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Center for Medicare & Medicaid Innovation

DATE: May 21, 2020

TO: Part D Senior Savings Model Applicant 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 2021 Model Application and Bid Submission

CMS is providing information and clarifying guidance to Part D Sponsors, including outlining the application provisional approval process and Part D bid submission process, that have submitted an application to the Part D Senior Savings Model (Model) for Calendar Year (CY) 2021.

CY 2021 Application Process

CMS thanks all the Part D Sponsors that applied to participate in the Part D Senior Savings Model. During the week of May 18th, CMS will be providing provisional approval notices that include the provisionally approved contracts and plan benefit packages (PBPs), confirming whether the PBP requested to be eligible for a narrower first risk corridor, and separately, providing provisional approvals for Part D Rewards and Incentives programs, where applicable. CMS will provide final Model approvals after completing bid desk review and by executing the Model contract addendum in September 2020.

Part D Sponsors are reminded to submit any changes to the contracts and PBPs included in the provisional approval letter to the Part D Senior Savings Mailbox at PartDSavingsModel@cms.hhs.gov by the June 1, 2020 bid submission deadline by **submitting updated final application and pricing supplemental files**. CMS will reconcile the contracts and PBPs included in the final supplemental files with the contracts and PBPs submitted in the bid.

CMS is providing the following guidance to Part D Sponsors in response to frequently asked questions.

1. Prescription Drug Event (PDE) reporting guidance related to covered Part D drugs not subject to a deductible, including Model drugs in the Part D Senior Savings Model.

To address recent questions about PDE reporting in the deductible phase as it relates to covered Part D drugs for which the deductible does not apply, we provide the following additional guidance. This guidance includes Model drugs under the Part D Senior Savings Model.

First, Part D Senior Savings Model participants are instructed that when the Model drugs that the participant is providing at a copayment of \$35 or less are dispensed to a beneficiary who does not receive the Part D low income subsidy (non-LIS beneficiary), such drugs should be treated, for the purpose of PDE reporting, the same as any covered Part D drug for which the deductible does not apply,

even if the drugs are placed on formulary tiers that are subject to a deductible under a Model-participating plan's benefit design. That is, these Model drugs dispensed to non-LIS beneficiaries must be adjudicated with a maximum \$35 copayment beginning with the first claim of the year, with none of the cost of the drug counting toward satisfying the deductible that otherwise applies under the plan. Model-participating plans must follow existing PDE reporting guidance for covered drugs that are not subject to the deductible when reporting plan payment fields on the PDE record – i.e., Covered Plan Paid Amount, or CPP, and Non-Covered Plan Paid Amount, or NPP. In particular, we direct Model participants to section 7.5.2.1 of the [2011 PDE Participant Guide](#), which demonstrates how to populate a PDE record for a drug that is not subject to a plan's deductible and is purchased when the beneficiary would otherwise be in the deductible phase under the defined standard benefit.

A summary of the existing PDE guidance as it relates to drugs for which a deductible does not apply, including Model drugs offered at a maximum \$35 copayment, when dispensed to a non-LIS beneficiary is the following:

- Like all enhanced alternative (EA) plans, Model-participating plans are required to map their enhanced benefits to the defined standard benefit when reporting CPP and NPP on the PDE record. A beneficiary's progression through the defined standard benefit prior to the coverage gap phase, including for the purpose of mapping for PDE reporting, is based on total gross covered drug costs (TGDC) for all Part D covered drugs purchased by the beneficiary. As a result, the TGDC Accumulator is tracked and reported based on all Part D covered drug costs, including costs for covered drugs not subject to the deductible. Additional information on EA mapping is available in Section 7.4 of the 2011 PDE Participant Guide.
- When adjudicating the benefit and determining beneficiary liability, however, the EA plan must account for its actual enhanced benefit design. That is, the benefit phase indicators, the Patient Pay field, and the True Out-of-Pocket Cost (TrOOP) Accumulator on PDEs must be reported according to the plan's own benefit design and cost-sharing structure.
- In the context of the Model, if, for instance, the first drug purchased in the year by a non-LIS beneficiary is a \$100 Model drug to which the maximum \$35 copayment applies, the Part D sponsor would report the initial coverage phase as the Beginning Benefit Phase, a maximum of \$35 as the Patient Pay Amount, that same maximum of \$35 value added to the TrOOP Accumulator, and \$100 added to the TGDC Accumulator on the PDE. If the subsequent drug purchased is a \$200 non-Model drug that was subject to the deductible, the PDE would report the deductible phase as the Beginning Benefit Phase, the total cost of the drug, or \$200, as the Patient Pay Amount (given that beneficiary liability is 100% in the deductible), and \$200 added to the TrOOP and TGDC Accumulators.
- It must be noted that, as stated in the September 10, 2010 HPMS memorandum, *Additional Guidance Concerning Closing the Coverage Gap in 2011*, a Part D deductible ceases to apply once a beneficiary's TGDC amount exceeds the initial coverage limit, irrespective of the enhanced benefit design, even if the beneficiary has not satisfied the deductible under the plan.

The two examples below further demonstrate how to populate a PDE record when certain drugs are not subject to the deductible under the EA plan's benefit design, which is the case for Model participants for at least the Model drugs that are offered at a maximum \$35 copayment. Table 1 demonstrates how an EA plan with a brand-only deductible currently populates PDE records for an example non-LIS beneficiary. Table 2 demonstrates how an EA plan that is a Model participant should populate the PDE records for the same non-LIS beneficiary. For these examples, we assume 2017 defined standard parameters with a \$400 deductible. The EA plan in both examples has a \$400 deductible that only

applies to drugs on tiers 3 and 4, a \$0 copay for tier 1, a \$5 copay for tier 2, and a \$40 copay for tier 3 in the initial coverage phase. Model drugs are subject to a \$35 copay through the coverage gap phase.

Table 1: EA plan with brand-only deductible, non-LIS beneficiary – not in Model

TGDCDC Accum.	TrOOP Accum.	Brand/ Generic	Deductible Applies?	Gross Drug Cost	Tier	Begin Phase*	End Phase*	Patient Pay	CPP	NPP
0.00	0.00	G	No (Tier 1, 2)	100.00	1	N	N	0.00	0.00	100.00
100.00	0.00	B	Yes	200.00	3	D	D	200.00	0.00	0.00
300.00	200.00	G	No (Tier 1, 2)	100.00	2	N	N	5.00	0.00	95.00
400.00	205.00	B	Yes	200.00	3	D	D	200.00	150.00	(150.00)
600.00	405.00	B	No (Deductible met)	400.00	3	N	N	40.00	300.00	60.00

* Beginning and ending phase: N = initial coverage phase, D = deductible

The next example focuses on how Model participants must report PDEs for Model drugs offered at a maximum \$35 copayment, given beneficiaries are charged the maximum \$35 copay through the coverage gap phase. These Model drugs are not subject to the deductible; therefore, the plan should report initial coverage phase, or N, as the benefit phase on the PDE record for these Model drugs, even though they are on tier 3 and would otherwise be subject to the deductible. The beneficiary will be responsible for satisfying the brand-only deductible on subsequent non-Model brand drugs, as shown in the last row in Table 2.

Table 2: EA plan with brand-only deductible, non-LIS beneficiary – in Model

TGDCDC Accum.	TrOOP Accum.	Brand/ Generic	Deductible Applies?	Gross Drug Cost	Tier	Begin Phase*	End Phase*	Patient Pay	CPP	NPP
0.00	0.00	G	No (Tier 1, 2)	100.00	1	N	N	0.00	0.00	100.00
100.00	0.00	B	No (Model drug)	200.00	3	N	N	35.00	0.00	165.00
300.00	35.00	G	No (Tier 1, 2)	100.00	2	N	N	5.00	0.00	95.00
400.00	40.00	B	No (Model drug)	200.00	3	N	N	35.00	150.00	15.00
600.00	75.00	B	Yes	400.00	3	D	D	400.00	300.00	(300.00)
1,000	475.00	B	No (Deductible met)	100.00	3	N	N	40.00	75.00	(15.00)

* Beginning and ending phase: N = initial coverage phase, D = deductible

PDE Reporting for Model Drugs Dispensed to LIS Beneficiaries:

Part D Senior Savings Model participants are reminded that the maximum \$35 copayment for certain Model drugs applies only to non-LIS beneficiaries. That is, for calculating the low income cost-sharing subsidy (LICS) for Model drugs offered at a maximum \$35 copayment, Model-participating plans should

use the normal cost-sharing of the formulary tier that the drug is on, and not the cost-sharing established under the Model for the drug.

