# **CY 2022 Part D Senior Savings Model**

# Communications and Marketing Guidance for Part D Sponsors August 10, 2021

#### Introduction

This document serves as Model Guidance for Part D sponsors participating in the Part D Senior Savings Model (Model). This Model Guidance addresses Calendar Year 2022 additions and changes to the Evidence of Coverage (EOC) and Annual Notice of Changes (ANOC) that Part D sponsors must make to reflect their participation in the Model, as well as other marketing and communications requirements under the Model. Part D sponsors should also comply with guidance laid out in both the CY 2022 CMS Model Marketing Materials<sup>1</sup> and the CY 2022 Part D Model Materials<sup>2</sup>, as modified by this guidance.

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<sup>&</sup>lt;sup>1</sup> The CY 2022 CMS Model Marketing Materials can be found at: <a href="https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial">https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial</a>.

<sup>&</sup>lt;sup>2</sup> The CY 2022 Part D Model Materials can be found at: <a href="https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials">https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials</a>.

# Section 1: Model Communications and Marketing Guidance

Participating Part D sponsors must follow all applicable Centers for Medicare & Medicaid Services (CMS) guidelines, including following standard tracking and submission requirements, for communications and marketing material for Part D plans. Specifically, all Part D communications and marketing regulations and guidance issued by CMS, as well as other applicable laws, continue to apply to materials and activities of participating Part D sponsors, including regulations at 42 CFR part 423, Subpart V and the Medicare Communications and Marketing Guidelines (MCMG). Participating Part D sponsors must also comply with all guidance set forth in the Contract Addendum and in this Communications and Marketing Guidance. The guidance in this document is intended to supplement and modify existing guidance from both the 2022 CMS Model Marketing Materials and the CY 2022 Part D Model Materials for the context of this Model, as well as provide other marketing and communications guidance related to this Model.<sup>3</sup> In the event of a conflict between the marketing requirements in the Underlying Contract and this Communications and Marketing Guidance, such that the Part D sponsor cannot comply with both, the Part D sponsor must comply with the marketing requirements in this document. Likewise, in the event of a conflict between the marketing requirements in other marketing and communications guidance related to Part D contained in previously issued subregulatory guidance and this Communications and Marketing Guidance, such that the Part D sponsor cannot comply with both, the Part D sponsor must comply with the marketing requirements in this document.

#### Select Insulins

Throughout all marketing and communications documents, Part D sponsors must use the term "Select Insulin," to refer to the subset of insulin drugs on the plan's formulary that includes all Plan-Selected Model Drugs and all insulin drugs that are not Plan-Selected Model Drugs that are offered at the same cost-sharing as a Plan-Selected Model Drug during the Deductible, Initial Coverage, and Coverage Gap drug payment stages throughout the Model contract period. Drugs that are not Plan-Selected Model Drugs may only be considered Select Insulins if the enrollee would be unable to distinguish those drugs from Plan-Selected Model Drugs based on the plan's structure, rules, and cost-sharing in the Deductible, Initial Coverage, and Coverage Gap drug payment stages. If a Part D sponsor uses a similar term (e.g., "select care", "select drugs") for other purposes, the Part D sponsor should include language distinguishing the two terms in all documents where both terms appear. If all insulin drugs on the plan's formulary are Select Insulins, the plan does not need to use the term "Select Insulins", but this should be clearly explained in the EOC and ANOC as described in Sections 2 and 3, where the brackets indicate that plans should explain how beneficiaries may identify Select Insulins.

<sup>&</sup>lt;sup>3</sup> This includes the CY 2022 Model EOCs, ANOCs, and formulary documents as relevant for each plan type.

<sup>&</sup>lt;sup>4</sup> "Plan-Selected Model Drugs" has the meaning set forth at Article 2 of the Model Contract Addendum.

