TECHNICAL GUIDANCE ON IMPLEMENTATION OF THE PART D PRESCRIBER ENROLLMENT REQUIREMENT

December 29, 2015

CMS is providing this technical guidance to Part D sponsors and their pharmacy benefit managers (PBMs) to apply once the Part D Prescriber Enrollment Requirement is enforced beginning June 1, 2016. We use the term "Part D Prescriber Enrollment Requirement" to refer generally to the provisions in the two applicable rules: 1) final rule CMS-4159-F Medicare Program; *Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs* (79 FR 29843; May 23, 2014); and 2) the interim final rule with comment ("IFC") CMS-6107-IFC Medicare Program; *Changes to the Requirements for Part D Prescribers* (80 FR 25958; May 6, 2015). In addition, we use the term "Part D sponsor" in this document to mean the "Part D sponsor and its PBM" unless noted otherwise.

This guidance addresses topics CMS acknowledged in the preamble to the IFC that would need further guidance and is also based on comments received on the IFC as to areas needing further technical guidance. In addition, CMS intends to publish a final rule that addresses the timely comments received on the May 6, 2015 IFC. This and other previously issued and posted guidance on the Part D Prescriber Enrollment Requirement can be found at www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Prescriber-Enrollment-Information.html and go.cms.gov/PrescriberEnrollment.

I. **Table of Contents:**

I. Part D Prescriber Enrollment Requirement

The Part D Prescriber Enrollment Requirement involves a sponsor performing the following new actions upon receipt of a pharmacy claim or beneficiary request for reimbursement:

1) The sponsor should determine whether the prescriber is active on the Medicare Individual Enrollment File for the date of service ("DOS"). If so, the sponsor does not need to separately confirm that the prescriber's National Provider Identifier ("NPI") is active and valid in the National Plan and Provider Enumeration System ("NPPES"). If the prescriber is active for the DOS, the drug is covered/not covered, as applicable, and the Prescriber Enrollment Requirement has been satisfied.
2) If the prescriber is not active on the Medicare Individual Enrollment File for the DOS, the sponsor should determine if the prescriber is an Other Authorized Prescriber ("OAP") for the DOS. (See section "Other Authorized Prescribers.") If so, the prescriber must have an active and valid individual NPI in NPPES. If so, the drug is covered/not covered, as applicable, as if the Prescriber Enrollment Requirement did not apply.
3) If the prescriber is not active in the Medicare Individual Enrollment File and is not an OAP for the DOS, but has an active and valid individual NPI in NPPES for the DOS, the Part D Prescriber Enrollment provisional drug supply and individualized written notice requirements apply, as provided in this guidance.
4) After a provisional supply of the drug has been provided (See section " 'Drug' for Purposes of Provisional Supplies"), claims for that drug must be rejected/requests for that drug must be denied by the sponsor when prescribed by the same prescriber, unless the prescriber's status has changed and the drug is covered as determined by repeating above steps 1 and 2.
5) If the drug is prescribed by a new prescriber, the steps apply again.

These steps are in addition to existing actions, such as determination of whether a drug is subject to utilization management and whether a beneficiary is entitled to transition, as appropriate. (See section "Utilization Management Requirements" if utilization management requirements also apply to the drug. See section "Transition Fills and Provisional Supplies" if the beneficiary is simultaneously entitled to transition.) These steps are not intended to require or even suggest a specific pharmacy claims processing hierarchy or order, but rather to provide a technical summary of the Part D Prescriber Enrollment Requirement at the beginning of this guidance to provide context. Sponsors must design their claims systems and hierarchies to incorporate edits to comply with the Prescriber Enrollment Requirement into existing claim edits in the manner that they deem most appropriate, for example, whether to check drug coverage or prescriber eligibility first, but the outcome of adjudication must be consistent with this framework.

A. "Other Authorized Prescribers"

"Other Authorized Prescribers" (OAPs), as defined in 42 CFR § 423.100[1], are exempt from the Part D Prescriber Enrollment Requirement pursuant to 42 CFR § 423.120(c)(6)(ii)(A). OAPs are prescribers who may prescribe drugs pursuant to state or other applicable law, but who are not in a provider category that is permitted to enroll in or opt out of Medicare.

From a regulatory perspective, nothing has changed with regard to Part D claims for prescriptions written by prescribers meeting the definition of OAPs. In other words, a Part D sponsor must continue to cover prescriptions written by OAPs as before enforcement of the Part D Prescriber Enrollment Requirement.

However, because prescriptions written by all prescribers, except OAPs, are now subject to new Part D rules, sponsors must now be able to separately identify pharmacy claims involving prescriptions written by OAPs at point of sale (POS) from other claims in order to continue to properly adjudicate them. To date, CMS has identified pharmacists and naturopaths as two categories of providers that might meet the definition of "Other Authorized Prescribers." See the Medicare Provider Enrollment Eligibility Reference Table posted at www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Prescriber-Enrollment-Information.html. CMS will update this reference table if CMS identifies additional categories of providers that might meet the definition of OAPs. Part D sponsors may rely on the National Provider Identifier (NPI) taxonomy in the National Plan & Provider Enumeration System (NPPES) to identify claims involving prescriptions written by OAPs at POS. The OAP's individual NPI must be active and valid for the DOS for the drug to be coverable under Part D. While taxonomy is not a verified source to determine a prescriber's health care provider category, it is the only source currently and readily available to all Part D sponsors without charge.

The main taxonomy for a pharmacist is: Pharmacist - 183500000X; and for a naturopath, it is Naturopath - 175F00000X. There are other pharmacist taxonomies, but there are no other naturopath taxonomies at this time. These taxonomies are provided as examples that a Part D sponsor may rely on to identify OAPs. Sponsors must determine which taxonomies they believe indicate that the prescriber is an OAP. The health care provider taxono.my code set used in NPPES can be found at the following link: http://www.wpc-edi.com/reference/.

