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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Washington, DC 20201

RE: CMS-2017-0163 (Draft CY 2019 Call Letter)

Centers for Medicare & Medicaid Services:

PerformRx is a pharmacy benefit manager (PBM) for Medicare Advantage Prescription Drug Plans (MAPDs) and Medicare-Medicaid Plans (MMPs) nationwide. Thank you for this opportunity to comment on CMS' draft 2019 Call Letter.

We would like to express our appreciation for CMS' partnership in administration of the Part D program on behalf of Medicare beneficiaries.

Please see our attached comments. Thank you for your consideration.

Sincerely,

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Section I – Parts C and D			
Enhancements to the 2019 Star Ratings and Future Measurement Concepts			
Enhancements to the 2019 Star Ratings and Future Measurement Concepts	106	After the 2019 Call Letter is finalized, CMS' current Part C & D Star Ratings contractor, RAND Corporation, will establish a Technical Expert Panel (TEP) in 2018 comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures. The TEP may also provide suggestions regarding the data integrity review process and how the Star Ratings should relate to audits and enforcement actions. RAND will analyze the suggestions from the TEP to provide feedback to CMS on potential future enhancements.	PerformRx supports CMS' decision to establish a TEP. We ask CMS to please include PerformRx as a part of the TEP.
New Measures for 2019 Star Ratings	107	For the 2017 measurement year, CMS proposes to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs to use along with the EDB ESRD indicator that is currently used. We propose to add the SUPD measure to the 2019 Star Ratings (based on 2017 data) with a weight of 1 for the first year. In subsequent years, we propose a weight of 3 as an intermediate outcome measure, as prescription fills are a proxy for patients taking their prescribed medications, and adherence is necessary to reach clinical/therapeutic goals.	PerformRx supports the decision to exclude ESRD members for these measures.
Changes to Measures for 2019 Medication Adherence (ADH) for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications (Part D).	109	For the 2017 measurement year, CMS proposes to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes found in both Part A & B claims and Risk Adjustment Processing System (RAPS) RxHCCs along with the EDB ESRD indicator (currently used).	PerformRx supports CMS' proposal to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from the measures to include ICD-10-CM codes.
Changes to Measures for 2019 MPF Price Accuracy (Part D)	110 – 111	We propose the following changes (please see Appendix 1 for a more detailed methodology): 1. Factor both how much and how often prescription drug event (PDE) prices exceeded the prices reflected on the MPF by calculating a contract's measure score as the mean of the contract's Price Accuracy and Claim Percentage scores, based on the below indexes: o The Price Accuracy index compares point-of-sale PDE prices to plan-reported MPF prices and determines the magnitude of differences found. Using each PDE's date of service, the price displayed on MPF is compared to the PDE price. The Price Accuracy index is computed as: (Total amount that PDE is higher than MPF + Total PDE cost) / (Total PDE cost). o The Claim Percentage index measures the percentage of all PDEs that meet the inclusion criteria with a total PDE cost higher than total MPF cost to determine the frequency of differences found. The Claim Percentage index is computed as: (Total number of claims where PDE is higher than MPF) / (Total number of claims) o The best possible Price Accuracy index is 1 and the best possible Claim Percentage index is 0. This indicates that a plan did not have PDE prices greater than MPF prices. o A contract's measure score is computed as: - Price Accuracy Score = 100 – ((Price Accuracy Index - 1) x 100) - Claim Percentage Score = (1 – Claim Percentage Index) x 100 - Measure Score = (0.5 x Price Accuracy Score) + (0.5 x Claim Percentage Score) 2. Increase the claims included in the measure: o Expand the days' supply of claims included from 30 days to 28-34, 60-62, or 90-100 days. O Identify additional retail claims using the PDE-reported Pharmacy Service Type code. Claims for pharmacies that are listed as retail in the MPF Pharmacy Cost file and also have a pharmacy	PerformRx supports CMS making this modified measure as a display measure for 2020 and 2021. We also support CMS adding this as a measure for the 2022 Star Ratings. PerformRx would need to see the impact on the score based on current methodology, and we do not wish to commit before seeing that. We also would need time to build the methodology.