#### General Guidance for Beneficiary-Facing Materials

In beneficiary-facing materials, Part D sponsors need not refer directly to participation in the PDSS Model, but instead may specifically describe the benefits and coverage that is available through the PDSS Model. For example, participating Part D sponsors may adopt an approach for naming PDSS Model benefits that is most apt for the specific model benefits it offers and to whom it is offered, makes clear what the benefit is, and engages enrollees. In whatever approach is adopted by participating Part D sponsors, the participating Part D sponsor must refer to plan benefits and coverage under the Model consistently throughout its plan documents using the terminology provided in this document.

Where Part D sponsors refer to insulin coverage under the Model (e.g., "insulins", "covered insulins", or "many insulins") in detailed written marketing or communications materials, the Part D sponsor must ensure that the material adequately includes the following:

- Details regarding which insulins are Select Insulins covered at the Model supplemental cost-sharing level, or language describing where an enrollee or prospective enrollee could find information regarding which insulins are Select Insulins; and
- If there is cost-sharing indicated on the material, indicate whether the cost-sharing represented is a preferred copayment or standard retail copayment. Part D sponsors are encouraged to specify where full cost-sharing information can be found.

In order to reduce beneficiary confusion regarding the scope of the Model, Part D sponsors are strongly encouraged to include details regarding the coverage stages for which the Model copayment is applicable, and that only non-LIS enrollees are eligible for the cost-sharing under the Model.

Please note that CMS will follow-up with additional information pertaining to the PDSS Model and how the Model is identified within the Medicare Plan Finder.

# Section 2: Evidence of Coverage (EOC) Updates

Part D sponsors participating in the Model must make the following changes to the EOC for each Model PBP based on the CY 2022 CMS Model Marketing Materials, as modified by this guidance.

<u>CY 2022—HMO, MA-PD, C-SNP, and I-SNP Model Evidence of Coverage and CY 2022—PPO, MA-PD, C-SNP, and I-SNP Model Evidence of Coverage model template updates</u>

Chapter 2, Section 7. Information about programs to help people pay for their prescription drugs

Under "Medicare Coverage Gap Discount Program", add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins]. Please go to Chapter 6, Section 2.1 for more information about your coverage during the Coverage Gap stage. Note: This cost-sharing only applies to beneficiaries who do not qualify for a program that helps pay for your drugs ("Extra Help"). To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

[Plans may insert additional ways to find out what drugs are Select Insulins. Plans are encouraged to create additional resources to assist enrollees in identifying Select Insulin, and/or to describe in the EOC how Select Insulins may be identified in the formulary.]

# Chapter 6, Section 2.1. What are the drug payment stages for [insert 2022 plan name] members?

Edit the Payment Stages Table to add the following to the Deductible, Initial Coverage and Coverage Gap stages.

During this stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins].

This language may be omitted for the deductible stage, if the plan does not have a deductible stage. If the coverage for Select Insulins is aligned with coverage for other drugs on the same tier in the initial coverage stage, plans may omit the above language in the Initial Coverage stage.

No language should be added for Stage 4: The Catastrophic Stage.

# Chapter 6, Section 4.1. You stay in the Deductible Stage until you have paid \$[insert deductible amount] for your [insert drug tiers if applicable] drugs

#### Add:

There is no deductible for [insert 2022 plan name] for Select Insulins. During the Deductible Stage, your out-of-pocket costs for these Select Insulins will be \$[amount or range of monthly copays for Select Insulins]. To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

This language does not need to be inserted if the plan does not have a deductible stage.

#### Chapter 6, Section 5.2. A table that shows your costs for a one-month supply of a drug.

Edit the table to add the copay for Select Insulins for each applicable tier/pharmacy type combinations.

Chapter 6, Section 5.4. A table that shows your costs for a long-term ([insert if applicable: up to a] [insert number of days]-day) supply of a drug

Edit the table to add the long-term copay for Select Insulins for each applicable tier/pharmacy-type combinations.

