**CMS-4182-P**

1. **Improving Quality, Accessibility, and Affordability**
2. **Implementation of the Comprehensive Addiction and Recovery Act of 2016**
3. **Frequently Abused Drugs**

CMS states that for plan year 2019, consistent with current policy, they propose that opioids are frequently abused drugs. They were not persuaded by comments that other controlled substances should be considered as frequently abused drugs.

The lock-in program is well established for lines of business other than Part D, and it seems counterproductive to limit the program to only opioids when Plan Sponsors have successfully applied this program to other drugs.

1. **Limiting access to coverage of frequently abused drugs to those obtained from a selected pharmacy**

We have concerns about how we can operationalize this requirement. We don’t believe that smaller retail chain pharmacies always have the functionality to share real-time data. This would be a necessity in order to be able to treat all locations of a pharmacy as one pharmacy.

1. **Prescribers associated with the same single Tax Identification Number (TIN) to be counted as a single prescriber.**

CMS should give flexibility in how to link physicians in the same practice. One prescriber can be linked to multiple TINs. The TIN is not present on the claim, further complicating the ability to use the TIN to connect prescribers.

1. **Palliative and end-of-life care**

Although we agree with commenters that believe that patients in palliative and end-of-life care could be exempted from this program. Since not all of those patients are enrolled in hospice, there isn’t a clear way to identify beneficiaries that meet those conditions. Unless CMS can send an indicator, similar to what currently occurs for hospice, we would not recommend implementing this exemption.

1. **Limitation on Access to Coverage for Frequently Abused Drugs**

CMS describes the tools that would be available to sponsors to limit an at-risk beneficiary’s access to coverage for frequently abused drugs through a drug management program. Can CMS also describe the process for documenting the attempts? What type of documentation is required? Is documenting conversations in the Case Management Tool notes sufficient? What does CMS recommend that we do if a prescriber doesn't agree? Can Plan Sponsors implement their own policies?

1. **Notice Requirements**

CMS proposes that sponsors provide an initial notice to a potential at-risk beneficiary if the sponsor intends to limit the beneficiary’s access to coverage for frequently abused drugs, and the sponsor would provide a second notice to an at-risk beneficiary when it actually limits the beneficiary’s access to coverage for frequently abused drugs. Does this notice have to be provided in the threshold languages? Does this count as a significant material from a LANN perspective? Are state laws superseded by Federal laws?

1. **Six Month Waiting Period**

CMS proposes that a sponsor may not limit an at-risk beneficiary’s access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. We believe that six months is much too long of a period to allow at-risk beneficiaries to take controlled substances. Plan Sponsors should be able to act urgently when a beneficiary has been identified as at-risk. Much damage could occur in six months. CMS should consider shortening the time frame, as six months does not seem to be addressing the current public health emergency.

1. **Maximum 12-month period for lock-in and POS edits**

CMS proposes a maximum 12-month period for both lock-in and POS claim edit for frequently abused drugs. At what point can a Plan Sponsor apply the lock-in provisions again if necessary after the initial 12-month lock-in period?

1. **General questions under CARA**

Will the reporting requirements for this program be included in the current Part D Appeals and Grievances reporting requirements?

For the people conducting case management, what kind of credentials is CMS expecting - the language just says appropriate credentialing.

**9. Part D Tiering Exceptions**

CMS has made efforts to clarify tier exception guidance through HPMS memos, the Call Letter, and now in this proposed rule, but each time we receive new guidance, new questions arise. The Tier Exception process described in Chapter 18, which refers to “lower” tier rather than “lowest” tier, and provides examples of non-preferred brand to preferred brand tier exceptions, and non-preferred generic to preferred generic tier exceptions, was easy to implement and less confusing to beneficiaries.

Whatever the outcome of the final rule, we request that CMS provide several examples of how this process is expected to be implemented. As a PBM, we want to provide quality services to our clients, but it is difficult when the guidance is unclear and our clients are interpreting it differently from one another. We also request that CMS provide very clear guidance about whether Select Tiers are included in the tier exception process, both for 2018 and when the new rule is effective in 2019. We request that Select Tiers are exempt from this process.

CMS needs to clarify what is considered a therapeutic alternative. Clarifications can include route of administration, same class of drug and/or mechanisms of actions and appropriate drug based on guidelines (place in therapy).

