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January 16, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS–4182–P

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' proposed Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

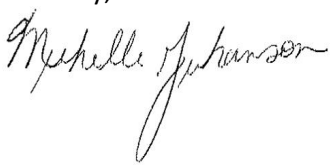
First, we would like to express our appreciation for CMS' partnership in administration of the Part D program on behalf of Medicare beneficiaries.

However, we are concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing the Regulatory Reform Agenda. While we appreciate CMS' efforts to reduce regulatory burden in some areas, such as elimination of the Medicare prescriber enrollment requirement, we see increased regulation through the proposed rule. Our attached comments point out specific areas. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders.

Further, we are concerned that implementation of all of the proposed changes, which are major in scope, could not be accomplished by January 1, 2019. First, the final rule would need to be issued. Second, CMS would need to provide any needed clarifications. Third, as explained throughout our comments, this ambitious timeline for implementation would not be feasible across the industry.

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

Sincerely,



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II.A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability (56340 – 56428) (PDF 5 – 93)			
1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions			
c.2.v. Limitations on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(3))	56349 (PDF 14)	(i) Implement a point-of-sale [POS] claim edit for frequently abused drugs that is specific to an at-risk beneficiary; or (ii) . . . limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are (A) Prescribed for the beneficiary by one or more prescribers; (B) Dispensed to the beneficiary by one or more network pharmacies; or (C) Specified in both paragraphs (3)(ii)(B)(1) and (2) of this paragraph.	First, PerformRx is concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing the Regulatory Reform Agenda. We see increased regulation through the proposed rule. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders. It is important that the transfer of data between plans be automated. PerformRx also recommends that CMS develop a clearinghouse of lock-ins, such as in MARx. This would enable new plans to know whether incoming beneficiaries have such limits. For example, automation currently occurs in the TrOOP balance transfer process.
c.2.vi. Requirements for Limiting Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(4))	56349 – 56350 (PDF 14 – 15)	We propose to add a paragraph (f)(4) to § 423.153 that reads: Requirements for Limiting Access to Coverage for Frequently Abused Drugs. (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following: (A) Conducted the case management required by paragraph (f)(2) of this section and updated it, if necessary; (B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate; and (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.	PerformRx recommends that CMS require prescriber agreement to implement pharmacy lock-in. This is consistent with our understanding of the current Medicaid practice, and this also would be for the good of the beneficiary.
c.2.vii.A. Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(5))	56350 – 56351 (PDF 15 – 16)	Initial Notice to Beneficiary. A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary.	Requiring the sponsor to send an initial notice to the beneficiary if there is no intent to lock-in would unnecessarily alarm the beneficiary. PerformRx currently sends a notice *after* we have contacted the prescriber and made a determination to limit the beneficiary (through POS edit and based on prescriber consensus). Thus, our notice provides this intent to the beneficiary. Therefore, we recommend requiring the sponsor to send only one notice when the decision to limit the beneficiary is made and provide a 30-day review timeframe.
c.2.vii.A. Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(5))	56350 – 56351 (PDF 15 – 16)	Initial Notice to Beneficiary. (3) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at § 423.580 et seq.; (4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under § 423.153(f)(3)(ii).	CMS states that the notice provided to the beneficiary is the notice of a decision to deny or limit service, with the right to redetermination. It would appear that the beneficiary would have the right to appeal the decision. Does CMS believe that the decision to place a POS edit or a lock-in would be a coverage determination? If so, would that mean this decision would be subject to Chapter 18 of the Medicare Prescription Drug Benefit Manual? PerformRx does not believe that these decisions are coverage determinations. They do not comprise coverage issues but involve access issues. We believe that Chapter 18 could not be applied in making these decisions. If CMS believes that these decisions are in fact coverage determinations subject to Chapter 18, could CMS release proposed changes to Chapter 18 for comment so sponsors can understand how to manage this process? For example, in proposed Chapter 18 changes, could CMS please explain how the CARA provisions would impact the coverage determination and redetermination processes? Would any consideration to approval, denial, and member specific approval/denial language need to be made? Currently, our Medication Therapy Management (MTM) and coverage determination processes are housed in different business units, and they utilize different systems. We believe that other plans and PBMs operate in similar fashion. Treating these decisions as coverage determinations would pose significant systems, policy, and process challenges. A standard process would have to be developed to ensure that all functional areas understand why claims are rejecting for new members if no plan limits have been exceeded. Extensive resources would be needed to ensure alignment. Further, audits would be impacted by treating these decisions as coverage determinations. For example, would these decisions need to be reported in the Coverage Determinations, Appeals, and Grievances (CDAG) or MTM universes? Thus, PerformRx recommends as an alternative that these initial decisions and appeals decisions be made by an independent agency such as the Independent Review Entity (IRE), after recommendation by a sponsor. Another alternative would be for the IRE handle all appeals. PerformRx recommends a separate appeals process that is more like a grievance process. Also, could CMS please provide clarity on how to effectuate a redetermination decision that requires the reversal of one limit,