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		service type on the PDE of either Community/Retail or Managed Care Organization (MCO) will be included.	
Changes to Measures for 2019 MPF Price Accuracy (Part D)	111	…[W]e propose to first publish the modified measure as a display measure for 2020 and 2021; we intend to then consider adding this measure for the 2022 Star Ratings.	PerformRx supports CMS making this a display measure.
Removal of Measures from Star Ratings Beneficiary Access and Performance Problems (BAPP) (Part C & D)	112	For the 2019 Star Ratings, CMS proposes to retire the current BAPP measure. We propose to modify the BAPP measure to only include Compliance Activity Module (CAM) data. The revised BAPP measure would be on the display page for the 2019 Star Ratings. We solicit stakeholders' input on the utility of this measure focused only on notices of non-compliance, warning letters, and ad-hoc corrective action plans and their severity.	PerformRx supports this change, as it is a better option for sponsors. We appreciate that CMS has considered prior feedback.
Data Integrity	113 - 114	We propose to define a contract as being non-compliant if it either receives a "No" or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation.	Data validation depends on data supplied by multiple parties, such as the plan and PBM. In addition, PBMs are not supplied with the data validation score. CMS should ensure that if there are multiple vendors and plans, positive and negative performances are isolated to the particular plan or vendor. Well-performing plans and vendors should not be penalized.
Proposed Scaled Reductions for Appeals IRE Data Completeness Issues	114 - 116	CMS is proposing statistical criteria to reduce a contract's Star Rating for data that are not complete or lack integrity using TMP data or audit. The reduction would be applied to the measure-level Star Rating for the applicable appeals measures… The methodology would employ scaled reductions (one-star, two-star, three-star, or four-star reduction) based on the degree of missing IRE data. Contracts with the highest IRE data quality issues (i.e., largest percentage of missing or compromised data) would receive the largest reductions, while contracts with a lower degree of missing IRE data would receive a smaller reduction. The most severe reduction for IRE data completeness issues would be a four-star reduction, thus resulting in a measure-level Star Ratings of one star for the associated appeals measures. If a contract receives a reduction due to missing Part C IRE data, the reduction would be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction would be applied to both of the contract's Part D appeals measures. Further, we propose to use multiple data sources whenever possible to determine whether the IRE data are complete and if not, the severity of the missingness and/or data issues. CMS' proposed scaled reduction methodology would be a three-stage process using the TMP data or audit for the means to determine: first, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, as the basis for the determination of the estimated error rate; and finally, whether the estimated value is statistically greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars. Once the scaled reduction for a contract is identified using the methodology, the reduction would be applied to the contract's associated appeals measure-level Star Ratings. Since the minimum measure-level Star Rating is one star, if the difference between the associated appeals measure-level Star Rating (before the application of the reduction) and the identified scaled reduction is less than one, the contract would receive a measure-level Star Rating of one star for the appeals measure. The error rate for the Part C and Part D appeals measures - using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period - would be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate is proposed to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP or audit data is dependent on the enrollment size of the contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and	PerformRx supports CMS' efforts to ensure data integrity in this measure. However, PerformRx is opposed to codifying the TMP as one of the data sources. First, TMP is one of five CMS monitoring events conducted across all or nearly all Part D sponsors (Transition Monitoring Program Analysis, Formulary Administration Analysis, PDE Data Validation). We sincerely appreciate CMS' willingness to stagger the timing of the TMP audit to decrease the burden on FDRs with multiple Part D plan sponsor clients. However, our experience with TMP is one that we would wish not to have to budget for and manage annually. The TMP auditor essentially holds the plan sponsors, and their FDRs, to a short timeframe similar to the Part D Program Audit. Yet the results were not shared with plan sponsors until December, nine months later. This is a similar habit that PerformRx has observed with the other CMS monitoring events. If CMS choses to continue the TMP process, would it please hold the auditor accountable for providing at least a draft audit report within 30 business days? Similarly, if CMS intends to finalize the rule and codify the TMP process, would CMS introduce an appeal process for Part D sponsors to have an opportunity to review the draft audit report? CMS provides a limited plan preview window in advance of releasing the annual report card. PerformRx believes it fair to provide the draft report and final report to plan sponsors at least 30 days before the first plan preview period. The timing of the TMP is also exceptionally burdensome. TMP occurs at the same time that the very departments being tested are trying to complete the Part D reporting process and respond to the Part D data validation audits. All three efforts are evaluating the same coverage determination and redetermination data. PerformRx recommends this as another opportunity to apply the requirements of Executive Order 13771 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs. We believe our solution would fulfill the star ratings integrity goal, be operationally less burdensome for plan sponsors /FDRs, and also save CMS and the Part D program the amount it paid for the TMP audit in 2017. Specifically, PerformRx recommends that CMS eliminate the TMP audit. In its place, CMS should modify the Part D Reporting Requirements and Technical Specifications for the Coverage Determination and Redetermination reports. Currently, CMS collects a summary report for these requirements. PerformRx recommends that CMS instruct the Part D sponsors to report this data in a detail file layout, similar to what CMS collects for the MTM report. Further, we recommend that CMS adopt the Part D Program Audit CDAG file layout for the universe with the highest number of fields (ECDER). We recommend that, instead of quarterly sub-reports, CMS instruct plan sponsors to report in the aggregate for the entire contract year. Given CMS' significant data analysis capabilities, parsing out the information by quarter can be done independent of the plan sponsor. The plans already have to pay an independent data validation auditor to confirm the accuracy and