**12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types**

**a. Any Willing Pharmacy Required for All Pharmacy Business Models**

CMS clarifies that Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in networks. There are some pharmacy business models that do not have a pharmacist onsite at the pharmacy (e.g., prescription drug vending machines, kiosk, telepharmacies). Because these business models do not have a pharmacist onsite at the location, it could result in beneficiaries having trouble understanding the medical information the vending machine/kiosk provides along with the drug. Further, these circumstances increase the potential for fraud, waste, and abuse. While there is not an objection to unique or innovative business or care delivery models, they should be limited to models that have a licensed pharmacist available at all times that the pharmacy is open.

In addition, CMS states: “In particular, we consider “similarly situated” pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.” It is unclear from this statement whether CMS is stating that a pharmacy can participate under multiple contracts with a plan sponsor and/or whether a pharmacy can choose which terms and conditions under which it wants to participate with that plan sponsor. If it is that a pharmacy can participate under multiple contracts (e.g., both retail and mail order contracts), that creates operational challenges. It would also require additional resources for auditing and monitoring purposes to verify that a pharmacy is billing correctly, thus adding additional costs to the health care delivery system as a whole. At a minimum, this would require further industry input to identify workable operational solutions to capture this sort of information at the claim level. If it is that a pharmacy can choose which terms and conditions under which it wants to participate, then that could result in less clinical care for beneficiaries and a higher cost to beneficiaries and the government. For example, a specialty pharmacy presumably “has the capability of complying with standard terms and conditions” for a retail pharmacy, thus it presumably could relieve itself of the additional clinical care obligations that typically are provided in connection with specialty distribution (e.g., skilled nursing services) simply by choosing to participate under retail terms and conditions. In addition, a pharmacy may choose terms and conditions purely based on which contract will yield the highest reimbursement, not which contract most accurately reflects its true business model. From a historical standpoint, there have been traditional mail order pharmacies that have constructed the appearance of an “open door” pharmacy in an effort to participate in a retail network even though it has no or very few patients that “walk-in” for prescriptions (everything is done through the postal service), and in some cases, the “open door” would even require a code or special key card to gain access to the pharmacy through the “open door”. Further, when these pharmacies appear in a directory as “retail” but the beneficiaries show up at the pharmacy and are unable to truly just “walk in” to the pharmacy, it creates beneficiary confusion and access concerns. Bottom line, “similarly situated” should not be based on whether the pharmacy has the “capability” of complying with the standard terms and conditions, but should be based on the pharmacy’s actual predominant business model.

**b. Revise the Definition of Retail Pharmacy and Add a Definition of Mail Order Pharmacy.**

CMS proposes to incorporate the concepts of being open to the walk-in general public for the definition of retail pharmacy and to define mail order pharmacy as one that dispenses and delivers “extended days’ supplies” via common carrier. In addition to the issues discussed above that tie to these defined terms, the definition proposed for retail pharmacies allows a mail order pharmacy to be classified as a retail pharmacy simply by allowing the general public to “walk-in”. As discussed above, in some cases, it has been shown that it truly is not “walk-in” as it requires a key card or other code to gain access to the pharmacy. In addition, just because a pharmacy allows for the general public to “walk-in”, it does not mean that the pharmacy’s business model is truly a retail “walk-in” pharmacy. Historic claims detail often shows that some of these pharmacies that claim to be open to the general public actually mail almost all of their prescriptions nationwide (not just local mailings to walk in patients). Further, under these definitions, there are pharmacies that mail all of their prescriptions nationwide that would not be considered a “mail order pharmacy” under the proposed definition because they do not mail extended day supplies; rather, they mail thirty day supplies as part of a “compliance” packaging arrangement. They are still prescriptions for chronic conditions, but they are mailed in thirty day, as opposed to extended day, supply packaging. These classifications of mail and retail pharmacies become important in connection with the terms and conditions that have to be made available to pharmacies, as they can result in increased cost to beneficiaries and the government in those situations where pharmacies that are mailing almost all of their prescriptions to beneficiaries claim they are entitled to be paid retail rates.

**c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions**

CMS seems to recognize that it is appropriate to apply accreditation requirements to pharmacies so long as they are applied consistently across all of the “similarly situated” pharmacies to which the accreditation requirement applies (e.g., specialty pharmacies). This provides further support for the position set forth in subsection (a) above in that a pharmacy should not be able to pick and choose which terms and conditions under which it wants to participate to the exclusion of those that actually apply to the pharmacy. For example, a specialty pharmacy should not be able to avoid an accreditation requirement by participating under the retail pharmacy terms and conditions.

