



Centers for Medicare & Medicaid Services

DATE: April 9, 2020

TO: All Part D Sponsors

FROM: Laura McWright, Deputy Director, Seamless Care Models Group
Center for Medicare & Medicaid Innovation

SUBJECT: Part D Senior Savings Model – Calendar Year (CY) 2021 – Frequently Asked Questions.

The parameters for the Part D Senior Savings Model in CY 2021 are outlined in the Part D Senior Savings Model CY 2021 Request for Applications (RFA) for Part D Sponsors: <https://innovation.cms.gov/files/x/partd-seniorsav-plan-rfa.pdf>. While the RFA describes Model requirements, CMS has received operational questions from Part D sponsors and other stakeholders. The information included in this frequently asked questions document (FAQ) serves to provide further clarity and transparency to the Model requirements and flexibilities raised by Part D sponsors and other stakeholders. This FAQ addresses questions on Model drugs (hereinafter “Model drugs” or “Model insulins”), cost sharing, formulary tier(s), days’ supply, deductible, and supplemental files.

CMS would like to remind Part D sponsors to submit a Notice of Intent by Friday, April 10, 2020 through the following link, available on the Model website and here: https://cms.gov1.qualtrics.com/jfe/form/SV_e2vWrogMTY4B5it.

The week of April 13th, CMS will make available the application portal link for Part D sponsors on the Model website. CMS will review and notify sponsors of their approval or any changes on an on-going basis as applications are submitted. Part D sponsors have until May 1, 2020 to submit their applications. Part D sponsors will finalize their participation through the bid submission on June 1, 2020.

Additional questions on the Part D Savings Model should be sent to PartDSavingsModel@cms.hhs.gov or visit <https://innovation.cms.gov/innovation-models/part-d-savings-model>.

Frequently Asked Questions

Q1. Can the cost sharing differ by pharmacy type (preferred and non-preferred pharmacies) and location (retail and mail) or must it remain the same?

A1. In the RFA CMS stated that for CY 2021, Model-participating Part D sponsors must offer a cost sharing no greater than their maximum copay (whether that is \$35 or lower) at all pharmacy types (preferred and non-preferred) and locations (retail and mail) for Model insulin.

CMS has received a number of questions about whether Model-participating Part D sponsors retain the flexibility to offer a benefit with different cost sharing at preferred and non-preferred pharmacies and retail and mail locations. Therefore, CMS is clarifying that for CY 2021, provided that the cost-sharing at all pharmacy types and locations is not greater than their maximum copay, Part D sponsors **will be allowed** to offer lower cost sharing at preferred pharmacies and select pharmacy locations for Model insulin. Any cost-sharing differential offered by pharmacy type and/or location must follow all current CMS program regulations and guidance.

Part D sponsors that want to offer differential cost sharing by pharmacy type and/or location for Model insulin products must: 1) Include this information in their application (due May 1, 2020); 2) Submit the non-preferred cost sharing for Model insulins offered by the Part D sponsor in the CY 2021 Part D Senior Savings Model Supplemental File (Please see Appendix 1 for the file record layout); and 3) Submit an additional supplemental file (Health Plan Management System (HPMS) upload to the Model Documentation section) during the Part D bid and benefit review, that contains the preferred cost sharing for Model insulins. The preferred cost-sharing information, provided to CMS via the additional supplemental file, will not be available for display on Plan Finder for CY 2021.

Q2. If a Part D sponsor has a \$0 deductible plan, could that plan continue charging a \$0 deductible and a maximum of \$35 copay in the deductible, initial coverage, and coverage gap phases for Model insulins?

A2. Yes, if the Part D sponsor has a \$0 deductible plan, the sponsor could continue to offer this \$0 deductible plan with a maximum of a \$35 copay for a 30-days' supply in the initial coverage and coverage gap phases of the benefit. The cost sharing (e.g., \$35) in the deductible, initial coverage, and coverage gap phases of the benefit will be the amount submitted for the associated cost sharing for Model insulins offered by the Part D sponsor in the CY 2021 Part D Senior Savings Model Supplemental File.

Q3. How should the cost share for a Model insulin be applied in the deductible phase? For example, if the member cost share is capped at \$35, what should apply to the deductible calculation? Should it be only the member cost share or the entire drug cost?

A3. The entire drug cost should be applied in the deductible phase. Part D sponsors are reminded of the requirement that beneficiaries move through the deductible and initial coverage phases of the Part D benefit based on the total gross drug costs accumulated, which includes costs for drugs that might not be subject to a deductible. Unless otherwise noted in Model materials, plans should continue to report prescription drug event data according to current CMS guidance located in HPMS and on the Customer Support Services Contract (CSSC) website at <https://www.csscooperations.com>.

Q4. If a Model insulin is on a participating plan's formulary tier where a deductible applies, will the deductible apply to Model insulins on that formulary tier?

A4. No, the deductible would not apply to Model insulins that have a maximum copay of \$35 per 30-day supply. The deductible would apply to all other drugs on the tier. Please see (Q3) and (A3) for additional information on the deductible.

Q5. If a plan defines "one-month" in the plan benefit package (PBP) as a days' supply between 30 and 34 days (for example "one-month" equals 31 days), is the intent of the Model to follow the plan's definition of a one-month supply (31 days) or is the cost share for Model insulin to be based on a 30-day supply, regardless of plan definition of a one-month supply?

A5. The intent of the Model is to follow the plan's definition (consistent with current program regulations and guidance) of a one-month (30-day equivalent) supply, in the plan benefit package, for the maximum \$35 copay for a 30-days' supply of Model insulin.