CMS is aware of industry efforts to develop a POS override to facilitate beneficiary access to drugs, if there is a discrepancy between the Part D sponsor's and the pharmacy's information about whether a

[1] For purposes of the Part D Prescriber Enrollment Requirement only, "Other Authorized Prescribers" are defined in 42 CFR § 423.100 as, "An individual other than a physician (as defined in section 1861(r) of the Act) or eligible professional (as defined in section 1848(k)(3)(B) of the Act) who is authorized under State or other applicable law to write prescriptions."

prescriber is an OAP.[2] CMS is supportive of the intent of the override, which is to preserve beneficiary access when the pharmacy's information proves to be correct. However, issues may also arise for a Part D sponsor, the pharmacy, and potentially the beneficiary, if a pharmacy incorrectly overrides a sponsor's rejection of a claim and the sponsor accepts the override. The sponsor's prescription drug event (PDE) record may not be accepted by CMS and the pharmacy may be subject to recoupment by the sponsor, if the applicable contract between the parties so allows. Given these considerations, pharmacies and sponsors must decide if and how they will use and accept such an override code.

CMS does not require Part D sponsors to validate a prescriber's prescriptive authority, with the exception of existing guidance that we expect Part D sponsors to confirm that a prescribed controlled substance is consistent with the prescriber's DEA Schedule registration, when it is possible to map a prescriber NPI to an individual DEA number.[3] While Part D sponsors may generally rely on pharmacies to dispense drugs only pursuant to valid prescriptions, Part D sponsors are still responsible if they submit prescription drug event records to CMS that are later determined not to be associated with valid prescriptions under applicable law, as they have always been.

Given the exemption for OAPs from the Part D Prescriber Enrollment Requirement, CMS encourages Part D sponsors to implement reasonable processes to minimize inappropriate Part D coverage for prescriptions written by OAPs. For example, it is our understanding that pharmacists and naturopaths are typically restricted by applicable law as to the drugs they are permitted to prescribe, i.e., they might not be permitted to prescribe any controlled substances. If they are not, CMS would not expect sponsors to submit PDEs for controlled substances with prescriber NPIs that have a pharmacist or naturopath taxonomy. In addition, Part D sponsors should consider regularly auditing claims for prescriptions written by OAPs to assist in preventing the submission of PDEs to CMS that are not associated with valid prescriptions and to identify possible cases of fraud and make referrals in accordance with Chapter 9 of the Prescription Drug Benefit Manual.

[2] With respect to the NPPES file, CMS has previously issued guidance concerning discrepancies between Part D sponsors and pharmacies about the status of a prescriber NPI at POS. See June 1, 2015 memorandum, "**Medicare Part D Prescriber Enrollment Update:** *Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)/ Part D Claims Beginning June 1, 2016.*"

[3] See "Clarification of Chapter 5 of the Prescription Drug Manual, Section 90.2.4.-- Controlled Substances," (May 21, 2013).

B. Provisional Drug Supply and Written Notices

1. 3-Month Provisional Drug Supply

A Part D sponsor or Medicare Advantage plan that offers Part D (MA-PD) must not reject a claim or deny a beneficiary request for reimbursement for a drug only on the basis of the prescriber's lack of Medicare enrollment/opt out status for the date of service (DOS), unless the sponsor has first provided a 3-month provisional supply of the drug in accordance with CMS guidance. Thus, a provisional supply does not result in a rejection at POS or a denial, but in a paid claim/direct member reimbursement. (As noted earlier, a prescriber's individual NPI must be active and valid for the DOS in NPPES for a sponsor to cover a provisional supply). For purposes of this guidance, when we refer to a covered provisional supply, we are assuming, for simplicity, no other coverage restrictions apply, such as a utilization management edit or applicable law. In addition, we assume there's been no change in the prescriber's status (i.e., prescriber enrolled in or opted out of Medicare during the provisional supply period) that would allow the drug to continue to be covered.

The purpose of the 3-month provisional drug supply and written notice is to minimize the potential for interruptions to a Part D-covered beneficiary's access to needed medications, when his or her prescriber is not enrolled in or opted out of Medicare and is not an OAP. Three months provides the beneficiary with 3 months of time to obtain a 3-month supply of a drug and for a prescriber to enroll in Medicare. Or, if the prescriber is unwilling or not able, the 3-month provisional supply provides time for a beneficiary to see a prescriber who is able to prescribe covered Part D drugs, if the beneficiary wishes for their prescribed drugs to continue to be coverable under Part D.

A 3-month provisional supply has two aspects: a days supply aspect and a timeframe aspect. A full 3-month provisional supply means the number of days supply that would constitute a 3-month supply for the drug in accordance with the applicable Plan Benefit Package (PBP), if the prescription is written and dispensed for a full 3-month supply. Given this, a 3-month provisional supply in terms of days' supply can vary from plan to plan, even under the same sponsor. Typically, a 3-month supply is either 90 or 93 days' supply. Sponsors are to apply cost-sharing for the covered drug as indicated in the PBP for the applicable Part D prescription drug benefit plan.

With respect to the timeframe aspect, 3-months means 90 days, and thus does not vary from plan to plan. For purposes of clarity in this guidance, we use "90 days" to refer to the timeframe in which a provisional supply must be dispensed, and we use "3-month supply" to refer to the days supply amount that a plan must cover during that time period, if the prescription is actually written and dispensed for a full 3-month supply.