Chapter 6, Section 6.1. You stay in the Coverage Gap Stage until your out-of-pocket costs reach \$[insert 2022 out-of-pocket threshold]

#### Add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins]. To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

#### CY 2022—PDP Model Evidence of Coverage model template updates

# Chapter 2, Section 7. Information about programs to help people pay for their prescription drugs

Under "Medicare Coverage Gap Discount Program", add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins]. Please go to Chapter 4, Section 2.1 for more information about your coverage during the Coverage Gap stage. Note: This cost-sharing only applies to beneficiaries who do not qualify for a program that helps pay for your drugs ("Extra Help"). To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

[Plans may insert additional ways to find out what drugs are Select Insulins. Plans are encouraged to create additional resources to assist enrollees in identifying Select Insulins, and/or to describe in the EOC how Select Insulins may be identified in the formulary.]

Chapter 4, Section 2.1. What are the drug payment stages for [insert 2022 plan name] members?

Edit the Payment Stages Table to add the following to the Deductible, Initial Coverage, and Coverage Gap stages.

During this stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins].

This language may be omitted for the deductible stage, if the plan does not have a deductible stage. If the coverage for Select Insulins is aligned with coverage for other drugs on the same tier in the initial coverage stage, plans may omit the above language in the Initial Coverage stage.

No language should be added for Stage 4: The Catastrophic Stage.

Chapter 4, Section 4.1. You stay in the Deductible Stage until you have paid \$[insert deductible amount] for your [insert drug tiers if applicable] drugs

Add:

There is no deductible for [insert 2022 plan name] for Select Insulins. During the Deductible Stage, your out-of-pocket costs for these Select Insulins will be \$[amount or range of monthly copays for Select Insulins]. To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

This language does not need to be inserted if the plan does not have a deductible stage.

Chapter 4, Section 5.2. A table that shows your costs for a one-month supply of a drug.

Edit the table to add the copay for Select Insulins for each applicable tier/pharmacy type combinations.

Chapter 4, Section 5.4. A table that shows your costs for a long-term ([insert if applicable: up to a] [insert number of days]-day) supply of a drug

Edit the table to add the long-term copay for Select Insulins for each applicable tier/pharmacy-type combinations.

Chapter 4, Section 6.1. You stay in the Coverage Gap Stage until your out-of-pocket costs reach \$[insert 2022 out-of-pocket threshold]

Add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins]. To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

# Section 3: Annual Notice of Changes (ANOC) Updates

### For Part D Sponsors Continuing Participation in the PDSS Model

Part D sponsors whose plans are continuing participation should only update their ANOC to the extent that there have been changes in the list of Select Insulins, or the cost-sharing for Select Insulins, or both. Part D sponsors whose plans are continuing participation, and whose cost sharing for Select Insulins as well as list of Select Insulins has not changed, do not need to add language referring to the Part D Senior Savings Model in the ANOC.

Part D sponsors that have changes ONLY in the list of Select Insulins should include the language (copied below), in the "Summary of Important Costs for 2022" Section:

To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

#### [Plans may insert additional ways to find out what drugs are Select Insulins.]

For changes in the cost-sharing of Select Insulins ONLY, Part D sponsors should not use the language listed above in blue. Instead, Part D sponsors offering MA-PD or SNP plans should adopt the following changes to their CY 2022 ANOC:

#### **Section 2.6. Changes to Prescription Drug Costs**

#### **Stage 1: Yearly Deductible Stage**

Edit the table to add the following:

There is no deductible for [insert 2022 plan name] for Select Insulins. You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

This language does not need to be inserted if the plan does not have a deductible stage.

#### **Stage 2: Initial Coverage Stage**

Edit the table to add the following:

You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

#### **Changes to the Coverage Gap and Catastrophic Coverage Stages**

Add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins].

Part D sponsors offering PDP plans should adopt the following changes to their CY 2022 ANOC:

#### **Section 2.3. Changes to Prescription Drug Costs**

#### **Stage 1: Yearly Deductible Stage**

Edit the table to add the following:

There is no deductible for [insert 2022 plan name] for Select Insulins. You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

This language does not need to be inserted if the plan does not have a deductible stage.

#### **Stage 2: Initial Coverage Stage**

Add the following:

You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

#### **Changes to the Coverage Gap and Catastrophic Coverage Stages**

Add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins].