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		larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria proposed.	completeness of the reporting process. This includes sampling a subset of cases to confirm that the data reported is consistent with the adjudication of the coverage determination or redetermination. The data validation auditors provide their reports directly to CMS. CMS has already proposed to use the data validation results in section 423.186(a)(2)(ii). CMS could choose to align the data validation audit instructions and methodology so that the independent auditors also cover the activities undertaken in the TMP. Our experience is that the process is almost identical where coverage determination and redetermination timeliness is concerned. This approach would cover the validation of the Appeals Auto-forward measure compared to the IRE data. CMS could also use the information to confirm the accuracy of the IRE's reporting of the Appeals Upheld measure as well. Aligning the reporting requirement to the universe also provides CMS with ample opportunity to conduct data analysis that it could use to arrive at the summary information it currently asks the plan sponsors to calculate. CMS could still chose to monitor a subset of Part D case files but would not need to burden the plan or itself with the arduous tasks of validating the universes. CMS may also choose to use that report/universe in its Part D Program Audit activities. The universe process is arguably the most difficult for CMS and the sponsors. The data validation process could be reasonably expected to improve sponsors' ability to produce accurate universes for the Part D program audits, as every Part D sponsor is subject to the requirement. For the sponsors and FDRs, this approach would significantly reduce the burden associated with simultaneous production of the Part D reports, the TMP universes/case files, and data validation materials. It would decrease the number of meetings, calls, webinars, and emails. It would give sponsors and their PBMs an opportunity to put the maximum effort into producing accurate and complete data for the benefit of the star ratings, Part D reporting, and the Program Audit process. While this approach would not eliminate two existing regulations, it would greatly decrease the operational burden and costs associated with meeting existing and duplicative requirements and prevent the need for a third. This is consistent with the spirit of the executive order. PerformRx would welcome the opportunity to partner with CMS to pilot this approach.
2019 Star Ratings Program and the Categorical Adjustment Index	123	We continue to engage the NCQA and PQA to review and determine if any measures are sensitive to the composition of the enrollees in a plan and whether case-mix adjustment of individual measures would be appropriate… The PQA has indicated that these draft recommendations will be included in the 2018 PQA Measure Manual, and will be finalized in 2019 once PQA completes the NQF measure endorsement maintenance of the three measures (NQF Endorsed # 0541). If finalized, CMS will consider how to implement the PQA recommendations in the future for these Star Ratings measures.	The NQF Foundation, PQA, and NCQA will develop recommendations for each measure. PerformRx would support PQA's recommendations.
2019 Star Ratings Program and the Categorical Adjustment Index	125	For the 2019 Star Ratings Program, CMS is proposing to continue the use of the interim analytical adjustment, the CAI. The overall methodology would remain unchanged for 2019.	PerformRx primarily serves the underserved. We support this proposal.
Disaster Implications Identification of Affected Contracts	133 – 135	We are proposing a policy to identify MA and Part D contracts affected by extreme and uncontrollable circumstances that may impact their performance on Star Ratings measures and/or may impact their ability to collect the necessary measure-level data. These "affected contracts" would be the contracts eligible for the adjustments proposed below to take into account the effects of the extreme and uncontrollable circumstances…	PerformRx supports these proposals. Accounting for disaster events would provide equity for affected sponsors. We appreciate CMS' efforts to work with these plans. PerformRx supports the proposal that the organization affected at the time of the disaster would receive the highest of the 2018 or adjusted 2019 star ratings.
2019 CMS Display Measures Changes to Existing Display Measures High Risk Medication (Part D)	140 – 141	This measure would remain on the display page for 2019 (based on 2017 data), and as no he 2018 ted in Call Letter, we propose to use the updated PQA HRM drug list for that display. We also propose to adopt a specification change made by the PQA to measure specifications for the numerator (beneficiaries with at least two fills of the same HRM drug on different dates of service) for the 2019 display measure.	Will CMS use display measures to bell curve the scores that sponsors can benchmark themselves? PerformRx recommends that CMS provide more guidance for display measures.
2019 CMS Display Measures	141	As discussed in the 2018 Call Letter, the PQA updated the DDI measure drug list. We propose	PQA updated the drug list using 2017 data. PerformRx supports CMS updating the standards based