A sponsor or MA-PD must track a separate 90 day consecutive time period for each drug covered as a provisional supply from the initial DOS, and must not reject a claim or deny a beneficiary's request for

reimbursement until the 90 day time period has passed or a 3-month supply has been dispensed, whichever comes first. We provide the following two examples to illustrate:

Example 1: Full 3-Months' Provisional Supply of Drug is Dispensed (30 days' supply=1 month's supply in PBP)				
Dates of Service →	01.02.2017	01.27.2017	02.21.2017	03.18.2017
Provisional Supply Coverage →	Covered: 30 days' supply	Covered: Refill for 30 days' supply (cumulative 2-months' supply)	Covered: Refill for 30 days' supply (cumulative 3-months' supply)	Not covered: Refill for 30 days' supply rejects, as a full 3-month provisional supply has been covered.
Provisional Supply Time Period →	Day 1 of 90 days	Day 25 of 90 days	Day 50 of 90 days	Day 75 of 90 days

Example 2: 90 Day Provisional Supply Time Period Passes (31 days' supply=1 month's supply in PBP)			
Dates of Service →	01.02.2017	02.21.2017	04.03.2017
Provisional Supply Coverage →	Covered: 31 days' supply	Covered: Refill for 31 days' supply (cumulative 2-months supply)	Not Covered: Refill for 31 days' supply rejects as 90 days has passed.
Provisional Supply Time Period →	Day 1 of 90 days	Day 50 of 90 days	Day 91 of 90 days

As noted earlier, beneficiaries must also receive additional provisional supplies of the same drug, if the prescription is written by a different prescriber who is not enrolled in or opted out of Medicare and who is not an OAP.

The provisional drug supply requirement applies both when a prescriber has not yet enrolled in or opted out of Medicare, and when a prescriber is no longer enrolled in or opted out of Medicare. In both scenarios, a beneficiary is likely to be unaware of the prescriber's enrollment status, and therefore in need of a provisional supply of a drug while the prescriber pursues Medicare enrollment or opt out status. However, if the prescriber is unwilling to pursue such status, the beneficiary may decide to find a prescriber who is already eligible to prescribe covered Part D drugs (or willing to timely pursue such status), if the beneficiary wishes the relevant prescriptions to still be coverable.

2. Medicare Advantage Organizations

If a Medicare Advantage (MA) organization anticipates that a contracted and/or network physician or eligible professional, including those contracted indirectly through a third party arrangement, such as a dentist, will write prescriptions for Part D drugs, the organization should confirm that the contracted physician or eligible professional is enrolled in Medicare in an approved status. See CMS Memo, "Requirements for Part D Coverage: Prescriber Requirements," (June 10, 2015).
Per 42 CFR §422.112, CMS requires that all MA organizations provide, maintain, and monitor a network of appropriate providers sufficient to provide adequate access to covered services to meet the

needs of the population served. Beneficiaries in MA-PD plans must have access to providers that can prescribe their Part D medications.

As CMS expects that MA organizations will confirm that the contracted providers of its MA-PD plans are approved to write prescriptions that will be covered under Part D, CMS does not anticipate that enrollees of MA-PD plans will generally need to receive provisional supplies of drugs. However, in the event that an MA-PD plan's contracted physician or other eligible prescriber is not enrolled in Medicare to allow Part D coverage of his/her prescriptions, an enrollee of that plan must receive a provisional drug supply on the same basis that an enrollee of a stand-alone Part D plan would.

We note that network-based MA-PD plans are required to have a network of providers that are qualified to furnish all plan-covered services, including supplemental and Part D benefits. In the event a contracted provider who would be expected to furnish Part D prescriptions is not enrolled in Medicare, the MA-PD plan must ensure that enrollees are no longer directed to that provider for the provision of prescriptions for covered Part D drugs, a service that the provider is not eligible to furnish. When an enrollee receives covered services from a plan-contracted provider who is not eligible to prescribe covered Part D drugs, the plan is responsible to cover the enrollee's visit to that provider, the provisional supply of any prescribed Part D drug(s), as well as any subsequent visit the enrollee is required to make in order to obtain a prescription for the drug(s) from a provider who is enrolled in Medicare. This may entail revisions to the plan directory and outreach to plan enrollees about the standards for coverage of a Part D covered drug.

In addition, there are circumstances when a beneficiary enrolled in an MA-PD plan may receive covered services from a non-contracted provider (e.g., a PPO enrollee). In the event the non-contracted provider is not eligible to have his/her prescriptions covered by Part D (because the non-contracted provider is not enrolled in or opted out of Medicare and is not an OAP), the MA Organization offering the MA-PD plan must cover the prescription that is written as part of the covered service provided as a provisional supply (with individualized written notice), as applicable. Additionally, the MA-PD plan should ensure that the enrollee is aware that the non-contract provider they received services from is not enrolled in Medicare and if they do not become enrolled future prescriptions from that provider will not be covered.

3. Rejected Claims

After the 90 day period for the provisional supply of a particular drug has expired, if the prescriber has not enrolled in or opted-out of Medicare, and the beneficiary presents an additional prescription from that prescriber, or requests a refill, for the same drug, the Part D sponsor must not cover the additional prescription or refill. These claims must be rejected at the point of sale.

If a claim is rejected only because of the prescriber enrollment issue after the enrollee has received a provisional supply, the National Council for Prescription Drug Programs (NCPDP) response code "569"

should not be transmitted to the pharmacy. In other words, the pharmacy is not required to deliver the standardized pharmacy notice, "Medicare Prescription Drug Coverage and Your Rights" (CMS-10147) to the enrollee. Similar to a situation where a prescription is written by a sanctioned provider, the reason for the rejection is an issue with the prescriber who wrote the prescription, and the beneficiary and the prescriber should have already received individualized written notice. As such, directing the beneficiary to the coverage determination process will not resolve the issue with the prescriber. If the claim contains additional reject codes that trigger the "569" code transmission, the network pharmacy should deliver the standardized pharmacy notice. Refer to the Medicare Prescription Drug Benefit Manual, Chapter 18, section 40.3.1 for additional information about the pharmacy notice.

4. Changing Pharmacies

If a beneficiary has obtained part of a provisional drug supply at one pharmacy and wishes to obtain the remainder from another pharmacy, including from a mail-order pharmacy, the sponsor must allow the beneficiary to do so (assuming the mail order pharmacy dispenses less than a 3-months supply).