Although LIS beneficiaries would not obtain Model drugs at a maximum \$35 copayment (because they would instead pay the LIS copayment), it is still possible that an LIS beneficiary would choose to enroll in a Model plan. In this scenario, LICS should be calculated according to the guidance provided in Module 6 of the *2011 PDE Participant Guide*, equal to the difference between the cost-sharing established under the plan for non-LIS beneficiaries and the nominal cost-sharing amount that the LIS beneficiary must pay out of pocket per section 1860D-14 of the Social Security Act. For calculating LICS for LIS beneficiaries enrolled in Model-participating plans, the non-LIS beneficiary cost-sharing would be the cost-sharing that would have applied if the Model were not offered at a maximum \$35 copayment, per the plan’s formulary design. This means that if an LIS beneficiary were to purchase a Model drug that is offered to non-LIS beneficiaries at a maximum \$35 copayment and is on a formulary tier that is subject to the deductible under a Model-participating plan’s benefit design, the corresponding PDE record should be reported as if the drug is subject to the deductible, and the plan should count the total cost of the drug towards the deductible. As a result, Model participants must report PDEs for LIS beneficiaries exactly as they normally would have had the plans not been participating in the Model – i.e., there is no change in PDE reporting requirements for drugs dispensed to LIS beneficiaries in Model plans.

Table 3 demonstrates how Model-participating plans should report PDE data for LIS beneficiaries in the deductible phase. The Model participant in this example is an EA plan with a brand-only deductible. The LIS beneficiary in this example is institutionalized and eligible for Category 3 benefits, meaning they pay nothing out of pocket throughout the benefit. For this example, as above, we assume 2017 defined standard parameters and assume that the example EA plan has a \$400 deductible that only applies to drugs on tiers 3 and 4, a \$0 copay for tier 1, a \$5 copay for tier 2, and a \$40 copay for tier 3 in the initial coverage phase.

Table 3: EA plan with brand-only deductible, LIS Beneficiary – applicable for plans in and not in Model

TGDCDC Accum	TrOOP Accum	Brand/ Generic	Deductible Applies?	Gross Drug Cost	Tier	Begin Phase*	End Phase*	Patient Pay	CPP	NPP	LICS
0.00	0.00	G	No (Tier 1, 2)	100.00	1	N	N	0.00	0.00	100.00	0.00
100.00	0.00	B	Yes (Model drug but LIS)	200.00	3	D	D	0.00	0.00	0.00	200.00
300.00	200.00	G	No (Tier 1, 2)	100.00	2	N	N	0.00	0.00	95.00	5.00
400.00	205.00	B	Yes (Model drug but LIS)	200.00	3	D	D	0.00	150.00	(150.00)	200.00
600.00	405.00	B	Yes	400.00	3	N	N	0.00	300.00	60.00	40.00

Explanation:

- The first dispensed drug is on Tier 2, which does not have a deductible or any cost-sharing for the non-LIS beneficiary. Since there is no deductible, the Beginning Benefit Phase is N. CPP is mapped to

the defined standard benefit. Patient Pay is the Category 3 LIS copay of \$0. LICS is equal to the difference between the non-LIS cost-sharing under the benefit (without regard to Model drugs offered at a maximum \$35 copayment), which is a \$0 copay in the initial coverage phase since the drug is not subject to the deductible, minus the LIS copay, so LICS is \$0. The remainder of \$100 is NPP.