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Changes to Existing Display Measures Drug-Drug Interactions (DDI) (Part D)		to implement the revised list for the 2019 display measure using 2017 performance and PDE data.	on PQA. PerformRx recommends that CMS provide more guidance for display measures.
		Enforcement Actions for Provider Directories	
Enforcement Actions for Provider Directories	165	Regarding inaccurate provider directories, Civil Money Penalties and other enforcement actions may be imposed against Medicare Advantage Organizations that have received a compliance notice or notices for violations that have gone uncorrected. CMS also has the discretion to take enforcement actions when egregious instances of non-compliance are discovered. Penalty amounts would initially be calculated on a per determination basis.	PerformRx disagrees with the use of Civil Money Penalties (CMPs) as a way to enforce noncompliance with Provider Directories, as pharmacies change daily through closures, openings, daily switching of group/chains, change of business hours, etc. Instead, we believe CMS should request that pharmacies update their Pharmacies Directories weekly, if not monthly, to rectify any directory issues.
Section III – Part D			
Expanding the Part D OTC Program			
Expanding the Part D OTC Program	196 – 197	…CMS is contemplating allowing additional flexibilities for Part D plan sponsors to offer access to OTCs. For example, CMS could consider allowing sponsors to include additional OTC products such as dietary supplements and cough medicines, without the requirement that the OTC product offset the use of a Part D drug… We are thus soliciting feedback from stakeholders on Part D OTC enhancements that could be considered for future policy. This feedback could include information on how well the current program is working, the deficiencies of the current program, what additional flexibilities would be helpful, and what the impact would be on spending, particulary premiums, as a result.	Currently, only Medicare-Medicaid Plans (MMPs) and Programs of All-Inclusive Care for the Elderly (PACE) allow for OTC coverage. This proposal could drastically change current plan benefits. PerformRx is concerned that this proposal, if implemented, would cause confusion for the beneficiary if they receive an NOI or denial for one OTC product stating the class is excluded from Part D coverage if another OTC product is formulary and is covered. PerformRx recommends that CMS clarify whether dietary supplements and cough medicines that are not added to the formulary would still be statutorily excluded drugs. And, would the OTC drugs that are covered still be considered excluded Part D drugs? PerformRx believes that CMS would need to revise Chapter 6 of the Medicare Prescription Drug Benefit Manual to build in exception language for these OTC products. We also believe that Chapter 18 and the statute would need revision to reflect these changes. Further, the proposal does not explain how the formulary would need to be submitted. Would these products need to be submitted on the supplemental file? Would this also apply to Medicare-Medicaid Plans (MMPs)?
Improving Drug Utilization Review Controls in Medicare Part D			
Retrospective DUR OMS Metrics	205	Beginning with the 2018 OMS reports, we propose to change the Opioid Daily Dose measurement period from 12 months to 6 months to align with the revised OMS criteria measurement period. In addition, we propose to report a second Opioid Daily Dose rate with a 90 MME threshold to further align with the revised 2018 OMS criteria. Therefore, in the April 2018 OMS reports, CMS will report: • 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during the last 6 months. • 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 6 months. We propose to discontinue reporting the 120 MME Opioid Daily Dose rate in the 2019 OMS reports.	PerformRx agrees with this proposal because it is more consistent with the patient safety measures.
Retrospective DUR Opioid Potentiator Drugs	206	CMS is concerned that the increase in gabapentin use and higher doses among opioid users may place beneficiaries at a higher risk for adverse events. These safety concerns extend to pregabalin, which is also a gapapentinoid. We propose to add a concurrent opioid-gabapentin/pregabalin flag to OMS. We are requesting feedback from stakeholders about what their experience has been with the potential overuse of gabapentin and pregabalin with opioids, whether this additional flag would be useful for Part D sponsors, and how the case management approach could help with gabapentin/pregabalin-opioid misuse and also with	PerformRx recommends that CMS clarify whether the flag would show up on the OMS file. Would the sponsor need to respond, or does CMS intend the flag to be informational only?