5. Remaining in the Same Part D Plan / Changing Part D Plans or Plan Benefit Packages (PBPs)

A beneficiary must only receive one provisional supply (with individualized written notice) of each drug prescribed by the same prescriber while in the same Part D plan. In cases when a beneficiary changes PBPs within the sponsor's organization, if a sponsor is able to determine from its adjudication records that the sponsor has previously complied with the provisional drug supply requirements involving the same drug and prescriber, and the beneficiary has been sent the required individualized written notice, the sponsor must not cover another provisional supply of the same drug or, if applicable, must only apply the remaining portion of the 90 day consecutive time period or cover the remainder of the 3-month supply, whichever comes first. If the sponsor is unable to determine prior provisional supplies from its adjudication records, the sponsor must provide a provisional drug supply (ies) to the beneficiary when applicable.

When a beneficiary changes Part D plans or PBPs outside the sponsor's organization, the new sponsor must provide the provisional supply, as there is currently no mechanism to alert the new sponsor that the beneficiary has already received a provisional drug supply involving the same drug and prescriber.

6. Long-Term Care (LTC)

There are no special instructions for the LTC setting. However, we have provided examples in the Transition Fills and Provisional Supplies section for the LTC setting.

7. "As Prescribed by the Prescriber"

The provisional supply must generally be dispensed "as prescribed by the prescriber" pursuant to 42 CFR § 423.120(c)(6)(v)(B)(1)(i). As we stated in the preamble to the IFC and indicated earlier, this means that the Part D sponsor is required to cover a full 3-month provisional supply, regardless of how the supply is dispensed, if it is written for a full 3-month supply and dispensed during the 90 day timeframe.

For example, a beneficiary may receive a provisional supply in accordance with a prescription written for a month's supply with two subsequent refills; a prescription written for a one-time 3-month supply; or three prescriptions written for a 1-month supply each. Conversely, as indicated earlier, the prescription might not be for a full 3-month supply, and in such a case, the sponsor would not be required to provide a 3-month provisional supply, but rather would be required to provide the amount prescribed, so long as it is dispensed during the 90 day timeframe.

The language, "as prescribed by the prescriber," does not mean that a Part D sponsor should cover more than a 3-month provisional supply, even if the prescriber wrote the prescription(s) for more than a 3-month supply, as indicated earlier.

8. "If Allowed by Applicable Law"

The purpose of this regulatory language is to emphasize that the provisional supply must still be covered pursuant to a valid prescription in accordance with current Part D policy. While a provisional supply must generally be dispensed as prescribed by the prescriber, it also must be "allowed by applicable law" pursuant to 42 CFR § 423.120(c)(6)(v)(b)(1)(i). For example, certain prescriptions cannot be refilled, such as Schedule II controlled substances, and continuing supplies of such drugs are dispensed only upon a new prescription, even if the prescriber included refills in the prescription.

9. " Subject to All Other Part D Rules and Plan Coverage Requirements"

There are other instances in which a beneficiary might not receive a full 3-month provisional supply, even when prescribed a full 3 months' supply and even when the 90-day provisional time period would be sufficient time, due to other existing Part D requirements which take precedence. Thus, the regulatory language in 42 CFR § 423.120 (c)(6)(v)(B)(1) states that a provisional supply is "subject to all other Part D rules and plan coverage requirements." The below includes example scenarios:

a. Transition Fills and Provisional Supplies

If a Part D sponsor determines when adjudicating a pharmacy claim that a beneficiary is to receive a provisional drug supply and individualized written notice, but the drug is off-formulary and the transition requirements set forth in § 423.120(b)(3) are also triggered under Part D transition fill

guidance, the beneficiary would not receive more than the applicable transition supply of the drug, unless a formulary exception is approved. CMS is testing a model beneficiary notice for a provisional supply and a combined transition fill / provisional supply notice for cases when both are applicable. (However, if the combined notice does not appear to significantly enhance beneficiary understanding of the overlay of a transition fill and a provisional supply, CMS will direct sponsors to send both notices separately to the beneficiary, when applicable.) CMS will provide sponsors with such a notice(s) in the future).

Part D sponsors should train their customer service representatives (CSRs) to answer questions from enrollees who meet the criteria to receive a transition fill and a provisional supply simultaneously about the steps the prescriber and enrollee should take: 1) to pursue coverage of the off-formulary drug or a formulary drug as an alternative; and 2) to pursue continued coverage of the drug after the provisional supply has been provided in light of the prescriber's current lack of Medicare enrollment/opt-out status. In this regard, CSRs should be able to explain to an enrollee that if the enrollee is not granted an exception for the off-formulary drug through the coverage determination process, he or she will not receive any remaining provisional supply of the off-formulary drug, but would receive a 3-month provisional supply if the prescriber switches the enrollee to a formulary drug.

The following examples are to illustrate transition fills and provisional supplies in the retail and LTC settings:

Example 3: Enrollee Meeting Criteria to Receive both a Transitional Fill and Provisional Supply for the Same Drug in a Retail Setting and No Favorable Coverage Determination (30 days' supply = 1 month's supply in PBP)			
Dates of Service →	01.02.2017	01.05.2017	01.27.2017
Supply Coverage →	Covered: 30 days supply	N/A	Not covered: Refill for 30 days' supply rejects, as 30 days' transition supply has been covered. Provisional supply requirement does not supersede transition rejection.
Transition Fill Time Period/Notices →	Day 1 of 90 days	Transition fill notices sent* (3 business days)	Day 25 of 90 days
Provisional Supply Time Period →	Day 1 of 90 days	Provisional supply notices sent* (3 business days)	Day 25 of 90 days

*As noted earlier, CMS will provide a model notice(s).