- Although the second dispensed drug is a Model drug for which non-LIS beneficiaries would pay a maximum \$35 copayment, it is on a tier to which the \$400 deductible applies and that is associated with a copay of \$40 in the ICP. Thus, because the Model maximum copayment of \$35 is disregarded, the benefit phase indicators are both D since the entire claim falls in the plan-defined deductible. LICS is calculated as the difference between the \$200 non-LIS beneficiary cost-sharing and the \$0 nominal amount paid out of pocket by the LIS beneficiary, or \$200.
- The third drug dispensed is on Tier 2, which has no deductible and a \$5 non-LIS copay. The benefit phase indicators are both N. CPP is mapped to the defined standard benefit. LICS is calculated as the difference between the \$5 non-LIS copay and the \$0 nominal amount paid out of pocket by the LIS beneficiary, or \$5.
- Although the fourth dispensed drug is a Model drug for which non-LIS beneficiaries would pay a maximum \$35 copayment, it is on a tier to which the \$400 deductible otherwise applies and that is associated with a copay of \$40 in the ICP. The beneficiary has satisfied \$200 of the \$400 brand-only deductible, so the entire claim falls in the deductible and the benefit phase indicators are both D. Because the Model maximum copayment of \$35 is disregarded, LICS is calculated as the difference between the \$200 non-LIS beneficiary cost-sharing and the \$0 nominal amount paid out of pocket by the LIS beneficiary, or \$200. To determine CPP, the EA plan must map back to the defined standard ICP, so 75% of the drug cost, or \$150, is reported as CPP. NPP is the difference between the cost of the drug and the amounts captured as LICS and CPP, or - \$150.
- The final dispensed drug is on Tier 3 and is not a Model drug. The brand-only deductible has been met, so the benefit phase indicators are both N. The non-LIS beneficiary would pay a \$40 copay, so LICS is the difference between the \$40 non-LIS copay and the \$0 nominal amount paid out of pocket by the LIS beneficiary, or \$40. To determine CPP, the EA plan must map to the defined standard ICP, so 75% of the drug cost, or \$300, is reported as CPP. NPP is the difference between the cost of the drug and the amounts captured as LICS and CPP, or \$60.

2. Updates to the Formulary Reference File

CMS is making the following additions for the May 2020 Formulary Reference File.

RxCUI	Rx_TTY	RxNorm_Description
2206092	SBD	3 ML INSULIN, REGULAR, HUMAN 100 UNT/ML PEN INJECTOR [NOVOLIN R]
2206099	SBD	3 ML INSULIN ISOPHANE, HUMAN 100 UNT/ML PEN INJECTOR [NOVOLIN N]

3. Meaningful Difference, Total Beneficiary Cost (TBC), and Out-of-Pocket Cost (OOPC) Values

CMS has received a number of questions on how participation in the Model is factored into the OOPC Model and the Meaningful Difference and TBC reviews performed by CMS.

Q1. Are the copay reductions for the Part D Senior Savings Model included in the CY 2021 OOPC Model?

A1. No, the copay reductions for the Part D Senior Savings Model would not be included in the CY 2021 OOPC Model. The supplemental benefit offered in the Senior Savings Model is not captured in the PBP and therefore would not be incorporated into the OOPC Model.

Q2. Can CMS provide an estimate of the OOPC impact (dollar amount) of the Part D Senior Savings Model on the meaningful difference and TBC of including the copay reductions for the Part D Senior Savings Model in the CY 2021 OOPC Model?

A2. Based on an analysis of CY 2020 Enhanced Alternative plans (EA), the median reduction in estimated out-of-pocket costs ranges between the following values depending upon the copayment amount:

- Stand-alone Prescription Drug Plan (PDP): \$0.98 and \$2.11 per member per month
- Medicare Advantage-Prescription Drug (MA-PD): \$0.88 and \$1.91 per member per month

Q3. If the only difference between a basic and enhanced PDP plan is the EA plan participates in the Part D Senior Savings Model is that enough to consider the plans meaningfully different?

