <drug name> will move from Tier [insert <tier number or name>] to a higher cost-sharing tier [insert <tier number or name>].[For any change involving any drug currently on or that will be moved to a cost-sharing tier with coinsurance, Part D sponsors are to insert the following: For information on how the change to our Drug List may change the amount you pay out of pocket, call [<member services> or insert term plan prefers] at the contact information provided at the end of this document. You can also use our Real-Time Benefit Tool [insert <direct website link>] to look up costs of drugs on the Drug List as of the moment of the search.] [Part D sponsors may insert as applicable, “This change will result in savings for you.” OR “Your costs will remain the same.”]

[**A.1.c.** Advance notice of addition of step therapy]

**[Insert <name of drug> subject to change; plans may also include the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]**

**Step Therapy**

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 *[insert as applicable:* is less costly, but*]* can be used to treat the same condition as *[insert* <name of step therapy drug>*]*. If *[insert one:* <the other drug does not> *OR* <the other drugs do not>*]* work for you, the plan will then cover *[Insert* <name of step therapy drug>*]*.

Step therapy criteria, which list the specific drug(s) required to be tried first, are posted on our website at *[Insert <*direct website link*>]* or can be obtained by calling *[*<member services> *OR insert term plan prefers]* using the plan contact information provided at the end of this document.

*[****A.1.d.*** *Advance notice of addition of quantity limit]*

**[Insert <name of drug> subject to change; plans may also include the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]**

**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 including how this compares to any current limits>*]*.

*[****A.1.e.*** *Advance notice of addition of prior authorization]*

**[Insert <name of drug> subject to change; plans may also include the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]**

**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. To obtain approval, you or your prescriber, or your authorized representative can ask for a coverage determination by calling *[*<member services> *OR insert term plan prefers]* using the plan contact information provided at the end of this document.

Prior authorization coverage criteria are posted on our website at *[insert <*direct website link*>]* or can be obtained by calling *[*<member services> *OR insert term plan prefers]* using the plan contact information provided at the end of this document.

*[****A.1.f.*** *Notice that can be adapted for a variety of negative and other formulary changes]*

*[Paragraph A.1.f. provides general language that can be adapted for many different kinds of negative formulary changes which can be used and adapted as applicable to the specific type of change. Plans may also provide additional explanation of changes if desired.* *To describe changes for which model language is not supplied, plans may use the model language in this form shown below as a guide. Plans also have the option to send notice of enhancements.]*

**[Insert <name of drug> subject to change; plans may also include the strength or form in which the drug is dispensed (e.g., tablets, injectable, etc.)]**

**[Insert <type of change>]**

Beginning on [insert <date>, <name of drug> [Part D sponsors must insert applicable type(s) of change: <is being removed from the Drug List> OR <is being moved to a higher cost-sharing tier> OR <subject to> [insert either: <new> OR <more restrictive>] [insert as appropriate <prior authorization (PA)>, <step therapy (ST)>, OR <quantity limit (QL)>] requirements.] [For any change involving any drug currently on or that will be moved to a cost-sharing tier with coinsurance, Part D sponsors are to insert the following: For information on how the change to our Drug List may change the amount you pay out of pocket, call [<member services> OR insert term plan prefers] at the contact information provided at the end of this document. You can also use our Real-Time Benefit Tool [insert <direct website link>] to look up costs of drugs on the Drug List as of the moment of the search.] [Part D sponsors may insert as applicable, “This change will result in savings for you.” OR “Your costs will remain the same.”]

*[All Part D sponsors providing notice of changes for scenarios A.1.b through A.1.f above must insert language explaining the reason for the change:]*

We are making the above change because [insert the reason for removing the drug from the formulary, moving the drug to a higher cost-sharing tier, or adding or increasing restrictions, as applicable. Part D sponsors must indicate, for example, if the change is due to new clinical guidelines; a new FDA boxed warning; long-term shortages; or issues of market availability.]

*[Part D sponsors providing notice only of a drug change under Section A.1 should not include Section A.2. Part D sponsors providing notice only of immediate substitutions should not include Section A.1 but rather insert language from Section A.2..]*

## *[Section A.2. Direct Notice of Immediate Substitutions]*

*[Direct notice under §423.120(f)(3) of immediate substitutions under §423.120(e)(2)(i)]*

**[Insert <name of drug> subject to change; plans may also insert information about the strength or form in which the drugs is dispensed (e.g., tablets, injectable, etc.)]**

**Immediate Drug Substitution**

On *[insert effective date of the change, which is date of the negative formulary change to the drug originally on the formulary]*, the *[insert* <brand name drug> *OR* <original biological product>*] [insert name of drug to be replaced or subject to negative formulary change] [insert either: <*was> *OR <*will be>*]* *[Insert as applicable <*removed> *OR [insert either or both of the following: <*moved to a higher cost-sharing tier*> OR <*subject to> *[insert either:* *<*new> *OR <*more restrictive*>] [insert as appropriate* <prior authorization (PA)> *OR* <step therapy (ST)> *OR* <quantity limit (QL)> requirements*.]* We *[insert either:* <added> *OR* <will add>*]* a new *[insert either: <*generic version> *OR <*biosimilar> *OR* <unbranded biological product>*]* of *[insert name of drug to be replaced or subject to a negative formulary change]* to the Drug List. It is called *[insert name of drug added to formulary]*.