Q6. Can you please clarify the cost-sharing requirements for those claims that are dispensed beyond a 30 days' supply including 60 or 90 days for both retail and mail order pharmacy locations?

A6. CMS has received a number of questions about whether Model-participating Part D sponsors retain the flexibility to offer a benefit that includes a 60-day equivalent and 90-day equivalent supply for Model insulin and the associated cost sharing. Therefore, CMS is clarifying that for CY 2021, provided that the cost-sharing is consistent with Chapter 5 of the Prescription Drug Benefit Manual - https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf - the cost sharing for a 60-day equivalent supply and 90-day equivalent supply, respectively, must not exceed what the enrollee would have paid for multiple 30-day (one-month) equivalent supply increments, Part D sponsors may offer extended day supplies at both retail and mail pharmacy locations for Model insulin. The 30-day equivalent cost-sharing provided to CMS via the Part D Senior Savings Model File (Please see Appendix 1 for the file record layout), will be multiplied by two-times and three-times respectively to determine the 60-day and 90-day equivalent cost-sharing for display on Plan Finder for CY 2021.

Q7. What are the cost-sharing requirements for the formulary tier that the Part D sponsor elects to place the Model insulin on for the participating plan's CY 2021 Part D formulary?

A7. Part D sponsors may include Model insulin on any formulary tier that is consistent with current program regulations and guidance including formulary design. The cost sharing for the formulary tier(s) that contain(s) Model insulin must be greater than or equal to the cost sharing of the Model insulin, a maximum \$35 copay for 30-days' supply.

Q8. If the selected formulary tier has a \$45 copay for all other non-model drugs would it be possible to offer the \$35 copay on only the Model insulins, or would all drugs on the tier need to offer the \$35 copay in order to participate in the Model?

A8. The cost sharing for Model insulins may be less than the cost sharing on the selected formulary tier for non-model drugs on that tier. Please note (A7) the cost sharing for non-Model drugs on a formulary tier(s) that contain(s) Model insulin products must be greater than or equal to the cost sharing for the Model insulin on that tier (i.e., a maximum \$35 copay for 30-days' supply). During the Part D bid and benefit review, Model applicants will submit a supplemental file that contains the reduced cost sharing for Model insulin.

Q9. Do Model insulins have to be included on the participating plan's formulary to be included on the CY 2021 Part D Senior Savings Model Supplemental File?

A9. Yes, participating plans' formularies must include at least one vial dosage form and one pen dosage form, when available as part of the Part D sponsors formulary, of each of the following: rapid-acting, short-acting, intermediate-acting, and long-acting insulins, at a maximum of \$35 copay for 30 days' supply. Model applicants will submit a supplemental file that contains the RxCUI concept unique identifier for each of the Model insulins that will be included on the formulary and the associated cost sharing. The RxCUI must be on the Part D sponsor's formulary to be included on the CY 2021 Part D Senior Savings Model Supplemental File.

Q10. Can different Model insulins have different cost sharing?

A10. Yes, the maximum cost share for a 30-days' supply of a Model insulin that the participating plan includes on its formulary and in this Model is \$35. Part D sponsors have the flexibility to offer a lower cost share for different types (e.g., rapid-acting, short-acting, intermediate-acting, and long-acting) and/or forms (e.g., pen, vial) of Model insulins that it is offering under the Model.

Q11. What is the format of the Model Insulin Supplemental file template and when will it be available?

A11. As part of the application process, Model applicants will submit via a supplemental file which will be available through the Model application portal: 1) the name, strength, and dosage form of each Model insulin the Part D sponsor will offer at a maximum of \$35 copayment for a

30-days' supply and 2) the specific enrollee cost sharing for each such Model insulin. CMS will review the application for the contracts and PBP(s) that Part D sponsors submit. Once approved, the Part D sponsor will indicate its intended participation in the Model in HPMS as part of its Part D bid. In addition, during the Part D bid and benefit review, Model applicants will submit a supplemental file that contains the Model insulins and associated cost sharing for those Model insulins offered by the Part D sponsor through HPMS. The file format for the CY 2021 Part D Senior Savings Model is included in Appendix 1.

Q12. The Model RFA states that supplemental benefits in the coverage gap are reported on prescription drug event (PDE) data as “patient liability reduction due to other payer” (PLRO) and supplemental benefits outside of the coverage gap are “non-covered plan paid” (NPP). Can you please clarify if a plan can submit all supplemental benefits as either NPP or PLRO?

A12. CMS is clarifying that a plan cannot submit all supplemental benefits inside and outside of the coverage gap as NPP or as PLRO. Rather, CMS is requiring Model-related supplemental benefits be reported differently inside versus outside of the coverage gap. Specifically, participating plans should report the supplemental benefits provided through this Model in the PLRO field while in the coverage gap and in the NPP field while in phases other than the coverage gap.

Appendix 1

CY 2021 Part D Senior Savings Model File Record Layout

Field Name	Field Type	Maximum Field Length	Field Description	Sample Field Value(s)
RxCUI	Number Always Required	8	RxCUI concept unique identifier from the active Formulary Reference File.	210597
Copay	Alphanumeric Always Required	6	Model-drug beneficiary copay	\$35.00

Required File Format = ASCII File – Tab Delimited

Do not include a header record

Filename extension should be “.TXT”

Please Note: Certain characters are restricted from HPMS. The submitted file will be rejected if any of the following characters are included in any field: 1) greater than sign (>), 2) less than sign (<), and 3) semi- colon (;).