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			but other limits remain? Which limit takes priority? For example, if there is a formulary restriction and a lock-in that are both appealed, and only the lock-in is reversed, would the beneficiary still have a formulary limit in place? Sponsors need to be able to abide by the remaining limits. Beneficiaries would have to receive decision notices explaining that because of remaining limits, their drug access will still be limited.
c.2.vii.A. Initial Notice to Beneficiary and Sponsor Intent to Implement Limitation on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(5))	56350 – 56351 (PDF 15 – 16)	We propose to require at § 423.153(f)(5)(iii) that the Part D plan sponsor make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i).	PerformRx believes that this may be difficult to do, as there may not be reliable prescriber contact information if the only prescriber data is what the pharmacy transmits on the claim. As a PBM, we have found that sponsors struggle to provide accurate and current prescriber information.
c.2.vii.E. Timing of Notices (§ 423.153(f)(8))	56353 – 56354 (PDF 18 – 19)	We propose permitting a gaining plan to provide the second notice to an at-risk beneficiary so identified by the most recent prior plan sooner than would otherwise be required.	PerformRx recommends that CMS documents the initial inquiry notice in the MARx system. The gaining plan does not always know about limits placed unless documentation is required. However, as explained above, PerformRx recommends that sponsors only send one notice.
c.2.viii.A. Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (§ 423.153(f)(4))	56354 – 56355 (PDF 19 – 20)	We propose 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 propose that this date be the date of the first OMS report that identified the beneficiary, so long as the beneficiary was also reported in the most recent OMS report that the sponsor received.	PerformRx believes that a six-month waiting period is too long a period of time for allowing an at-risk beneficiary to continue to obtain frequently abused drug(s). Currently, once we engage in case management and are in contact with the prescriber, we are prepared to make an informed clinical decision to implement in 30 days.
c.2.viii.B.3. Reasonable Access (§§ 423.100, 423.153(f)(11), 423.153(f)(12))	56356 – 56357 (PDF 21 – 22)	(ii)(A) . . . in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy.	PerformRx believes it would be challenging to implement a lock-in to all stores in a chain. There is only one prescriber indicator allowed in the claims processing system, which is filled in by the particular pharmacy's claim. PerformRx recommends that the lock-in apply to a single pharmacy with a single NPI number. Furthermore, the addition of other pharmacies should be handled through exceptions. Further, the group pharmacy definition proposed does not meet the definition of a chain pharmacy. PerformRx recommends that group pharmacies not be included.
c.2.viii.B.3. Reasonable Access (§§ 423.100, 423.153(f)(11), 423.153(f)(12))	56356 – 56357 (PDF 21 – 22)	(ii)(B) . . . in the case of a group practice, all prescribers of the group practice shall be treated as one prescriber.	PerformRx believes it would be challenging to implement a lock-in to all prescribers in a group practice. Many sponsors currently do not have the ability to align prescribers with their practice groups. PerformRx recommends locking-in to a single prescriber with their individual NPI number and handling additional prescribers as exceptions. Automating adjudication of multiple prescribers is not technically feasible currently and would take at least a year to implement. Currently, sponsors would have to manage tables on the back end, which would be technically cumbersome. If sponsors were still required to lock-in to all prescribers in a practice, PerformRx recommends that CMS develop with NCPDP a list of group practice NPIs.
c.2.ix. Drug Management Program Appeals	56357 – 56358 (PDF 22 – 23)	We are proposing to integrate the lock-in provisions with existing Part D Opioid DUR Policy/OMS. Determinations made in accordance with any of those processes, proposed at § 423.153(f), and discussed previously, are interrelated issues that we collectively refer to as an ''at-risk determination'' made under a drug management program.	If CMS concludes this is a coverage determination, could CMS please clarify how this process would impact the appeals auto-forward star measure? As referenced above, PerformRx does not believe that these decisions would be coverage determinations.
c.2.x. Termination of a Beneficiary's Potential At-Risk or At-Risk Status (§ 423.153(f)(14))	56358 – 56359 (PDF 23 – 24)	Termination of Identification as an At-Risk Beneficiary. The identification of an at-risk beneficiary as such shall terminate as of the earlier of the following—(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary[.]	Could CMS please clarify whether there would be a washout period for when a beneficiary can be identified again for lock-in and/or POS claim edits?
9. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))			
9.b. General Rules	56371 (PDF 36)	We are proposing to revise § 423.578(a)(2) to read as follows: ''Part D plan sponsors must establish criteria that provide for a tiering exception	First, PerformRx is concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing