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		other potentiators.	
Retrospective DUR Opioid Potentiator Drugs	206 – 207	As with concurrent benzodiazepine and opioid use, we expect that when sponsors perform case management, they would include the use of other drugs (e.g., gabapentin and pregabalin) that can potentiate the risk of overdose within the case management.	PerformRx supports this proposal. We already include the use of other drugs in our case management.
Retrospective DUR Patient Safety Reporting	207	Sponsors may use the reports to supplement their DUR programs to address overutilization of opioids across a population broader than OMS. CMS expects sponsors to routinely monitor these data to compare their performance to overall averages and assess their progress in reducing the number of beneficiaries using high doses of opioids, with or without multiple providers and pharmacies.	PerformRx supports this proposal. We already supplement our DUR programs across a broader population. We submit monthly during the OMS file submission.
Concurrent DUR Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users	210	…[W]e propose that sponsors should implement these edits in 2019 to allow beneficiaries to receive a 7 days supply of the prescription that triggered the hard edit as written. This would provide a short term supply to patients to allow time to pursue coverage through the exceptions process. However, if the exception request is approved, the patient may need to obtain a new prescription from their prescriber for amounts beyond the 7 days supply. Alternatively, the patient could elect not to receive the partial 7 days supply fill (e.g., they are not out of the medication) and go through the exceptions process. In that case, if approved, the original prescription could be filled. Also, in the case of opioid prescriptions that trigger the 90 MME hard edit where the packaging is only available in a days supply greater than 7 days, we would not expect any supply to be provided. The beneficiary would need to obtain an approved exception in order to get the medication. Nonetheless, we are not aware of any State laws or labeling that would prohibit prescription opioids from being dispensed in a smaller quantity.	PerformRx has concerns about this proposal with respect to existing guidance, effects on beneficiaries' access to drugs, and operationalization, as follows. PerformRx first recommends that CMS determine whether Chapter 18 of the Medicare Prescription Drug Benefit Manual already addresses these cases. We believe that Chapter 18 already does. PerformRx has the following concerns and recommendations. • Is this proposal for new or old starts? Could CMS please clarify whether this proposal would be limited to chronic users or to naïve users? • Could CMS please clarify what type of exception would be sought? This proposal pertains to days supply, not quantity limit (QL). Or, is the beneficiary seeking another type of exception? • Could CMS please clarify which letter should be provided to the beneficiary who does not get a days supply beyond 7 days? • Does "days supply allowance" refer to the section on page 210 to allow members already exceeding 90 MME per day of opioids to receive a 7 days supply of a prescription that triggered the hard edit as written? • Could CMS please clarify whether members already on higher doses of opioids will have an MME limit implemented with no days supply limit? • PerformRx is concerned that the refill too soon known exception ("reasonable overlapping dispensing dates for prescription refills") would not be followed under this proposal. • PerformRx believes that this proposal would affect LTC beneficiaries' access and operationalization. LTC facilities use distinct, specific codes and days' supply. • If the packaging exceeds 7 days, it would appear risky not to provide the medication at all, especially if it is for pain. Having the pharmacist choose which prescription to fill if there are multiple prescriptions does not seem to be the best approach. PerformRx is concerned that putting the burden of determining which medication to fill on the member and the dispensing pharmacist would cause confusion and may have liability implications for the dispensing pharmacist. • How would this proposal work with level of care (LOC) changes? A beneficiary returning to home, LTC, or hospice from the hospital or other facility (cancer, LTC) will not be able to take their medication with them. This proposal could impede medication access. Would refill too soon be overridden in these circumstances of LOC changes? This proposal would present overrides, coding, and criteria challenges.

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			• How would this proposal work under transition? PerformRx recommends that these drugs be excluded from transition logic because otherwise they would not follow this 7 days supply policy. • PerformRx recommends allowing a 7 days supply **per medication**. Only allowing one medication in the member's established opioid regimen would risk unintended consequences and withdrawal. If the member only receives a 7 days supply of the short acting (SA) medication in their regimen (and not their long acting [LA] opioid), this may promote misuse/abuse in the interim. In addition, as stated above, PerformRx is concerned that putting the burden of determining which medication to fill on the member and the dispensing pharmacist would cause confusion and may have liability implications for the dispensing pharmacist. • PerformRx recommends that CMS outline a formal process. Where would the election be documented when the beneficiary elects the drug? Where will pharmacy track this information?
Concurrent DUR Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users	211	We generally expect coverage determination requests seeking exceptions to the MME edit to meet the criteria for expedited review, which means that the plan sponsor must issue a decision within 24 hours of receipt of the prescriber's supporting statement (attestation).	PerformRx notes the use of "generally." PerformRx believes that "generally" does not mean "all." Could CMS please define "generally"? Defining "generally" would allow for better operationalization and would be important for audit purposes. Further, PerformRx recommends that CMS clarify whether *all* coverage determination requests must be handled as urgent *even if* the prescriber or beneficiary specifically request standard review. Shortening the review timeframe may not be favorable to the beneficiary if it is not aligned with the way the request was submitted. Extra time can be needed to get the supporting statement, which is in the beneficiary's interest.
Concurrent DUR Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users	211	Consistent with current guidance, if the only issue in dispute is the MME, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested.	In the CY 2018 Call Letter, CMS stated: "Thus, if the only issue in dispute is the MED, CMS expects the Part D sponsor to only rely on prescriber attestation that the higher MED is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested, **and to not require additional clinical criteria** [emphasis added]." PerformRx recommends that CMS clarify whether additional criteria specific to the MME edit can be submitted and approved by CMS. Can plan sponsors still have quantity limits (QLs) on formulary opioids? Can there be prior authorization (PA) criteria for specific opioid medications? Can a sponsor have an MME limit, days supply limit, and a QL on the drug?
Concurrent DUR Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users	211	The authorization of the higher MME level should be considered an approved exception and be valid through the remainder of the plan year.	PerformRx recommends that CMS clarify the following for sponsors. • What should the coverage determination type be for an approval or denial for only the MME? • How should this coordinate with other utilization management (UM) restrictions such as PA, QL exception, non-formulary (NF) exception? • If the requested drug also has PA criteria, but an exception is not specifically requested upon submission of the coverage determination, 1) what coverage determination type should be chosen, and 2) would the tolling timeframes apply? Other edits may be involved. Could CMS please clarify whether there is a ceiling once the MME is approved? PerformRx would recommend that CMS expand Chapter 18 if a sponsor is to apply coverage determinations in this manner because the beneficiary may also challenge other criteria.
Concurrent DUR Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety	211	The exception should apply to the cumulative MME level for the beneficiary, not just one specific drug, or one prescriber.	If provider attestation is received and the beneficiary receives an approval for an exception to the MME, can the MME limit be lifted entirely **without** a ceiling on what dose can be prescribed until the end of the contract year? If not, how should the authorization be entered to account for a dose change or change in medication?