Example 4: Enrollee Meeting Criteria to Receive both a Transitional Fill and Provisional Supply for the Same Drug in a Retail Setting and a Favorable Coverage Determination (30 days' supply = 1 month supply in PBP)				
Dates of Service	01.02.2017	01.05.2017	01.27.2017	04.03.2017
Supply Coverage →	Covered: 30 days' supply	N/A	Covered: Refill for 30 days' supply due to favorable coverage determination about drug. (2-months cumulative provisional supply)	Not covered: Refill for 30 days rejected even though less than 3-months' provisional supply has been covered, as 90 day provisional supply time period has passed. Favorable coverage determination does not supersede provisional supply reject.
Transition Fill Time Period →	Day 1 of 90 days	Transition notice sent* (3 business days)	Day 25 of 90 days	N/A due to favorable coverage determination about drug.
Provisional Supply Time Period →	Day 1 of 90 days	Provisional supply notice sent* (3 business days)	Day 25 of 90 days	Day 91 of 90 days

*As noted earlier, CMS will provide a model notice(s).

Example 5: Enrollee Meeting Criteria to Receive both a Transitional Fill and Provisional Supply for the Same Generic drug in LTC setting and No Favorable Coverage Determination (31 days supply = 1 month supply in PBP)					
Dates of Service →	01.02.2017	01.05.2017	02.02.2017	03.05.2017	04.05.2017
Supply Coverage →	Covered: 31 days' supply	N/A	Covered: Refill for 31 days' supply (2-month cumulative supply)	Covered: Refill for 31 days' supply (3-months' cumulative supply)	Not covered: Refill for 31 days' supply rejects, as 93 days' transition fill & 3-months' provisional supply has been covered and transitional fill & provisional supply time periods have also passed.
Transition Fill Time Period →	Day 1 of 90 days	Transition notice sent* (3 business days)	Day 31 of 90 days	Day 62 of 90 days	Day 93 of 90 days
Provisional Supply Time Period →	Day 1 of 90 days	Provisional supply notice sent* (3 business days)	Day 31 of 90 days	Day 62 of 90 days	Day 93 of 90 days

*As noted earlier, CMS will provide a model notice(s).

Example 6: Enrollee Meeting Criteria to Receive both a Transitional Fill and Provisional Supply for the Same Brand Drug in LTC Setting and No Favorable Coverage Determination (31 days supply = 1 month supply in PBP)				
Dates of Services →	01.02.2017	01.05.2017	↓ 01.16.2017 01.30.2017 02.13.2017 ↓ 02.27.2017 03.13.2017 →	03.27.2017
Supply Coverage →	Covered: 14 days' supply	N/A	Covered: 14 days' supply dispensed on each day (cumulative 84 days supply)	Covered: 9 days supply (cumulative transition fill supply limited to 93 days by provisional supply limitation of 3-months supply)
Transition Fill Time Period →	Covered: Day 1 of 90 days	Transition notice sent* (3 business days)	↓ Day 14 Day 28 Day 42 ↓ Day 56 Day 70 of 90 days	Day 84 of 90 days
Provisional Supply Time Period →	Covered: Day 1 of 90 days	Provisional supply notice sent* (3 business days)	↓ Day 14 Day 28 Day 42 ↓ Day 56 Day 70 of 90 days	Day 84 of 90 days

*As noted above, CMS will provide a model notice(s)

b. Utilization Management Requirements when Transition Does Not Apply

If a Part D sponsor determines when adjudicating a pharmacy claim that a beneficiary is entitled to a provisional supply and individualized written notice, but the drug prescribed is subject to prior authorization or step therapy requirements, such utilization management edits still apply. For example, if a drug is subject to step therapy under the applicable plan's approved formulary, the step therapy requirement must still be satisfied, unless an exception is approved through the coverage determination process.

10. Provisional Supply Notices

a. Beneficiary Notice

While a provisional supply of the drug provides the beneficiary with immediate continuity of drug therapy, the required individualized written notice to the beneficiary is likely the only means by which the beneficiary will be alerted that an action must be taken to allow for continued Part D coverage of the drug. These actions are: 1) the prescriber must enroll in or opt out of Medicare (the latter option is not appropriate for a provider who is a contracted or network provider with an MA plan) for future dates of service; or 2) the beneficiary must find another prescriber who meets the Medicare requirements to write Part D prescriptions. Therefore, this notice is crucial for the beneficiary.

Accordingly, the sponsor must send an individualized written beneficiary notice within 3 business days after processing the first claim or direct member reimbursement for a prescription that the sponsor has determined should be covered as a provisional supply. The sponsor is not required to send additional notices with additional dispensing events for that drug. However, the sponsor is required to send an individualized written notice to the beneficiary for the first dispensing event of other drugs prescribed by the same prescriber. While the beneficiary would have already received notice about the prescriber's status, the consequences to the beneficiary in terms of Part D coverage are significant enough to warrant a notice for each drug for which coverage will end if there is no change in the prescriber's status.

The written notice must be sent via U.S. First Class mail, unless the beneficiary has consented to notices from the plan via another means, such as by email. As noted above, CMS will provide Part D sponsors with model beneficiary provisional supply notice(s).

Once the Part D sponsor has provided the written notice to the beneficiary that a drug is being covered on a provisional basis because of the prescriber's current lack of Medicare enrollment/opt out status, and the sponsor has covered a provisional supply of the drug, the sponsor must reject subsequent claims and deny subsequent requests for reimbursement from the beneficiary for the same drug, if the prescription is written by the same prescriber, unless the prescriber has since enrolled in Medicare or opted out. If the prescription is written by a new prescriber who is also not enrolled in or opted out of Medicare, and it

qualifies for provisional coverage, the sponsor must provide the provisional supply and send another individualized written notice to the beneficiary, as the purpose of the notice is to inform the beneficiary about the prescriber's status, not the drug status.

b. Prescriber Notice

42 CFR § 423.120(c)(6) requires that Part D sponsors and their PBMs ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a provisional supply notice. CMS believes the following examples constitute reasonable efforts on the part of a Part D sponsor to notify prescribers of such affected enrollees. These examples are not exhaustive of actions that may constitute reasonable efforts:

1) *Providing a copy of the individualized written beneficiary provisional supply notice labeled as the "PRESCRIBER COPY" directly to the prescriber of record.* The copy may be provided to the prescriber via mail, fax, or electronic means. Adding this label to a copy of the provisional supply notice to be supplied by CMS does not require submission of the notice for review and approval by CMS.
2) *Notifying the prescriber of record directly of the adjudication of the beneficiary's provisional supply via a phone call, or individualized or batch fax/electronic notification.* This separate communication to the prescriber does not need to be submitted to CMS for review and approval.
3) *Only notifying a prescriber about the first provisional drug supply for a beneficiary pursuant to a prescription written by the prescriber, regardless how many provisional drug supplies involving that prescriber are ultimately covered for the beneficiary.*
4) *Ceasing to notify the prescriber about any beneficiaries who receive provisional drug supplies if the prescriber requests that the sponsor cease doing so.*

CMS expects that Part D sponsors will exercise due diligence in sending provisional notices/ communications to the prescriber of record's correct address, whether that entails using NPPES, acquiring contractor support, contacting the network pharmacy for information on the prescription, or other means. Sponsors are expected to keep an appropriate record of the time and type or copy of the communication. However, CMS does not expect sponsors to verify that the prescriber has received a provisional supply notice/communication.

C. "Drug" for Purposes of Provisional Supply

For purposes of the provisional supply requirement, "drug" is defined by the generic name, dosage form, and route of administration. If an individual is concurrently taking more than one strength of a drug, the individual must receive a 3-month provisional supply of both, if applicable. Thus, overlapping days of different strengths of a drug count once toward a 3-month provisional supply. The following examples

illustrate the concept of only counting consecutive, non-overlapping days' supply of multiple strengths as additional days for purposes of counting towards a 3 month supply.

Example 7: Two Strengths of Same Drug Filled Simultaneously for Entire 3 Months			
Same Drug, Different Strengths	Date of Service	Accumulated Provisional Supply	Result
Drug X 10mg 30 days' supply	January 1—Day 1		Claim Pays
Drug X 20mg 30 days' supply	January 1—Day 1	30 days' supply	Claim Pays
Drug X 10mg 30 days' supply	January 31—Day 31		Claim Pays
Drug X 20mg 30 days' supply	January 31—Day 31	60 days' supply	Claim Pays
Drug X 10mg 30 days' supply	March 3—Day 62		Claim Pays
Drug X 20mg 30 days' supply	March 3—Day 62	90 days' supply	Claim Pays

Example 8: Three Strengths of Same Drug Filled Consecutively without any Overlapping Days			
Same Drug, Different Strengths	Date of Service	Accumulated Provisional Supply	Result
Drug X 10mg 30 days' supply	January 1—Day 1	30 days' supply	Claim Pays
Drug X 20mg 30 days' supply	January 31—Day 31	60 days' supply	Claim Pays
Drug X 30mg 30 days' supply	March 3—Day 62	90 days' supply	Claim Pays
Drug X 30mg 30 days' supply	March 25—Day 84	120 days' supply	Claim Rejects

Example 9: Three Strengths of Same Drug Filled with Some Overlapping Days			
Same Drug, Different Strengths	Date of Service	Accumulated Provisional Supply	Result
Drug X 10mg 30 days' supply	January 1—Day 1	30 days' supply	Claim Pays
Drug X 20mg 30 days' supply	January 10—Day 10	40 days' supply	Claim Pays
Drug X 30mg 30 days' supply	January 31—Day 31	60 days' supply	Claim Pays
Drug X 30mg 30 days' supply	February 25—Day 56	90 days' supply	Claim Pays
Drug X 20mg 30 days' supply	March 25—Day 84	118 days' supply	Claim Rejects because greater than 90 days' supply. Accumulated supply would equal only 118 because of 2 overlapping days.

For purposes of compounds, if any ingredient is the same drug as defined in this guidance (e.g., generic name, dosage form, and route of administration), then the compounds are considered the same drug for purposes of a provisional fill.

Protected class drugs are not exempt from the 3-month provisional supply requirement. Also, Part D sponsors must not cover more than a 3-month provisional supply only because the drug prescribed is a protected class drug. In such situations, for the protected class drug to continue to be covered by Part D, the prescriber must enroll or opt-out, or the beneficiary must switch to a prescriber who is able to prescribe coverable Part D drugs. Finally, over-the-counter, enhanced, and $0 generics drugs are not exempted from the Part D Prescriber Enrollment Requirement.

With respect to drugs in unbreakable packages, if the smallest available package size provides less than a 3-month supply of a drug, we expect the sponsor to provide the number of packages that constitutes a 3-month supply under the applicable PBP. If the smallest available package size provides more than a 3-month supply of a drug, we expect the sponsor to provide one package.

D. Direct Member Reimbursement (DMR)

A sponsor should not deny a beneficiary's request for reimbursement of out-of-pocket expenses (a "Direct Member Reimbursement" (DMR)) on the basis of a prescriber's status, if the prescriber is enrolled in or opted out of Medicare or if the prescriber is an OAP on the DOS. If the prescriber is not enrolled or opted out, and is not an OAP, the sponsor must cover a provisional supply of the drug and send the required beneficiary written notice.

With respect to prescriber identifying information, a beneficiary is only required to submit the name of the prescriber in the request, and is not required to submit the prescriber NPI. Therefore, the sponsor must research the request to identify the NPI in order to process the DMR. Pursuant to the existing policies in Chapter 18, section 30.3, if the beneficiary's reimbursement request does not contain all the information the plan needs to make a decision, CMS expects the plan to make reasonable and diligent efforts to obtain the information within the adjudication timeframe before denying the request.

E. Data Files

Part D sponsors should understand the importance of keeping current with the Medicare Individual Provider List and NPPES downloadable data files for proper Part D claim adjudication and to avoid issues with PDE submission. These files are publicly available from CMS's website. They are located at https://data.cms.gov/dataset/Medicare-Individual-Provider-List/u8u9-2upx and http://download.cms.gov/nppes/NPI_Files.html, respectively, and will be used by CMS for PDE editing. CMS provided technical guidance to Part D sponsors about the new Medicare Individual Enrollment file in the December 3, 2014 memo, "Provider Enrollment File."