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		consistent with paragraphs § 423.578(a)(3) through (a)(6) of this section.''	the Regulatory Reform Agenda. We see increased regulation through the proposed rule. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders. PerformRx has found that providers generally do not make tiering exception requests exclusively. They typically check off all of the boxes under "Type of Coverage Determination Request" on the request form. PerformRx recommends that SNP, MMP plans, and defined plans be prohibited from tiering exceptions on basis that: (a) their members already pay the lowest amount because they receive the LIS, and (b) the 25% coinsurance cannot be lowered (defined standard benefit). Tiering exceptions only apply in the Initial Coverage Limit phase, not the Coverage Gap or catastrophic phase. CMS should explain to beneficiaries how tiering exceptions work. Finally, could CMS please describe tiering exceptions for LIS beneficiaries? PerformRx would like to note that the definition of preferred drug as outlined by CMS in the 2018 Call Letter on tiering exceptions is somewhat contradictory. The definition neglects to include an understanding of rebates provided for those preferred drugs. Preferred drugs have rebates, but non-preferred drugs do not have rebates.
9.e. Approval of Tiering Exception Requests	56373 (PDF 38)	We are proposing to revise § 423.578(c)(3) by renumbering the provision and adding a new paragraph (ii) to codify our current policy that cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers. Under this proposal, assignment of cost sharing for an approved tiering exception must be at the most favorable cost-sharing tier containing alternative drugs, unless such alternative drugs are not applicable pursuant to limitations set forth under proposed § 423.578(a)(6). We are also proposing to delete similar language from existing (c)(3) that proposed new paragraph (c)(3)(ii) would replace.	PerformRx recommends that CMS evaluate this proposed rule against prior guidance. Chapter 18, Section 30.2.4, illustrates that a tiering exception to cover a Tier 3 drug at a Tier 1 cost-sharing level cannot be done. This consideration is not only about making a coverage determination. This requirement is new and contradictory. It would allow coverage of a tier 5 drug at a tier 1 cost-sharing level. PerformRx has significant concerns about this substantial change. The change would affect multiple aspects of the formulary and coverage determination processes, as well as rebates. We would anticipate a major increase in tiering exception requests as well. This could require hiring a significant amount of new staff. PerformRx recommends that CMS define these tiering exception requests and not only default to Chapter 18. We recommend that CMS provide an example to illustrate, similar to the examples already provided under Chapter 18, Section 30.2.4. Further, could CMS please clarify that if the sponsor is processing a tiering exception request from tier 3 to tier 1 and there is a viable alternative on tier 2, should the tiering exception request be denied or should a tiering exception be approved to pay at a tier 2 copayment? Also, what if the alternative on the lower tier does not have the same mechanism of action? For example, if CMS raises a concern on clinical decision making when offering alternatives that do not work in the same way, how could this alternative then make the beneficiary eligible for a tier exception?
11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System			
11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System	56377 (PDF 42)	Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.	PerformRx is committed to innovation in health care services and appreciates CMS' commitment to encouraging the adoption of technology for the greater good of the beneficiary experience. However, in our opinion, the adoption of technology is not evidence of quality. To that end, the proposed measure would in fact measure beneficiary usage of technology as opposed to the adoption of technology by the plan sponsors. PerformRx is also concerned that simply calculating the rate of use of certain technologies would result in a significant disadvantage to health plans with higher low income and rural beneficiary populations. Technology also still presents a challenge for many of elderly persons and persons with disabilities, who also comprise a large portion of members for certain plans. Many of our health plan partners service these vulnerable beneficiaries across the country. PerformRx has piloted several programs, such as in-home electronic pill stations, tablet-based disease management and gamification software, and telemedicine for medication therapy management. In all cases, we have found that most beneficiaries cannot afford or do not have the corresponding technology (i.e., computer, smartphones, unlimited data, home internet access, accessible technology for people with disabilities) to use the services. Unless the plan provides the hardware, many beneficiaries cannot take advantage of the services. Thus, plans that serve these vulnerable beneficiaries would be at a disadvantage with the application of this proposed measure. Correspondingly, for these beneficiaries, access to technology may not be an important measure in choosing a plan.