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Edits for High, Chronic Prescription Opioid Users			
Concurrent DUR Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid Users	211 – 212	It is integral that sponsors have the ability to efficiently process associated exceptions and appeals, including expedited requests…Plans are not permitted to instruct an enrollee who is requesting coverage that only their prescriber can initiate the request.	PerformRx recommends that CMS clarify for sponsors all of the limits associated with MME that a claims processor and coverage determination would address. This would include MME, QL, and other limits.
Concurrent DUR Days Supply Limits for Opioid Naïve Patients	212 – 213	We expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain.	Page 204 states: Implementing a days supply limit for initial fills of prescription opioids (e.g., 7 days) for the treatment of acute pain with or without a daily dose maximum (e.g., 50 MME per day). PerformRx recommends that CMS define "initial fill." Is this intended to correlate with the section referring to opioid naïve members on page 212? If yes, CMS recommends that CMS define "naïve." How are naïve members identified? If a coverage determination request is submitted to exceed the days supply limit: • What criteria would be applied for approval/denial? • What would be the appropriate coverage determination type? • What would be the appropriate approval duration? PerformRx is concerned that sponsors cannot determine at POS if the drug is for acute pain because they do not have access to the diagnosis at POS. PerformRx recommends that CMS address exceptions for opioid naïve if in hospice, LTC, or a disease state. What is the expectation for these new members? If the drug is covered under A, does the member get the 7 days supply, and if there is a coverage determination, does Part D cover it? Could CMS clarify whether the days supply is 7 days for a new medication? If the member switches to a new medication, is that another new fill, or would this policy apply across the class of drugs? Further, PerformRx is concerned about significant resources needed to change claims processing logic if a new 7 days supply is not allowed.
Concurrent DUR Days Supply Limits for Opioid Naïve Patients	213	We request feedback from stakeholders, especially Part D sponsors, providers, and PBMs, on the implementation of a days supply limitation at 7 days or if an alternative days supply limit would be more appropriate (such as 3 days or 5 days), including their experience with such limitations or the basis for their recommendations.	PerformRx is concerned that the 7 days supply would not be appropriate for all members. It is difficult to operationalize days supply limits. Not all conditions fit into 7 days. We have received feedback from providers that certain acute regimens would be appropriate to exceed 7 days, specifically for acute trauma/post-op pain. Titration is also used by prescribers, not just a 7 days supply. Clinically, 7 days would often be the minimum for many beneficiaries. Thus, titration may be a better option, and PerformRx also recommends that CMS account for various conditions, such as post hospitalization. PerformRx is concerned that the volume of coding for exceptions and coverage determinations would be significant. This would result in significant organizational capacity concerns. PerformRx recommends that CMS hold conversations with and issue guidance for the prescribers. CMS should focus upstream. Further, state-level sanctions and Part D sanctions for OIG directly can now be raised. State-level lists are updated much more frequently than OIG lists. PerformRx recommends that CMS partner with OIG to assure timely release of information to sponsors.
Concurrent DUR Days Supply Limits for Opioid Naïve	213	We also solicit comment on whether a days supply limit with or without a daily dose maximum (e.g., 50 MME per day) would be more effective. In particular, we request information on both inclusions and exceptions for specific clinical situations (i.e., whether and to what extent a	PerformRx recommends that the MME be set at 90 MME to coincide with the MME edit for all other members. We also recommend that disease states be addressed.