Part D sponsors should incorporate these data files into their claim adjudication systems within 3 business days of their posting for appropriate PDE editing. In addition, sponsors should not use a new file until midnight on the 3rd business day after its posting in order to synchronize with PDE editing. The Medicare Individual Provider File provides Medicare enrollment and opt-out effective and end dates for physicians and eligible health professionals and is updated weekly on Mondays. The NPPES file provides information about the status of health care provider NPIs. A full replacement file is available monthly on the second Tuesday and an incremental file is available weekly on Monday.

CMS issued PDE guidance, "Provider Enrollment, Chain, and Ownership System (PECOS) and Updates to the Prescription Drug Event (PDE) File Layout and Edits," (PDE Guidance) on June 9, 2015. In this guidance, CMS indicated that PDE editing is largely based on the Medicare Individual Provider File available on DOS. Such editing generally avoids PDE submission issues due to prescriber disenrollments after a Part D pharmacy claim has been adjudicated by a sponsor, but before a PDE has been submitted. We extended this concept of editing based on DOS to instances when PDEs are edited against the NPPES file for provisional supplies and for fills when the prescriber is an OAP. In that

guidance, we stated that the DOS on the PDE must be within the NPI start and end dates on either NPPES or the Medicare Individual Provider File, as appropriate. To clarify, that means that the DOS must be equal to or greater that the NPI start date and less than (but not equal to) the NPI end date in order for the PDE to be accepted.

The PDE guidance also explains how PDEs may be submitted to address retroactive prescriber enrollments. For example, this could occur when a beneficiary paid out-of-pocket for a prescription, because the claim was rejected at POS. The beneficiary makes a request for reimbursement to the Part D sponsor, and from the time the prescription was filled to the time when the Part D sponsor receives the request, the prescriber is enrolled retroactively on the Medicare Individual Provider File to a date prior to or on the date the beneficiary filled the prescription. Under these circumstances, the beneficiary must be reimbursed, and the PDE may be submitted to CMS in accordance with the PDE guidance.

CMS is aware of concerns that sponsors have for situations when sponsors are re-processing claims after the DOS for audit or other reasons (but the DOS remains the same). The following examples are provided to illustrate the concerns:

Example 10: Retroactive Enrollment Date in Post-DOS Re-Processing

Claims Processing Dates			PDE Result
09/05/2016 Pharmacy claim rejected based on Medicare Individual Enrollment File available for the sponsor to use on 09/05/2016. Provisional supply has already been covered. Beneficiary pays cash.	09/10/2015 Prescriber is added to Medicare Individual Enrollment File with an Effective Date of 09/01/2016.	09/20/2016 Pharmacy reprocesses the claim (same DOS). The claim pays based on the updated Medicare Individual Enrollment File. Pharmacy reimburses the beneficiary.	The PDE will be edited against the most recently available Medicare Individual Enrollment File, if it is submitted as an “E” PDE.**

** See PDE Guidance

Example 11: Retroactive Disenrollment Date in Post-DOS Re-Processing

Claims Processing Dates			PDE Result
10/05/2016 Pharmacy claim paid based on the Medicare Individual Enrollment File available for the sponsor to use on 10/05/2016.	10/10/2016 Prescriber is not active on the Medicare Individual Enrollment File with an End Date of 10/01/2016	10/26/2016 The plan reprocesses the claim (same DOS). The claim would reject based on the updated Medicare Individual Enrollment File. The sponsor could evaluate the claim against the Medicare Individual Enrollment File that was used on 10/05/2016 when the original claim was processed.	Assuming that the sponsor used the Medicare Individual Enrollment File that was used when the original claim was processed and paid the reprocessed claim, the PDE will be evaluated against the Medicare Individual Enrollment File that was available for the sponsor to use on the DOS of the original claim, 10/05/2016.**

**See PDE Guidance.

Sponsors will have to best assess how to handle these claim and PDE scenarios given their systems. For the first example, which is a post-DOS adjudication that pays, the sponsor can consider submitting a PDE for such a claim as an "E" PDE. While this would not guarantee that the PDE will be accepted by CMS, the PDE will be edited against the most recently available Medicare Individual Enrollment File. For the second example, which is post-DOS adjudication that would reject, the sponsor can check the Medicare Individual Enrollment File that was used for the original processing of the claim, which is the file CMS will use to edit the PDE. As noted above, PDEs are edited against the Medicare Individual File available at DOS, unless the PDE is submitted as an "E" PDE, in which case the PDE will be evaluated against the most recently available Medicare Individual Provider File.

With respect to OAPs and provisional supplies, NPIs are not retroactively active in NPPES. However, while NPIs are usually not retroactively deactivated in NPPES, they can be. Therefore, this example is also instructive for post-DOS re-processing involving OAPs and provisional supplies in cases when the NPI is retroactively deactivated.

Prior to enforcement of the Part D Prescriber Enrollment Requirement, CMS edited PDEs for active and valid NPIs, but with a +1 year allowance from the DOS to allow for PDEs based on valid prescriptions involving deceased prescribers, as Part D sponsors asserted many states deem prescriptions of deceased prescribers valid for one year. However, such PDE editing also may have unintentionally disincentivized Part D sponsors from keeping current with the downloadable NPPES files. If so, the Part D sponsors should update their processes accordingly.

CMS is aware of industry efforts to develop a POS override process to facilitate beneficiary access to drugs, if there is a discrepancy between the sponsor's and pharmacy's information about the enrollment/opt-out status of the prescriber. CMS is supportive of the intent of the override, which is to preserve beneficiary access when the pharmacy's information proves to be correct. However, issues may also arise for the sponsor, the pharmacy, and potentially the beneficiary, if a pharmacy incorrectly overrides a sponsor's rejection of a claim, and the sponsor accepts the override. The sponsor's PDE may not be accepted and the pharmacy may be subject to recoupment by the sponsor, if the applicable contract between the parties so allows. Thus, given these considerations, pharmacies and sponsors must decide if and how they will use and accept such an override code.