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			Similarly, PerformRx has, since 2009, offered web-based prior authorization submission to prescribers and members at no cost. We process approximately 600,000 prior authorizations annually, and only three percent of those submissions are web-based. Likewise, while we have offered e-prescribing consistent with the NCPDP standard since 2008, fewer than three percent of total transactions are e-prescribed. The prescriber community has not fully adopted the technologies that have been in place for nearly a decade for a multitude of reasons. Thus, plans again would be at a disadvantage with the application of this proposed measure due to prescriber behavior that is beyond plans' control. PerformRx encourages CMS to continue to explore ways to evaluate the value of the use of technology and how it can be best quantified for measurement purposes. Would CMS consider surveying the plan sponsors for at least one year to determine what technologies they offer and the utilization rates? CMS could then analyze use and impediments to adoption by the beneficiary and provider community and then partner with the industry and advocacy community to close the gaps. In the spirit of the proposed measure, what data can CMS share about the use of the Medicare Prescription Drug Plan Finder versus all other types of enrollment? Would CMS be willing to pilot the proposed measurement on its own systems and share the results with the industry?
11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System	56377 (PDF 42)	Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services, and we would welcome comments.	PerformRx requests that CMS continue to only include beneficiaries in its CAHPs survey process for the purpose of the star ratings. There appears to be conflicting CMS policy by including physicians. In the case of MAPD plans, the physicians are contracted providers of the health plans. CMS' position has been that the network providers are part of the plan. Specifically, during CMS program audits, CMS has expressed that it holds plans accountable for the participation of their network prescribers in the coverage determination and appeals process. By contrast, including physician feedback in the CAHPS survey suggests that CMS now views physicians in the same role as the consumer. PerformRx requests that CMS maintain a consistent approach in its evaluation of the position of the prescriber in relation to the plan sponsor. In our opinion, prescribers have the education and tools necessary to navigate the CMS and plan rules more effectively than beneficiaries. The plans already have mechanisms for measuring physician satisfaction with that relationship. There are existing industry standards and NCQA and URAC accreditation requirements to conduct provider satisfaction surveys. Plans and PBMs routinely use this information as part of their quality programs to identify opportunities for improvement. Regarding the exclusion of pharmacies, would CMS consider the role of the pharmacist as a provider in future measure development? Pharmacists see beneficiaries more often than prescribers in many cases. Pharmacists have to explain POS pharmacy rejections to beneficiaries. Our opinion is that pharmacies are also subcontractors or downstream entities of Part D plan sponsors and therefore should not be included in the CAHPS survey. Pharmacies are expected to understand the applicable Part D rules and NCPDP error messages, and provide beneficiaries with the CMS Notice 10147 about the Part D appeals process. The pharmacy agreements contain provisions and guidelines for complaint resolution.
11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System	56378 (PDF 43)	Under our proposal, the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings.	PerformRx commends CMS for approaching the star ratings programs through transparency and partnership. The success of the Part D program, as measured by the number of beneficiaries enrolled in 4-5-star plans, is a reflection of CMS' partnership with the industry, focus on data accuracy and integrity, and reliance on expert organizations like the Pharmacy Quality Alliance and NCQA. We appreciate when CMS gives plans time to mature and improve through measure stabilization because measure improvement takes more than one contract year in most cases. We also generally support the use of the proposed rule process to formally introduce potential changes to the program, in addition to further collection of feedback through the draft Call Letter. Would CMS consider issuing proposed rules earlier in the year, such as in the third quarter, annually? In the fourth quarter, plans are responding to the Readiness Checklist, the annual election period, one-third financial audits, and testing for the upcoming plan year. The star ratings are critically important, and we routinely comment when CMS provides the opportunity. In the third quarter, there are fewer demands on sponsors and their PBMs, which allows for the time necessary to evaluate CMS' proposals and develop thoughtful and meaningful commentary.
11. Medicare Advantage and Part D Prescription Drug	56379 (PDF 44)	*Highest rating* means the overall rating for MA–PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.	Regarding the definition of "highest rating," would CMS please consider another term to describe the overall rating? Specifically, would CMS use "summary rating" instead? The use of the term highly rated is confusing, when in all other cases, "high" is a