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Patients		supply limit could be based on specific indications or other criteria) and other parameters and what safeguards should be in place to protect appropriate beneficiary access.	
Concurrent DUR Opioid Duplicative Therapy Safety Edits	215	…[W]e expect all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion. When such an edit is triggered for concurrent use of opioids and buprenorphine, the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims… We are requesting feedback from stakeholders, especially Part D sponsors and PBMs, on the proposed expectation that sponsors to implement a soft duplicative LA opioid therapy POS edit (e.g., current experience in implementing such edits or concerns with the complexity or capacity to be able to implement for 2019) and recommendations on the most effective edit specifications (e.g., the specifications used in CMS's analysis or other specifications).	PerformRx has several concerns and questions regarding this proposal, as follows. • No plans have duplicative edit criteria that can be cited. If a coverage determination request is submitted as a result of these edits, what criteria would be applied for approval/denial? • If a coverage determination request is submitted as a result of the MME edit, but this edit would also return, should it be addressed as part of the coverage determination process? • Could CMS also please clarify whether the authorization would apply to both the hard edit and soft edit? • Finally, it is difficult for sponsors to operationalize overriding a buprenorphine edit. So, it is likely that sponsors would not add buprenorphine to the edit.
Concurrent DUR Opioid Duplicative Therapy Safety Edits	215	We also recognize that multiple opioid POS edits could potentially generate a combination of messages and soft or hard rejects that may cause confusion. Therefore, we recommend that contracts create a hierarchy for the opioid POS edit messaging in an effort to reduce confusion… We also seek feedback on how best to manage multiple opioid POS edits that a single prescription may trigger, for instance, a duplicative therapy and cumulative MME POS edit.	There are potentially up to 6 errors that could return: QL, PA, MME limit, days supply limit, duplicate LA opioid, and concurrent use of benzodiazepines. This can cause confusion at POS in determining what is actually required for the drug to be covered. PerformRx urges CMS to provide recommendations regarding the POS edit hierarchy so that there will be consistency across PBMs and to limit confusion at POS. Could CMS please inform sponsors in the final Call Letter of the edits that it wants sponsors to apply at POS and in what order? We believe that this clarity is critical.
Concurrent DUR Opioid Duplicative Therapy Safety Edits	215	In addition, we request feedback on extending the specifications in the future to include SA opioids and defining duplicative therapy as previously described for LA opioids (i.e., generic entity, dosage form, strength and/or differing prescribers) or another unique drug classification scheme (e.g., removing strength). We will delay specifying the parameters for the duplicate SA opioid POS edit until additional testing can be completed and we have a better idea of the feasibility and operational considerations for such edits.	PerformRx urges CMS that, before implementing this proposal for SA opioids, CMS first assess the challenges and outcomes of its LA opioids proposal. This would include, for example, a "lessons learned." PerformRx also recommends that CMS focus on hospitals' practices, to address the use of SA opioids. How many hospitals are prescribing SA opioids? We are concerned that hospitals prescribe and dispense a significant amount of SA opioids. If CMS proceeds with this proposal, PerformRx recommends that CMS provide clearly-defined expectations. Would sponsors need to handle the SA edit in a different way than the LA edit? SA opioids have different days supply and MME limits. PerformRx believes that one inclusive edit for LA and SA opioids will not work consistently.
Concurrent DUR Concurrent Use of Opioids and Benzodiazepines	216	We propose that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit. We are requesting feedback from stakeholders, especially Part D sponsors and PBMs, on their experience with concurrent or duplicative soft POS edits including an opioid and benzodiazepine and other drug combinations.	Could CMS please clarify that if a coverage determination request is submitted as a result of these edits, what criteria would be applied for approval/denial? Further, if a coverage determination request is submitted as a result of the MME edit, but this edit would also return, should it be addressed as part of the coverage determination process?
Timely Updates to LIS Status Based on Best Available Evidence			
Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs Immunosuppressants Used to Prevent Transplant Rejection	218 – 220	In all cases Part D sponsors should document the basis for their determinations to cover immunosuppressants and make such documentation available upon audit. <u>1. No Prior Part D Claims History for Immunosuppressants</u> a) The plan has received information from CMS (e.g. via MARx) indicating that Medicare covered the enrollee's transplant or, in the case of a Medicare Advantage enrollee, the MA Plan has medical claims history of a covered transplant regardless of previously received information from a prescriber on whether or not the transplant was covered by Medicare. In this situation, plans are expected to rely on the CMS information (or in the case of an MA plan, its own medical claims history) and cannot cover immunosuppressants under Part D even if information is also provided by the prescriber that indicates that the transplant was not Medicare covered.	PerformRx has significant concerns about operationalization of this proposal. We recommend that CMS **not** move forward with this proposal. Use of MARx is a plan function. The PBM would not have access to this information at POS or for coverage determinations.