Part D sponsors that have changes in BOTH the list of Select Insulins and the cost-sharing for Select Insulins should refer to the guidance below for Part D sponsors newly participating in the Model, and update their ANOCs in alignment with that guidance.

# For Part D Sponsors Newly Participating in the PDSS Model

Part D sponsors newly participating in the Model must make the following changes to the ANOC for each Model PBP based on the CY 2022 CMS Model Marketing Materials, as modified by this guidance.

<u>CY 2022—HMO, MA-PD, C-SNP, and I-SNP Model Annual Notice of Changes and CY 2022—PPO, MA-PD, C-SNP, and I-SNP Model Annual Notice of Changes model templates updates</u>

#### **Summary of Important Costs for 2022**

Edit the table to inform beneficiaries of the copays for Select Insulins.

Add the following language in the chart:

To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

[Plans may insert additional ways to find out what drugs are Select Insulins.]

## **Section 2.6. Changes to Prescription Drug Costs**

#### **Stage 1: Yearly Deductible Stage**

Edit the table to add the following:

There is no deductible for [insert 2022 plan name] for Select Insulins. You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

This language does not need to be inserted if the plan does not have a deductible stage.

#### Stage 2: Initial Coverage Stage

Edit the table to add the following:

You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

### **Changes to the Coverage Gap and Catastrophic Coverage Stages**

Add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins].

#### <u>CY 2022—PDP Model Annual Notice of Change model template update</u>

## **Summary of Important Costs for 2022**

Edit the table to inform beneficiaries of the copays for Select Insulins.

Add the following language in the chart:

To find out which drugs are Select Insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically]. You can identify Select Insulins by [insert any language or symbol used to refer to Select Insulins in the Drug List]. If you have questions

about the Drug List, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

[Plans may insert additional ways to find out what drugs are Select Insulins.]

# **Section 2.3. Changes to Prescription Drug Costs**

#### **Stage 1: Yearly Deductible Stage**

Edit the table to add the following:

There is no deductible for [insert 2022 plan name] for Select Insulins. You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

This language does not need to be inserted if the plan does not have a deductible stage.

#### **Stage 2: Initial Coverage Stage**

Add the following:

You pay \$[amount or range of monthly copays for Select Insulins] for Select Insulins.

#### **Changes to the Coverage Gap and Catastrophic Coverage Stages**

Add:

[Insert 2022 plan name] offers additional gap coverage for Select Insulins. During the Coverage Gap stage, your out-of-pocket costs for Select Insulins will be \$[amount or range of monthly copays for Select Insulins].

# For CY 2021 PDSS Participating Part D Sponsors not Participating for CY 2022

Part D sponsors who are participating in the PDSS Model for CY 2021 but will not be continuing participation in the Model for CY 2022 must make the following changes to the ANOC for each former Model PBP based on the CY 2022 CMS Model Marketing Materials, as modified by this guidance.

# <u>CY 2022—HMO, MA-PD, C-SNP, and I-SNP Model Annual Notice of Changes and CY 2022—PPO, MA-PD, C-SNP, and I-SNP Model Annual Notice of Changes model templates updates</u>

#### **Summary of Important Costs for 2022**

Add the following language below the chart:

This plan will no longer be providing additional coverage on Select Insulins through the [insert here language plan uses to refer to the PDSS Model in beneficiary-facing materials]. To find details on cost-sharing for insulin products, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically] and review the chart above. If you have questions, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

[Plans may insert additional ways to find out updated cost-sharing and coverage details for insulin drugs.]

#### **Section 2.6. Changes to Prescription Drug Costs**

# **Stage 1: Yearly Deductible Stage**

Edit the table to add the following:

The deductible for [insert 2022 plan name] will apply for insulins.

This language does not need to be inserted if the plan does not have a deductible stage.

#### **Stage 2: Initial Coverage Stage**

Edit the table to add the following:

You pay \$[amount or range of monthly copays for Select Insulins] for insulins.