In addition, CMS states that it is not relevant for Part D sponsors to require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to participate in the network. However, if a mail order pharmacy (or any other pharmacy) does not dispense drugs typically prescribed for the applicable beneficiaries, it can create beneficiary confusion and result in beneficiaries not timely receiving their drugs. For example, if a pharmacy is classified as a mail order pharmacy, a member may send a prescription to that pharmacy for fulfillment, only to find out days later that the pharmacy does not dispense the medication requested. For this reason, we recommend that plan sponsors be permitted to require that pharmacies dispense prescription medications that are typical for the plan sponsor’s member population.

**d. Timing of Contracting Requirements**

CMS requested comments on whether the two business day turn-around time to provide standard terms and conditions to a pharmacy upon request is reasonable. In light of the comments above and to more accurately ensure that pharmacies are receiving the correct terms and conditions of participation, it is recommended that it be acceptable to have a pharmacy complete a general application with minimum credentialing requirements and that plan sponsors have ten business days to review the information provided in the application and provide the relevant terms and conditions to the pharmacy. This may help to avoid some of the issues that pharmacies have reported to CMS when seeking participation.

**14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes**

1. We would like to request that CMS allows for maintenance negative change requests for brand removal, generic substitution without a time constraint. This allows plan sponsors flexibility to perform the brand/generic offsets even when there is a timing issue with RXNORM mapping that is not apparent/visible to CMS. There are scenarios when a newly approved generic is mapped under an existing generic that was previously submitted to CMS due to RXNORM mapping and CMS has approved the formulary as such. For example, generic Glumetza was mapped to the same CMS CUI as generic Glucophage. In this specific example, the intent was to remove brand Glumetza, but was not able to because the generic Glucophage (i.e. metformin hcl) had been submitted to CMS and received formulary approval. Another recent example is timolol ophthalmic, a new generic for Istalol 0.5% ophthalmic solution being mapped under generic for Betimol 0.5% ophthalmic solution and Timoptic 0.5% ophthalmic solution. Clinically, Istalol 0.5% ophthalmic solution is given once daily, whereas Betimol 0.5% ophthalmic solution and Timoptic .5% ophthalmic solution are given twice daily. The generic CUI for Betimol and Timoptic 0.5% would have been submitted to CMS and received approval and we would not be able to remove brand CUI for Istalol 0.5% ophthalmic solution.

2. While it is clear that expedited substitution of certain generics in the proposed rule can be done immediately and notifications to members/providers/other entities are recommended to be provided retrospectively, but no later than by the end of the month after the changes are effective, it is not clear the requirement for prospective notification of 30 days "advance direct written notice" prior to the effective date. We are requesting for clarification from CMS to provide specific examples of "certain other midyear formulary changes," which are subjected to the 30 days prospective notification process and are NOT considered non-maintenance negative changes.

3. Does CMS anticipate the proposed changes to apply to other maintenance negative changes, as specified below?

a. Removal of a non-Part D drug inadvertently included on the formulary.

b. Addition of utilization management tools based upon a new FDA boxed warning.

c. Removal of a drug based upon a new FDA market withdrawal notice.

d. Removal of a drug based on long term shortage and market availability (described in chapter 5, section 50.13).

e. Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g., CDC’s recommendation against using older antivirals for treatment and prophylaxis of the flu).

f. The addition of utilization management when necessary to effectuate other approved formulary changes (e.g., prior authorization on a brand name drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to

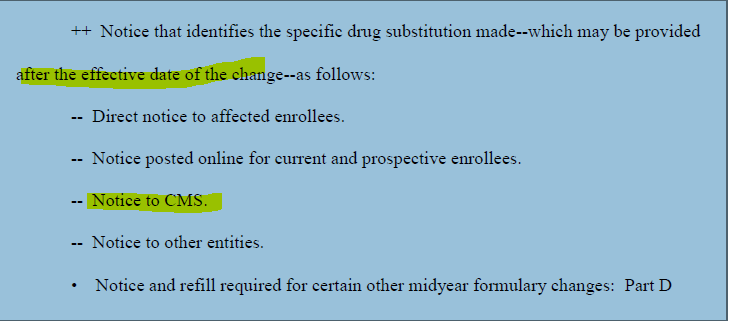
CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

4. The proposed changes do not address the timeframe/deadline for negative changes to be submitted to HPMS (i.e. the deadline to submit maintenance and non-maintenance negative changes is July 31st in HPMS). We interpret the proposed changes as there is no requirement to follow the July 31st deadline for generic substitutions since the last brand removal can be effective 12/01 and retrospective notifications are sent by 12/31. Assuming that CMS will reduce the 60 days advance notification requirement to 30 days for non-maintenance negative changes, does the July 31st deadline submission to HPMS still apply?