A3. No, an EA plan must meet the definition of an EA plan as defined under section 423.104(f) independent of participation in the demonstration. If the only difference between the basic and enhanced PDPs is the supplemental benefit applied to insulins through the Model, all non-insulin utilizers will be subject to the Part D supplemental premium for what is otherwise a basic Part D benefit design in their experience. Part D sponsors may offer various supplemental benefits in addition to basic prescription drug coverage as a means to provide enhanced alternative benefit designs such as including coverage of a subset of drugs throughout the coverage gap. However, as discussed in the Medicare Prescription Drug Benefit Manual, Chapter 5, section 20.4.2.2 Enhanced Alternative Gap Coverage, "coverage of only insulin through the coverage gap would not be sufficient to be labeled gap coverage."

Q4. What flexibilities are being offered for meeting PDP meaningful difference for Part D Senior Savings Model participants?

A4. During the review of the PDP plan benefit packages, enhanced alternative (EA) offerings that do not meet the CY 2021 minimum monthly cost-sharing out-of-pocket costs (OOPC) difference of \$22 as compared to the basic offering in the same region will be subject to additional reviews. CMS will utilize the results from analyses that estimate the impact of the Model on OOPC when comparing basic and enhanced plans offered by a parent organization. If the basic to enhanced threshold could not be reasonably met by incorporating these estimates, Part D sponsors will be asked to provide justifications, or change their bids to resolve these outliers.

Q5. What flexibilities are being offered for the MA total beneficiary cost (TBC) evaluation for Part D Senior Savings Model participants?

A5. As stated in the HPMS Memo titled "Final Contract Year 2021 Part C Benefits Review and Evaluation issued April 8, 2020 (pages 15 to 18)": "...In applying the TBC evaluation, plan bids with a TBC change amount greater than the thresholds discussed below will be further scrutinized on a case-by-case basis and a MA organization may be requested to provide a justification or change its bid(s)...."

CY 2021 Bid Submission Process

Part D sponsors must do the following to finalize participation in the Model through their Part D bid submission, due by 11:59 PDT on June 1, 2020:

1. Indicate participation by marking “Yes” to participating in Part D Senior Savings Model in the Set-up Plans section of HPMS. The navigation path in HPMS is as follows: Plan Bids>Bid Submission> CY2021 > Set-up Plans > Select applicable contract/plan ID > Answer “Yes” to the question “Is this plan participating in the Part D Senior Savings Model?”
2. Bid submission of the final CY2021PDSSPricing_ParentORG.xls supplemental file (upload to the Model Documentation section in HPMS). Please note the contracts and PBPs included in the final Pricing file must be consistent with the contracts and PBPs included in provisional approval letter. If there are any updates after the provisional approval letter, including the addition of new contract(s) or PBPs, those must match the final application and pricing supplemental file submissions to be submitted to both the Model at PartDSeniorSavings@cms.hhs.gov and to the bid by no later than June 1, 2020 at 11:59pm PDT.
3. If provisionally approved to offer Part D Rewards and Incentives in the Part D Senior Savings Model, indicate “The PBP will implement a Part D RI program in accordance with the Part D sponsor’s Approved Proposal.” in the MRx Notes section of the Part D PBP.
4. Populate the participation indicator in the CY2021 Part D Bid Pricing Tool. The input is located in “I. General Information”, Section 17 and is labeled “SSM.”

In July, Part D Sponsors participating in the Model will submit the CY 2021 Part D Senior Savings Model Supplemental File during the July 7-10, 2020, supplemental file submission window. Part D sponsors will submit one supplemental file for each contract/plan that is provisionally approved to participate in the Model. The Model drugs for which the Model-participating plans will offer a maximum \$35 copayment and included on the supplemental file will be validated against the formulary that is associated with the contract/plan. A Part D sponsor may submit multiple (contract/plan) supplemental files per formulary ID. The format for the supplemental file is included in Appendix 1 of the April 9, 2020, HPMS Memo on the Part D Senior Savings Model – Calendar Year (CY) 2021 – Frequently Asked Questions document and is available at the following link: <https://innovation.cms.gov/media/document/partd-senior-savings-model-cy21-faqs>.