# **Changes to the Coverage Gap and Catastrophic Coverage Stages**

Add:

During the Coverage Gap stage, your out-of-pocket costs for insulins will be \$[amount, percentage, or range of cost-sharing for insulins].

#### CY 2022—PDP Model Annual Notice of Change model template update

#### **Summary of Important Costs for 2022**

Add the following language in the chart:

This plan will no longer be providing additional coverage on Select Insulins through the [insert here language plan uses to refer to the PDSS Model in beneficiary-facing materials]. To find details on cost-sharing for insulins, review the most recent Drug List we [insert: sent you in the mail] OR [insert: provided electronically] and review the chart above. If you have questions, you can also call Member Services (Phone numbers for Member Services are printed on the back cover of this booklet).

[Plans may insert additional ways to find out updated cost-sharing and coverage details for insulin drugs.]

# **Section 2.3. Changes to Prescription Drug Costs**

#### **Stage 1: Yearly Deductible Stage**

Edit the table to add the following:

The deductible for [insert 2022 plan name] will apply for insulins.

This language does not need to be inserted if the plan does not have a deductible stage.

#### Stage 2: Initial Coverage Stage

Add the following:

You pay \$[amount or range of monthly copays for Select Insulins] for insulins

#### **Changes to the Coverage Gap and Catastrophic Coverage Stages**

Add:

During the Coverage Gap stage, your out-of-pocket costs for insulins will be \$[amount, percentage, or range of cost-sharing for insulins].

# Section 4: Summary of Benefits and Other Materials

# Summary of Benefits

Participating Part D sponsors should include cost-sharing for Select Insulins where applicable in the description of Part D benefits, under the appropriate tiers, days' supply, pharmacy status, and pharmacy location. For example, if a Part D sponsor participating in the Model includes Select Insulins on Tier 3, information on the cost-sharing for Select Insulins should be included where cost-sharing is indicated for all other drugs on Tier 3. This should include, where applicable, details on any preferred cost-sharing on Select Insulins, cost-sharing by days' supply, and variation by pharmacy location (e.g., long term care or mail order). This should be described consistently with the corresponding cost-sharing for the same tier and cost-sharing type (e.g., after the description of the cost-sharing for all other drugs on that tier, and at the same location). Plans must indicate when describing cost-sharing for Select Insulins that this cost-sharing is applicable in the Deductible, Initial Coverage, and Coverage Gap phases of the Part D benefit. Plans without a deductible do not need to include the deductible phase in this description (i.e., may just indicate that this cost-sharing is applicable in the Initial Coverage and Coverage Gap phases).

Participating Part D sponsors need not directly reference participation in the PDSS Model, but instead may specifically describe the benefits and coverage that are available through the PDSS Model. For example, the participating Part D sponsor may adopt an approach for naming PDSS Model benefits that is most apt for the specific model benefits it offers and to whom it is offered, makes clear what the benefit is, and engages enrollees. In whatever approach is adopted, the participating Part D sponsor must refer to plan benefits and coverage under the Model consistently throughout their plan documents using the terminology provided in this document. In addition, Part D sponsors must follow existing CMS guidance for Summary of Benefits, including, without limitation, Appendix 5 of the Medicare Communications and Marketing Guidelines (MCMG) (found here).

# Non-Beneficiary-Facing Materials

If a Participating Part D sponsor is directly referring to participation in the PDSS Model, the Part D sponsor should use the official title of the Model, which is "Part D Senior Savings Model." If the Part D sponsor is referring to Model benefits/coverage, the Part D sponsor should refer to these consistently throughout its documents using the terminology provided in this document. As a reminder, Article 3.F in the Contract Addendum governs the release of information that references Part D sponsor's participation in the Model.