5. Based on the proposed changes for generic substitutions, plan sponsors can provide the notice to CMS retrospectively. Currently, the negative change requests (NCRs) have to be submitted through HPMS at least 60 days prior to the effective date and the Brand CUI Deletions have to be submitted at the submission cycle that aligns with the effective date of the negative change. We would like to get clarifications on the following:

1). Does CMS expect NCRs to be submitted through HPMS? If yes, when does CMS expect the NCRs to be submitted (i.e. within the same notification timeframe as the direct notice to affected enrollees, notice posted online for current and prospective enrollees, etc.)?

2). Will there be a change in HPMS upload validation process of the formulary flat files to allow for the brand removals? For example, generic drug X gets added to formulary on 2/15/18 and brand gets removed on 2/15/18 from the formulary. Generic drug X CUI will be submitted during March submission as an ADD while the Brand CUI will be submitted as a DELETION. Will the formulary file pass validation?



Can you please confirm that “direct notices of these generic substitutions no later than by the end of the month after which the change becomes effective” is the same time frame as the MEOB notice which states “Part D sponsors must ensure that enrollees who utilize their prescription drug benefits in a given month receive their Explanation of Benefits (EOB) by the end of the month following the month in which they utilized their prescription drug benefits”. By way of an example, if a brand generic offset was made in April, a plan would have until the end of May to notify a member.

**15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing**

When CMS says “biosimilar” do they mean *non-interchangeable* biosimilar?

**B. Improving the CMS Customer Experience**

**2. Reducing the Burden of the Compliance Program Training Requirements**

Although we agree that Plan Sponsors and FDRs have developed robust Compliance and FWA training, we are concerned that by removing the requirement for standard training, instead of reducing the burden, the lack of a standard will inadvertently increase the burden. CMS states that many sponsors are unwilling to accept completion of the CMS training as fulfillment of the training requirement and identify which critical positions within the FDR are subject to the training requirement. Since CMS specifically stated in HPMS memos that Plan Sponsors must accept the CMS training as fulfillment of the training requirement, it seems that it would be better to enforce that requirement, rather than leaving it up to the Plan Sponsors to determine what does or does not meet the training requirements. In this past year, NCPDP implemented an online form where pharmacies could indicate that they completed the CMS training, which greatly reduced the burden for both pharmacies and PBMs, as the pharmacy only had to attest once, rather than filling out an attestation for multiple PBMs and Plan Sponsors. PBMs can receive the data through a report from NCPDP, instead of tracking the information from individual pharmacies and chains. If the CMS Compliance and FWA training is no longer the standard, we will lose the efficiencies that were gained through our partnership with NCPDP.

**6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations**

CMS proposes to change the timeframe for issuing decisions on payment determinations for requests for payment from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request.

We support this change.

**10. Preclusion List – Part D Provisions**

**a. Background**

* Due to weak enrollment numbers, CMS proposes to rescind current rules – and not finalize the IFR – at §423.120(c)(6) that require prescribers to enroll or opt-out of Medicare to have a prescription be covered. CMS also proposes a new paragraph (c)(5) requiring PDE submission with an active NPI.

**Comments:**

We applaud & support CMS’ revised approach to move from an enrollment/opt-out model to a preclusion approach. We do however continue to have a number of questions and concerns that need to be addressed before we can move forward with updating our processes and systems.

We already require that all PDE records contain an active and valid NPI as a result of MACRA legislation.

**b. Effective Date**

* Proposed effective date of new paragraph (c)(5) is 60 days after rules published in final.
* Proposed effective date of new paragraph (c)(6) is January 1, 2019.

**Comments**:

From a PBM standpoint, given the continued complexity of these requirements, we require at a minimum 1 full year to modify our processes and systems once the requirements have been finalized by CMS, including CMS’ release of the final precluded file layout. Even with this modified guidance we continue to have an overwhelming amount of questions and concerns that will require ongoing & frequent collaboration with CMS and CPI.

Once the requirements have been finalized, the precluded file layout released and the majority of significant operational questions & concerns have been worked through with all industry partners, we require 1 year from that point to modify our processes/systems.

As a result of the above and assuming these matters are addressed by 6/1/18 at the latest, we would propose an effective date of 6/1/19.