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Program Quality Rating System		*Highly-rated contract* means a contract that has 4 or more stars for their highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor). *Overall Rating* means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.	relative term intended to represent the degree of the rating. The term "summary rating" better reflects the intent, which we understand to mean the Overall Rating, which is also defined. If our understanding of the intent is accurate, would CMS be willing to provide examples highlighting the fields/numbers on the report card template?
11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System	56380 (PDF 45)	We are soliciting comments on balancing the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures; we ask for comments about this for D–SNPs and for all plans as we continue to consider whether rating at the plan level is feasible or appropriate.	PerformRx urges CMS to maintain contract-level reporting as opposed to plan-level reporting. First, the Part D reporting requirement collects information at the contract level. Consistent with CMS' concerns about data validity, we have observed that most small and mid-sized plan sponsors do not have enough beneficiaries enrolled to be measurable. Several of our special needs plans (SNP) clients routinely receive "not enough data to measure" in multiple Part D measures at the contract even though from our internal tracking the plans have measurable data. Therefore, as conceded by CMS, measuring at the plan level would result in even less data for measurement. Also, from a plan quality and process perspective, our experience is that the work is being done the same way within a single contract. To the extent that the star ratings measure the quality of the controls and underlying procedures, measurement at the contract level is fair and also accurate.
11.f. Contract Consolidations	56380 (PDF 45)	We are also exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting and still remain useful (for example, call center measures as we anticipate that parent organizations use a consolidated call center to serve all contracts and plans) to incorporate into the Star Ratings.	PerformRx urges CMS to maintain contract-level reporting as opposed to parent-level reporting. In the age of buy-outs, the parent organization may operate contracts whose operations and FDRs are different. For example, we have a client who operates a D-SNP contract under the insurance license of a large organization. That organization also has subsidiary Part D PDP and MAPD plans that are not PerformRx clients. The star ratings for our client are a reflection of very distinct delegation and internal procedures. The D-SNP contract has fewer enrollees than the MAPD and PDP contracts. In this example, one negative impact of measuring data at the parent level is that PerformRx would not be able to determine its direct contribution to the measures aligned to our delegated functions, such as the CMR completion rate. Part D sponsors are using the star ratings to evaluate potential FDR candidates. Parent-level reporting for those measures would mask our work and could be unfairly advantageous or disadvantageous based on the performance of the other health plans under the parent. There is more operational consolidation at the contract level, in our experience, than at the parent level. The same concerns that CMS correctly identified in section f. Contract Consolidations, are the concerns that PerformRx has were parent level ever to be used as the method of measurement.
11.g. Data Sources	56382 (PDF 47)	We also propose, primarily so that the regulation text is complete on this point, a regulatory provision at §§ 422.162(c)(2) and 423.182(c)(2) that requires MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data as described in paragraph(c)(1) of each section. This proposed regulation text would clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance.	PerformRx supports CMS' efforts to ensure data integrity and accuracy. We are not convinced, however, that the proposed provision is necessary or, in the case of the term "unbiased," consistent with other CMS regulations that require accuracy and completeness of Part D data. As discussed previously in our comments, our understanding is that Presidential Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs applies to the Department of Health and Human Services including CMS. In the order, the expectation is that "for every one new regulation issued, at least two prior regulations be identified for elimination." The order further states that "[u]nless prohibited by law, whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed." As it relates to this proposed change, would CMS identify the two existing regulations that it has identified for elimination? For example, of the Part D report card measures, there are only two measures plan sponsors currently report to CMS (appeals auto-forward and MTM program completion rate for CMR). That data is reported in accordance with the Part D reporting requirements. Similarly, CMS finalized regulations requiring plan sponsors to pay independent data validation audit contractors to validate the accuracy and completeness of their reported data. The proposed rule is, in our opinion, already sufficiently accomplished with the existing regulations. The remaining Part D measures are collected by CMS through its own data analysis or that of its subcontractors, including MAXIMUS Federal Services and Acumen LLC. With regard to the desire for unbiased data, would CMS please provide a definition for the term and explain specifically what it would expect plan sponsors to do over and above confirming the accuracy and completion of the data to eliminate bias? Would CMS please consider offering examples of bias that it has observed? CMS generally requires plans to attest to the accuracy and completeness of data on a monthly basis, for claims payment, and annually for the Part D bid and financial reconciliation processes. That data is critically important to the government's management and oversight of the Part D program. To the extent

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			that CMS has not previously used the term “unbiased,” PerformRx encourages CMS to strike the term should it decide to finalize this change.
11.h. Adding, Updating, and Removing Measures	56383 (PDF 48)	To address these anticipated changes, we propose in §§ 422.164 and 423.184 specific rules to govern the addition, update, and removal of measures. We also propose to apply these rules to the measure set proposed in this rulemaking, to the extent that there are changes between the final rule and the Star Ratings based on the performance periods beginning on or after January 2019.	PerformRx supports the proposed rule in its entirety and requests that CMS finalize it without modification.
11.k. Data Integrity	56395 (PDF 60)	We propose to use multiple data sources whenever possible, such as the TMP [Timeliness Monitoring Project] data or information from audits to determine whether the data at the Independent Review Entity (IRE) are complete.	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 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.