F. Deceased Prescribers

There are no special instructions for deceased prescribers. If a Medicare prescriber who is enrolled or opted out dies, the deceased prescriber's existing prescriptions are coverable under Part D, so long as the deceased prescriber's NPI is still effective on the Medicare Individual Provider file (assuming the prescriptions are valid under applicable law). Once the deceased prescriber is no longer showing as effective on the file, the deceased prescriber's existing prescriptions are still coverable under Part D as provisional supplies, if the applicable regulatory criteria are met, so long as the deceased prescriber's NPI is still active and valid in NPPES. Existing prescriptions of deceased OAPs are likewise still coverable under Part D, so long as the prescriber's NPI is still active and valid in NPPES.

However, Part D sponsors should note that CMS updates both data sets regularly due to provider death. Thus, it is likely that Part D sponsors will encounter scenarios in which existing prescriptions from deceased prescribers are valid under applicable law, but not coverable under Medicare Part D.

The following are to illustrate possible deceased prescriber scenarios:

Example 12: Deceased Prescriber 123456789						
Dates →	10/31/2016	11/05/2016	11/15/2016	11/28/2016	11/29/2016	12/20/2016
Prescriber Status →	Prescriber 123456789 dies	Prescriber 123456789 is active on the Medicare Individual Provider File available for the sponsor to use on 11/03/2016	Medicare Individual Provider File updated to show Prescriber 123456789 with End Date 10/31/2016	N/A	NPPES File updated to show Prescriber 123456789 inactive on 10/31/2016	N/A
Claims Processing →	N/A	DOS 11/05/2016 Covered: 30 days' supply as prescriber is active on the Medicare Individual Provider File for DOS	N/A	DOS 11/28/2016 Covered: 30 days' supply dispensed pursuant to provisional supply requirement	N/A	DOS 12/20/2016 Not covered: Claim rejects, as prescriber is no longer active in NPPES (prescription may still be valid under applicable state law)
Time Period →	N/A	N/A	N/A	Day 1 of 90 day provisional supply time period	Day 2 of 90 day provisional supply time period	Day 22 of 90 day provisional supply time period

Example 13: Deceased Prescriber 101121314					
Dates →	10/31/2016	11/05/2016	11/15/2016	11/15/2016	11/30/2016
Prescriber Status →	Prescriber 101121314 dies	Prescriber 101121314 is active on the Medicare Individual Provider File available for the sponsor to use on 11/05/2016	Medicare Individual Provider File updated to show Prescriber 101121314 with End Date 10/31/2016	NPPES File updated to show Prescriber 101121314 inactive on 10/31/2016	
Claims Processing →	N/A	DOS 11/05/2016 Covered: 30 days' supply covered as prescriber is active on the Medicare Individual Provider File for DOS	N/A	N/A	DOS 11/30/2016 Not covered: Claim rejects, as prescriber is not active in NPPES (prescription may still be valid under applicable state law).

Example 14: Deceased Prescriber 161718192					
Dates →	10/31/2016	11/15/2016	11/15/2016	11/20/2016	12/05/2016
Prescriber Status →	Prescriber 161718192 dies	NPPES File updated to show Prescriber 161718192 inactive on 10/31/2016	Prescriber 161718192 is active on the Medicare Individual Provider File available for the sponsor to use on 11/15/2016	Medicare Individual Provider File updated to show Prescriber 161718192 with End Date 10/31/2016	N/A
Claims Processing →	N/A	N/A	DOS 11/15/2016 Covered: 30 days' supply covered as prescriber is active on the Medicare Individual Provider File for DOS		Claim rejects, as prescriber not active in NPPES.

G. Dual-Eligible Beneficiaries Enrolled in a Part D Plan

If a Part D drug is not covered due to the Medicare Part D Prescriber Enrollment Requirement, the drug is also not coverable and not eligible for federal matching funds under Medicaid for dual eligible beneficiaries (because the drug could be coverable under Part D if the prescription were written by a prescriber who is enrolled, opted-out, or an OAP). For non-Part D drugs, current Medicaid rules and guidance for coverage apply and have not changed.

II. Special Note about Opt Out Physicians/Practitioners

Please note that if a physician/practitioner (including dentists) opts out of Medicare, the physician/practitioner will not be eligible to receive reimbursement for items and services covered by traditional Medicare or a Medicare Advantage plan, including those covered as supplemental benefits, except for emergency and urgent care services as permitted by 42 CFR § 405.440. If a physician/practitioner wants to terminate his/her opt out early, the physician/practitioner must not have previously opted out, must do so within 90 days of the effective date of the initial 2-year period, must refund excess amounts collected from beneficiaries, and notify all beneficiaries with whom the physician/practitioner entered into a private contract with (see 42 CFR § 405.445(b)). Otherwise, the physician/practitioner is required to maintain his/her opt-out until the initial 2-year period expires.

Prior to enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), physician/practitioner opt-out affidavits were only effective for 2 years. As a result of changes made by MACRA, valid opt-out affidavits signed *on or after June 16, 2015* will automatically renew every 2 years. If physicians and practitioners who file affidavits effective on or after June 16, 2015 do not want their opt-out to automatically renew at the end of a two year opt-out period, they may cancel the renewal by notifying all Medicare Administrative Contractors with which they filed an affidavit in writing at least 30 days prior to the start of the next opt-out period. Valid opt-out affidavits signed *before June 16, 2015* will expire 2 years after the effective date of the opt out. If physicians and practitioners that filed affidavits effective before June 16, 2015 want to extend their opt out, they must submit a renewal affidavit within 30 days after the current opt-out period expires to all Medicare Administrative Contractors with which they would have filed claims absent the opt-out.

Questions concerning this guidance should generally be sent to PartDPolicy@cms.hhs.gov. However, questions concerning PDEs should be sent to pdejan2011@cms.hhs.gov and questions concerning the Medicare Individual Provider File or NPPES File should be sent to ProviderEnrollment@cms.hhs.gov.