**c.** **Prescriber NPI Validation on Part D Claims**

* Current § 423.120(c)(5) contains detailed rules on Part D sponsor submission of PDEs only with active and valid prescriber NPI.
* NPI submission and validation rules no longer effective since January 1, 2016 end date has passed.
* CMS believes that submission and validation rules are critical to new preclusion list and is mandated by MACRA and is proposing to re-implement most of them.
* Re-proposed provisions include requiring PBM to reject a Part D claim unless the claim contains NPI for prescriber.
* CMS specifically asks for comment on burden or unintended consequences and alternative approaches.

**Comments:**

MACRA legislation, which included the valid NPI requirement, was signed into law on April 16, 2015 and became effective January 1, 2016. As a result we, alongside other major PBMs, have been enforcing the active NPI requirement at the Point of Sale since 1/1/16, and are thus confused by these modifications and request for comments.

We will continue to enforce the active/valid NPI requirement and seek clarification from CMS regarding the intent of this modified guidance.

**d**. **Targeted Approach to Part D Prescribers**

* Focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers – including providers where enrollment was revoked, or could have been revoked
* Precedents for “risk-based” approach screening for providers and suppliers.
* Steps to be taken by CMS:
* Research internal and other systems for data;
* Review each revoked prescriber on case-by-case basis; and
* Review of both actual and potential prescribers.
* CMS seeks comment on an alternative by which it would identify, through PDE data, Part D prescribers.
* Concern over delays due to data lags
* Want to hear about potential risks to beneficiaries, especially in light of opioid epidemic

**Comments:**

We defer to CMS’s judgment regarding what types of behavior should warrant preclusion, though we would ask CMS/CPI NOT to duplicate exclusion efforts already administered via the OIG.

We agree that use of PDE data makes sense for identifying prescribers that should potentially be added to the preclusion file but defer to CMS/CPI and other industry partners regarding appropriate preclusion criteria.

**e.** **Compilation of Preclusion List**

* Based on results of provider search, CMS compiles preclusion list composed of (1) current revoked providers; and (2) providers that engaged in behavior that could have had them revoked (see reasons for preclusion in Appendix)
* CMS seeks comment on whether some of the basis for revocation (discussed below) should not apply to preclusion list and whether final rule should specify which basis are or are not applicable and under what circumstances.

**Comments:**

We **very strongly recommend** that CMS/CPI identifies a way to include precluded & excluded prescribers in a single file that is made available to the industry on a regular basis. It would make logical sense for CMS to regularly pull the exclusion (OIG) data into its system and then generate a single file containing all excluded & precluded prescribers for the industry’s use.

If CMS/CPI moves forward with a 2-file approach, the industry will require more detailed guidance to determine how this will impact areas like provisional fills, member letters and appeal rights, among others.

We do recommend that the final rule specifies the basis for inclusion on the preclusion list.

**f.** **Grounds for Prescribers Being on Preclusion List**

* Currently revoked from Medicare, under a reenrollment ban, and CMS determines underlying conduct detrimental to best interests of Medicare program. Factors CMS would consider:
  + Seriousness of prescriber’s conduct;
  + Degree to which conduct could affect integrity of Part D; and
  + Any other evidence CMS deems relevant.
* CMS again references the opioid crisis and how including problematic prescribers on preclusion list might help.
* CMS seeks comment on whether actions in §424.535(a) are appropriate basis from preclusion, what else should be included, what should be excluded, and how should CMS monitor abuses regarding prescribing practices.

**Comments:**

We are most concerned in cases where the prescriber’s medical license has been revoked and recommend this serve as a basis for inclusion on the preclusion list. We defer to CMS’s judgment regarding what other behavior should warrant preclusion, though we would ask CMS NOT to duplicate exclusion efforts already administered via the OIG.

We strongly recommend that no matter the inclusion reason that the prescriber has access to a timely appeal process (excluding prescribers with an active OIG exclusion). In addition, CMS should notify prescribers in writing upon an addition to or removal from the preclusion list.

We do not recommend any opioid-specific criteria for inclusion on the list. The end result (suspension/termination of medical and/or DEA license) should serve as the inclusion criteria.

**g.** **Updates to Preclusion List**

* Preclusion list would be updated monthly by CMS based on internal data.
* PBMs would not be required to retroactively reject claims based on the effective date of the revocation.
* CMS seeks comments on reasonable time for PBMs to incorporate the preclusion list into their claims adjudication system.