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			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.
11.k. Data Integrity	56396 (PDF 61)	CMS' proposed scaled reduction methodology is a three-stage process using the TMP or audit information to determine: First, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, the basis for the estimate of the error rate; and finally, whether the estimated error rate is significantly greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars	PerformRx understands that there is only one Part D appeals measure that measures timeliness, Appeals Auto-forward. Would CMS confirm that it is only referring to the Appeals Auto-forward as the Part D appeals measure?
12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)			
12.c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions	56410 – 56411 (PDF 75 – 76)	. . . [W]e do not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy . . . It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and § 423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states . . .	First, PerformRx is concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing the Regulatory Reform Agenda. We see increased regulation through the proposed rule. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders. It appears that CMS' policy statement could negatively impact sponsors' ability to contract with specialty pharmacies. PerformRx believes that CMS policy should allow sponsors the ability to develop criteria that is reasonable and relevant for the Part D program.
13. Changes to the Days' Supply Required by the Part D Transition Process			
13. Changes to the Days' Supply Required by the Part D Transition Process	56411 – 56412 (PDF 76-77)	. . . [We] propose to shorten the required transition days' supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting . . . [We] propose a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.	PerformRx supports the finalization of this rule as it would provide for more efficient operationalization. It would also provide for easier explanation of rejected claims during the Transition Monitoring Program Analysis and other CMS audits and monitoring. Further, we believe that the impact on beneficiaries would be minimal. Currently, most LTC claims that we process are for fewer than a 14-day supply.
14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)			
14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)	56413 (PDF 78)	. . . [W]e propose to add a new paragraph (b)(5)(iv) to § 423.120 to permit Part D sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. The generic drug would need to be offered at the same or a lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug. The Part D sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market. Also, the Part D sponsor must have previously provided prospective and current enrollees general notice that certain generic substitutions could occur without additional advance notice.	PerformRx supports this framework to allow for expedited substitutions or changes in cost-sharing. The proposed rule would reduce the burden on sponsors and allow members quicker access to generic versions of their drugs. PerformRx has identified one barrier to sponsors' ability to take this immediate action. Would the "immediate switch" only take place during the open window directly following the generic drug being released on the Formulary Reference File (FRF)? Would the Utilization Management (UM) criteria spreadsheet need to be sent? If so, we are concerned that the current timeline for submission of the UM criteria worksheet after the FRF release would prevent sponsors' ability to implement the new rule. Specifically, if there is UM criteria that contains the drug name being removed, the timing of the FRF release to the window for sending the UM criteria worksheet to CMS may be small or not open (the spreadsheet currently must be sent five days prior to the monthly submission). If the FRF release is delayed, and the UM criteria spreadsheet is unable to be sent, this would prevent the immediate formulary switch from taking place. PerformRx thus recommends that CMS expand the timeframe for sending the UM criteria worksheet to facilitate these immediate formulary changes. Specifically, we believe it would be beneficial to allow plans to make the brand/generic switch, following the proposed new process, for the current FRF when the generic is released and the next FRF/submission. This would

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			allow ample time for the UM criteria spreadsheet as well as working with Explanation of Benefits (EOB) vendors, and authorizations in place for those members who would be affected.
14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)	56509 (PDF 174)	PROPOSED RULE § 423.120 Access to covered Part D drugs. . . . (D) Before making any permitted generic substitutions, the Part D sponsor provides advance general notice to CMS and other specified entities.	Could CMS please clarify how the advance general notice to CMS would be completed? Would this be accomplished through the attestation process or perhaps via HPMS prior to the submission window opening?
14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)	56413 – 56414 (PDF 78 – 79)	We also propose to specify in a revision to § 423.120(b)(3)(i)(B) that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug under paragraph (b)(6) of this section . . . [W]e do not believe a transition policy would be appropriate for these situations . . .	Transition lookback for most plans is at the Hierarchical Ingredient Code List (HICL) level. Therefore, these types of transitions will still occur. Sponsors would need to spend significant resources to implement coding options to prevent this transition from taking place. Sponsors and claims processors would need well beyond January 1, 2019, to update the claims processing system transition logic and policies and procedures.
14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)	56416 (PDF 81)	. . . [W]e plan to decrease the amount of direct notice required in cases where the removal of a drug or change in cost-sharing status will affect enrollees currently taking the drug. (This would contrast proposed notice requirements that would apply to immediate substitution of specified generics…) . . . We propose to reduce the notice requirement in both instances to at least 30 days and the refill requirement to a month. Beneficiaries would be affected, and therefore receive the 30 days' notice or a month refill, in cases in which, for instance, Part D sponsors planned to add prior authorization requirements as a result of new safety-related information or clinical guidelines.	PerformRx supports decreasing direct notice to 30 days or providing for a month (rather than 60 days) supply. We believe that the proposed rule would provide sufficient notice to affected members and allow them time to work with their prescriber, while reducing the burden on sponsors.
14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)	56416 (PDF 81)	Summary: The following provides a high level summary of notice changes proposed in § 423.120(b) . . .	Sponsors would need significant time beyond January 1, 2019, to implement the notice changes. Sponsors would need time to coordinate with their claims processors to implement any needed coding changes.
15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing			
15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing	56416 – 56417 (PDF 81 – 82)	We propose to modify the definition of generic drug at § 423.4 to include follow-on biological products approved under section 351(k) of the PHS Act (42 U.S.C. 262(k)) solely for purposes of cost-sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D)(ii–iii) of the Act.	First, PerformRx is concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing the Regulatory Reform Agenda. We see increased regulation through the proposed rule. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders. It would be challenging to add this layer for LIS cost-sharing in the claims processing system. Significant programming and testing resources would be needed and we could not guarantee that the implementation would be ready by January 1, 2019. Further, if these drugs are already specialty drugs, then they are typically in their own tier with specific cost sharing. As a result, PerformRx believes this proposed rule to be unnecessary. Could CMS please clarify that if there is a biosimilar on formulary, does that count as one of the two therapeutics per class?
17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale			
17.c. Manufacturer Rebates to the Point of Sale	56421 (PDF 86)	. . . [W]e are considering requiring, through future rulemaking, Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. We will refer to the rebate amount that we would require be included in the negotiated price for a covered Part D drug as the ''point-of-sale rebate.'' Under such a policy, sponsors could apply as DIR at the end of the coverage year only those manufacturer rebates received in excess of the total point-of-sale rebates. In the unlikely event that total manufacturer rebate dollars received for a drug are less than the total point-of-sale rebates, the difference would be reported at the end of the	PerformRx has serious concerns regarding CMS' proposal to require a minimum percentage of rebates to be applied at POS and to require all pharmacy price concessions to be applied at POS. First, we question CMS' authority to promulgate the rule. Second, this proposed rule is unworkable operationally, would have limited value, and would interfere with private relationships. First, PerformRx is concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing the Regulatory Reform Agenda. We see increased regulation through the proposed rule. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders. Relatedly, we are concerned that CMS is overreaching in its interpretation of Section 1860D-2(d)(1)(B) (p. 56420, 56421): "(B)