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		b) The plan has NOT received information from CMS (via MARx or otherwise) indicating that Medicare covered the transplant for the enrollee; in the case of a Medicare Advantage enrollee, the MA Plan does not have medical claims showing a history of a covered transplant; and the plan has not previously received information from a prescriber that the transplant was covered by Medicare. In this situation, CMS expects plans to default to covering the immunosuppressants under Part D and no longer expects plans to reach out to prescribers to inquire about Medicare coverage of the transplant. Such outreach is burdensome for plans and prescribers, and has been shown to be unreliable for accurately determining if Medicare covered a transplant. Nevertheless, the plan should approach this coverage decision using the best available information; if the plan has previously reached out to the prescriber and received information indicating that the that the transplant was covered by Medicare (in full or in part), the Part D plan may not cover immunosuprressants under D. <u>2. Prior Part D Claims History AND MARx currently indicates that Medicare covered the transplant:</u> A plan might have covered the drugs under Part D previously because either: • MARx information was updated after the Part D sponsor relied on prior information from the prescriber that the transplant was NOT covered/ paid by Medicare; or • The Part D sponsor had relied solely on information from the prescriber that the transplant was NOT covered/paid by Medicare without regard to MARx. Under either scenario, the Part D sponsor must now rely on the MARx information going forward and notify the enrollee that the plan can no longer cover the immunosuppressant(s) because it is covered under Medicare Part B. No changes need to be made to prior Part D claims. <u>3. Prior Part D Claims History , no MARx indicator or MA plan medical claims history of a covered transplant BUT the Part D sponsor receives information from CMS that the transplant was covered by Medicare (e.g. Part D sponsor receives the information from CMS as part of a CMS Program Integrity audit or otherwise).</u> Under this scenario, the Part D sponsor must now rely on the CMS information going forward and provide notice to the enrollee that the plan will no longer cover the immunosuppressant(s) under Part D because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.	
Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs Inhalation Durable Medical Equipment (DME) Supply Drugs	220	<u>B) Inhalation Durable Medical Equipment (DME) Supply Drugs</u> Previous guidance documents indicate that inhalation drugs administered in a long term care setting where the stay is not covered under Medicare Part A can be covered under Part D. We are now clarifying how Part D plans can determine that a beneficiary is residing in a long term care facility. Medicare Part B covers certain inhalation drugs, such as Albuterol and Levalbuterol nebulizer solutions, as supplies under the DME benefit. The DME benefit, however, is not available to beneficiaries residing in long-term care facilities (i.e. Nursing Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities). Consequently, if the beneficiary is not on a Part A stay in one of these facilities, these inhalation drugs can be covered under Medicare Part D. While Part D sponsors generally have relied on the prescriber's statement that the	PerformRx has significant concerns about operationalization of this proposal. This proposal raises numerous questions and concerns. • How is this proposal intended to work for non-formulary drugs or for drugs with additional UM restrictions? If a coverage determination is received and approved, an authorization would need to be entered under the appropriate benefit based on the information provided. The authorization is not coordinated with the patient residence codes submitted. • If information is provided that does not align with the patient residence code, it may be a pharmacy processing error. How would CMS expect that to be addressed via the coverage determination process? • If a coverage determination is submitted, should it be decisioned based on the presence or absence of patient residence codes alone? • How does a sponsor deny a coverage determination if there is no patient residence code?

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		beneficiary resides in long-term care facility to authorize Part D coverage, since 2013 CMS has required sponsors to report the patient residence code on prescription drug events (PDEs). We expect that patient residence codes submitted to CMS are accurate and because they represent a recent dispensing event; the residence codes offer a more timely view of patient's location than previous information communicated by the prescriber. Therefore, CMS permits Part D sponsors to rely on a patient residence code of "3" or "9" on a pharmacy claim for determining when such inhalation drugs may be covered under Part D. Moreover, we expect that sponsors will only pay claims for these products when the pharmacy claim includes these specified patient residence codes regardless of any prior coverage determination based upon a prescriber statement indicating that the beneficiary resides in a long-term care facility (i.e. the prescriber statement and patient residence code must be aligned).	
Part D Mail-Order Refill Consent Policy – Solicitation for Comments			
Part D Mail-Order Refill Consent Policy – Solicitation for Comments	220-221	CMS is also interested in receiving feedback on data that rebuts concerns that such programs increase waste (to include unwanted or unneeded medications that go unused, as well as additional cost to the beneficiary or Part D program).	PerformRx agrees that mail-order auto-ship programs create waste. The current mail-order auto-ship policies mean that for those members who have frequent dose changes, they could have a backlog of medications. This could subsequently cause member confusion, and lead to beneficiaries taking the incorrect strength. Further, we have concerns about how the beneficiaries are disposing of the medications they are not using.