**Comments:**

Monthly is an insufficient update interval. The data should be updated weekly, ideally, but no less frequently than bi-monthly. This is important for the following reasons:

* Upon removal/resolution of the prescriber’s preclusion the industry needs to be able to begin paying the claims ASAP in order to prevent beneficiary access issues. Even if NCPDP creates a new override mechanism to account for data delays, most pharmacies won’t be willing to override the rejection for fear of audit risk and/or payment recoupment. We must not create a situation where claims are rejecting for up to a month for prescribers whose preclusions have been resolved.
* The same is true for newly precluded prescribers. If an event occurs that warrants that the prescriber be precluded, we don’t want to risk paying claims for these prescribers for up to a full month, particularly if the prescriber’s behavior puts beneficiaries at risk.

We agree with and appreciate CMS’ approach to not require PBMs to retroactively reject claims.

A reasonable timeframe for incorporating the preclusion list into our claims adjudication system would be within 4 business days of the file’s posting.

**h**. **Provisional Coverage**

* CMS proposes to maintain the provisional coverage requirement with adjudication.
* CMS is proposing to change to a 90-day provisional coverage instead of the current three-month/90-day time period drug supply. In other words, a PBM need only track a single 90 day period from the date a drug is first dispensed pursuant to a prescription written by an individual on the preclusion list.
* CMS seeks comment on modification and time period, including any specific rules for opioids
* Not proposing any change to transition policy except that transition would not apply during the provisional fill period.

**Comments:**

If the prescriber is found on both the Precluded & Excluded (OIG) list, CMS needs to clarify whether or not the 90-day provisional period is still applicable. Related to this:

* If the provisional period is not applicable in this scenario, does the beneficiary need to be notified why the provisional period is not applicable?
* If the provisional period IS applicable in this scenario, CMS will need to clarify whether or not it will be necessary to send the Excluded Provider letter (an existing Part D Model letter) to the beneficiary in addition to a provisional fill letter.

We agree with and fully support CMS’ adoption of a 90-day provisional period per distinct beneficiary/precluded prescriber combination.

We are concerned regarding the language “…and if allowed by applicable law..” with regard to provisional fills, as this implies a requirement to validate state-by-state prescriptive authority at the Point of Sale. The previous technical guidance issued made it clear that this was not a Point of Sale requirement and would ask that CMS confirm whether or not this is still true.

We do not have any opioid-specific recommendations with regard to the provisional period. This should be handled by all existing opioid management processes.

We do not understand the comment regarding transition not applying during a provisional period and require more detail. The beneficiary’s access to drugs via transition cannot be disrupted because a provisional period has begun. There is no way to avoid overlap between provisional and transition periods, thus CMS will need to answer the industry’s open questions regarding the interaction between transition and provisional coverage.

1. **Opioid Specific Issues**

* CMS also considering other solutions when the script from the precluded prescriber is for opioids.
* CMS seeks comments on limits that CMS should set up regarding number of doses, initial dosing, and type of product for particular clinical presentations.

CMS is considering requiring sponsors to immediately transfer the beneficiary to a new provider when the prescriber is on the preclusion list.

**Comments:**

We do not have any opioid-specific recommendations with regard to the provisional period. The PBM can temporarily override the preclusion to allow for a provisional fill while still enforcing all approved Utilization Management edits on the opioid. This should be handled by all existing opioid management processes.

Stand-alone Prescription Drug Plans (PDPs) and PBMs have no contractual relationship with network prescribers. Only an MAPD with a contracted provider network could manage a requirement to transfer the beneficiary to a new provider upon preclusion. We suggest instead that this can be managed through the provisional fill notification to the beneficiary whereby the beneficiary is instructed that coverage will not continue after the 90-day provisional period ends. In addition, MAPDs should be instructed to remove precluded prescribers from their provider network.

**j.** **Appeals**

* Prescribers on the preclusion list may appeal their inclusion.
* Beneficiary would have right to appeal alleged errors in applying the preclusion list.

**Comments:**

To keep the preclusion & exclusion (OIG) processes aligned, we **strongly recommend** that CMS not allow beneficiaries to appeal a prescriber preclusion. CMS should either allow or disallow beneficiary appeals in BOTH instances for consistency and to prevent beneficiary confusion, as they will not understand the difference between an exclusion versus a preclusion.

IF CMS allows beneficiaries to appeal a preclusion only, CMS must confirm whether or not the Point of Sale appeal notice (NCPDP Reject Code ‘569’) requirement applies.