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		coverage year as negative DIR.	Negotiated prices.—For purposes of this part, negotiated prices *shall take into account* negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs" [emphasis added]. Indeed, CMS acknowledges this current law provides for sponsor flexibility in this area. Specifically, CMS states: Under current law, when not explicitly *required* to do so for certain types of pharmacy price concessions, Part D sponsors can *choose* whether to reflect various price concessions, including manufacturer rebates, they or their intermediaries receive in the negotiated price. Specifically, section 1860D–2(d)(1)(B) of the Act merely requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . . .'' In other words, Part D sponsors are allowed, but generally not currently required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. (p. 56420) . . . [T]he statutory definition of negotiated price in section 1860D–2(d)(1)(B) of the Act requires that ''negotiated prices shall *take into account* negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .'' (emphasis added). We believe this language, particularly when read in the context of the requirement in section 1860D–2(d)(2) of the Act that Part D sponsors report the aggregate price concessions made available ''by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers,'' contemplates that Part D sponsors have some flexibility in determining how to apply manufacturer rebates in order to reduce costs under the plan. (p. 56421) . . . preserve the flexibilities provided under section 1860D–2(d)(1)(B) of the Act with respect to the treatment of manufacturer rebates . . . (p. 56426) [emphases added] But, CMS also believes that not requiring 100 percent of manufacturer rebates to be applied at POS but instead specifying a minimum percentage is akin to the flexibility that that Act provides for sponsors. However, a minimum percentage would be an amount dictated by the government rather than, as provided for under current law, an amount chosen by sponsors. CMS also believes that "requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices 'take into account' at least some price concessions and, therefore, would be consistent with the plain language of section 1860D–2(d)(1)(B) of the Act." However, this again would be an amount dictated by government rather than chosen by sponsors. In sum, requiring that a minimum percentage of manufacturer rebates and that all pharmacy prices concessions be reported at POS would appear to be regulatory provisions that are contrary to the plain language of the Act. This appears to be an overreaching interpretation of the Act. Second, CMS already has several valuable programs to ensure reporting of manufacturer rebates and price concessions and to assure that beneficiaries are paying a reasonable amount for their drugs. These programs provide for the sought-after transparency. The programs should continue, and CMS should highlight these programs for concerned stakeholders. • In the Coverage Gap Discount Program, drug manufacturers have already agreed to close the gap by 2020, as reflected in law. • Direct and Indirect Remuneration (DIR) reporting requirements already exist. The proposed rule would add an unnecessary, contradictory added layer. Currently, beneficiaries receive lower premiums due to rebates applied as DIR. Application of the proposed rule would cause premium increases. CMS should instead continue with the DIR reporting requirements. • CMS One-Third Financial Audits are extensive audits that analyze the solvency of the company, related party activities, non-benefit expenses, prescription drug plans, and direct medical. This includes price concessions. Also, PerformRx does not believe that this rule could be operationalized effectively starting January 1, 2019. Current claims processing systems are not set up to accommodate this major change. Like others, our claims processor currently cannot apply