# *Formulary*

Participating Part D sponsors must provide information in their formulary which identifies all Select Insulins. Part D sponsors should use a symbol or other method to identify Select Insulins in the full formulary drug tables, even if the Part D sponsor also provides a separate list of Select Insulins. This symbol/method to identify Select Insulins should be included in the Requirements/Limits column, to be easily identifiable for the beneficiary. Part D sponsors may use abbreviations to indicate Select Insulins in the formulary, as described in the CY 2022 Part D Model Materials, but should clearly identify that the abbreviation indicates Select Insulins within the formulary document and otherwise use the term, Select Insulins, to refer consistently to the insulins contained in the plan's formulary that meet the definition of Select Insulins.<sup>5</sup> As noted above in Section 1, if all insulin drugs (including Plan-Selected Model Drugs and others) on the plan's formulary are Select Insulins, there is no need for Part D sponsors to include a distinction in the plan's formulary.

#### Section 5: Submission of Materials and Timeline

This section provides additional guidance for participating Part D sponsors on how to submit marketing items related to the Model for CMS review in HPMS. As described in the table below, all ANOCs, EOCs, and Summaries of Benefit must be submitted for CMS review consistent with 42 CFR § 423.2261; there are no Model-specific requirements for these documents.

All of the following materials should be submitted in HPMS via the PDSS subcategories (see table below for details):

- Marketing or communications materials relating to Part D Rewards and Incentives programs under the Part D Senior Savings Model; and,
- Other marketing and communications materials with content related to the Part D Senior Savings Model.

<sup>&</sup>lt;sup>5</sup> Further information on CY 2022 Part D Model Materials may be found at the following link in the 2022 Part D Model Materials, "CY 2022 Formulary Abridged and Comprehensive": https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials

Submissions with Part D Rewards and Incentives content are all subject to prospective review, which under the regulations at 423.2261(b) have a review timeframe of forty-five (45) days, which begins on the date the material was submitted. However, for purposes of the PDSS Model, CMS will conduct prospective review of the materials with Rewards and Incentives content in a shorter timeframe, as noted in the chart below. Consistent with the Part D program, formulary documents do not need to be submitted through HPMS. Materials may be submitted on a rolling basis, but any materials with Part D Rewards and Incentives content that a participating Part D sponsor intends to use starting on October 1<sup>st</sup>, 2021 must be submitted by September 10<sup>th</sup>, 2021 to permit prospective review as noted in the chart below. Please note that Part D sponsors' ANOCs, EOCs, and other documents describing benefits should not include RI content, as RI are not benefits. Therefore, these documents should not need to be reviewed prospectively through the process for RI materials outlined below.

Material	Type of Review	Timeline to Submit to CMS
ANOC	File & Use (if the conditions have been met under 42 CFR § 423.2261(b)(3)) and the Part D sponsor certifies compliance (5 Days)	See CMS regulations and guidance on HPMS submission timing for additional instructions. Resubmission using the PDSS HPMS subcategories is not necessary.
EOC	File & Use (if the conditions have been met under 42 CFR § 423.2261(b)(3)) and the Part D sponsor certifies compliance (5 Days)	See CMS regulations and guidance on HPMS submission timing for additional instructions. Resubmission using the PDSS HPMS subcategories is not necessary.
Summary of Benefits	File & Use (if the conditions have been met under 42 CFR § 423.2261(b)(3)) and the Part D sponsor certifies compliance (5 Days)	See CMS regulations and guidance on HPMS submission timing for additional instructions. Resubmission using the PDSS HPMS subcategories is not necessary.
Material with Part D Senior Savings Model Rewards and Incentives Program Content	Prospective CMS review & approval (42 CFR § 423.2261(b)) (15 Days—see next column)	Send materials with PDSS Rewards and Incentives Program content to CMS at PartDSavingsModel@cms.hhs.gov. CMS will provide a prospective review within 10 days. Then, once reviewed by CMS, submit within HPMS via "PDSS- Rewards and Incentives" subcategory under Plan-Created Materials.
Other Marketing or Communications Material with content related to the Part D Senior Savings Model	File & Use (if the conditions have been met under 42	For Marketing materials, submit within HPMS via "PDSS Other (non R&I)" subcategory under Plan-Created Materials.

CFR § 423.2261(b)(3) and the Part D sponsor certifies compliance (5 days)	For Communication materials, submit within HPMS via "Communications with PDSS Content" subcategory under CMS Required.
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