We *[insert* <made> *OR* <are making this change>*]* because *[insert name of drug added to formulary],* a new <generic version> *OR* <biosimilar> *OR* <unbranded biological product version>*]* of *[insert name of drug to be replaced or subject to a negative formulary change],* *[insert either <*is available now on> *OR <*is being added to>*]* our Drug List.>*]* *[Indicate tier placement of drug added to formulary. (For instance,* *“[Insert name of drug added to formulary]* is on tier *[insert cost-sharing tier number or tier name]* which is *[insert either:* <the same> *OR*  <a lower>*]* cost-sharing tier *[insert <*than>*]* *[insert name of drug to be replaced ],* the drug you have been taking and with the *[insert either* <the same> *OR* <fewer>*]* restrictions. *[Plan has the option to provide more information on restriction changes, such as describing the extent to which there are fewer restrictions.]*

*[Insert when making a substitution of or applying negative formulary changes to a reference product:* If any of the above terms are new to you, for a discussion of drug types, please see our Evidence of Coverage, Chapter *[MA-PD insert <*5*>] [PDP insert <*3*>],* Section 3.1, “The ‘Drug List’ tells which Part D drugs are covered.”*]*

[For any change involving any drug currently on or that will be moved to a cost-sharing tier with coinsurance, Part D sponsors are to insert the following: For information on how the change to our Drug List may change the amount you pay out of pocket, call [<member services> or insert term plan prefers] at the contact information provided at the end of this document. You can also use our Real-Time Benefit Tool [insert <direct website link>] to look up costs of drugs on the Drug List as of the moment of the search.] [Part D sponsors may insert as applicable, “This change will result in savings for you.” OR “Your costs will remain the same.”]

***[Section B. Information on Alternative Drugs on the Drug List]***

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

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

*[Insert as applicable:* You can continue to stay on the drug that is still on the Drug List as long as you *[insert either:*  <meet the *[insert as applicable:* <prior authorization> *OR* <step therapy> *OR* <quantity limit>*]* requirements> *OR* <are willing to pay the higher cost-sharing amount>.*]*

**Perhaps you can find a different drug** covered by the plan that might work just as well for you.

You may be able to use another drug on our Drug List that treats your medical condition that is in the same or lower cost-sharing tier as the drug you are taking. These drugs include:

*[Under §423.120(f)(4), Part D sponsors must indicate alternative drug(s) and their respective cost-sharing tiers that treat the same condition as the drug subject to the formulary or cost-sharing change.]*

*[Insert <*name of drug(s)> on <Tier>*]*.

This list can help your prescriber to find a drug on the Drug List that might work for you and is on the same or a lower cost-sharing tier than the drug you are taking. You can also use our Real-Time Benefit Tool *[insert <*direct website link*>]* to look up alternative drugs on the Drug List that could treat the same condition*.* 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 *[*<member services> *OR insert term plan prefers]* using the plan contact information provided at the end of this document or use our Real-Time Benefit Tool *[insert <*direct website link*>]* to find out how much you will pay.

***[Section C. Information on Exceptions]***

*[Plans must insert the language in this section unless the only change included in the notice is an immediate formulary removal due to a market withdrawal under § 423.120(e)(2)(ii).]*

**You can ask us for an exception.** You, your prescriber, or your appointed representative can also ask us to make an exception for you. This means asking us to agree that the change to the drug(s) you take should 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* <direct website link >*]*. 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 *[*<member services> *OR insert term plan prefers]* using the plan contact information provided at the end of this document.
* Please call *[*<member services> *OR insert term plan prefers]* using the plan contact information provided at the end of this document for help in asking for an exception.

***[Section D. Grievances]***

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 *[*<member services> *OR* *insert term plan prefers]* using the plan contact information provided at the end of this documentif 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*.*]*

***[Section E. Close and Contact Information]***

If you have any questions about this document or how the changes described will affect you, including changes to your cost sharing, please contact *[<Member Services*> OR insert term plan prefers*]* at *[insert phone number]*. (TTY users should call *[insert TTY number]*).

Thank you.

< Part D sponsor name>