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			rebates at POS. Our claims processor states that it would need at minimum one year to implement this change. Our claims processor further states that in the meantime, it could allow for a POS reduction in copayments, which would essentially be the plan underwriting. Plans would incur significant reprogramming and testing costs that would be better spent complying with existing requirements. Further, implementation of the rule would have limited value in several ways. The significant costs for sponsors and CMS would not be outweighed by this limited value. • The scope of beneficiaries benefitted is narrower than would appear. If CMS' intent is to reduce costs for beneficiaries, we believe that this regulation would have limited value. o For one, a significant number of beneficiaries would not benefit because of plan design. The rule would only assist beneficiaries who pay cost sharing outside of the defined standard benefit. The rule would not assist beneficiaries who pay copayments or receive the standard defined benefit. This would include LIS beneficiaries not being assisted by the proposed rule. o Second, premiums would increase for all beneficiaries, as CMS acknowledges. (p. 56421) • The impact would also be minimal because the universe of rebatable drugs is significantly smaller than the universe of all drugs. Generic drugs are not rebatable. Brand name drugs are only about 20% of the drugs on the formularies that we administer. Only a subset of those drugs is rebatable. This would mean a narrow group of rebatable drugs. We estimate that 4 – 8 percent of total spend (Medicare, Medicaid, commercial) is actually rebated. Finally, PerformRx believes that the proposed rule would interfere with private contractual relationships. Retrospective contract negotiation would be impacted. It could take up to one year to renegotiate contracts. Sponsors would not be able to negotiate effectively because they would have already have been made to apply a certain percentage of rebates and all price concessions at POS. To avoid cumbersome PDE reconciliation, sponsors would be inclined to keep contracts as is, and incur losses. Further, PerformRx is concerned that the proposed rule would significantly change the bargaining landscape between sponsors and pharmaceutical manufacturers, to pharmaceutical manufacturers' benefit. PerformRx is concerned that the regulation may encourage pharmaceutical manufacturers to eliminate supplemental rebates altogether.
17.c.(1) Specified Minimum Percentage	56421 – 56422 (PDF 86 and 87)	We are soliciting comment on the minimum percentage of manufacturer rebates that should be reflected in the negotiated price in order to achieve this balance . . . We also are seeking comment on the effect that specifying a minimum percentage of rebates that must be reflected in the negotiated price would have on the competition for rebates under Part D and the total rebate dollars received by Part D sponsors and PBMs.	Contractually, sponsors and PBMs could not support this because we do not know what the rebates are until confirmation is received from the pharmaceutical manufacturers.
17.c.(2) Applicable Average Rebate Amount	56422 (PDF 87)	We are also particularly interested in stakeholder feedback regarding the following methodology to calculate the applicable average rebate amount, a specified minimum percentage of which would be required to be applied at the point of sale: . . . • Rebated Drugs: We are considering requiring that the average rebate amount be calculated using only drugs for which manufacturers provide rebates…Additionally, we would likely consider each drug product with a unique 11-digit national drug code (NDC) separately for purposes of calculating the average rebate Amount…We solicit comment on whether specifying such a requirement would also serve to ensure consistency in how average rebates are calculated across sponsors, which would make prices more comparable across Part D plans and enforcement easier.	If CMS proceeds with this proposed rule, a methodology of a weighted average at the NDC level is the only methodology that could be feasible. Other approaches would provide for even more complicated reconciliation.
17.c.(2) Applicable Average Rebate Amount	56422 (PDF 87)	We are also particularly interested in stakeholder feedback regarding the following methodology to calculate the applicable average rebate amount, a specified minimum percentage of which would be required to be applied at the point of sale: . . . • Drug Category or Class: We are considering requiring that the manufacturer rebate amount applied to the point-of-sale price for a covered drug be based on the plan's average rebate amount calculated for the rebated drugs in the same category or class. We are considering requiring sponsors to determine the average rebate amount at the therapeutic	PerformRx would not support the methodology of "Drug Category or Class." Drug classes change too frequently to provide for an accurate weighted average. Some drug classes contain both rebate and non-rebate products.

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		category or class level, rather than a drug-specific rebate amount, in order to maintain the confidentiality of any manufacturer sponsor/PBM pricing relationship with respect to an individual drug . . .	
17.c.(5) Additional Considerations	56426 (PDF 91)	We seek comment on the extent to which a point-of-sale rebate policy might be expected to further align the incentives for beneficiaries, sponsors, and taxpayers . . . We solicit comment on whether basing the rebate applied at the point of sale on average rebates at the drug category/class level, as described previously, would meaningfully increase price transparency over the status quo by ensuring a consistent percentage of the rebates received are reflected in the price at the point of sale, while also protecting the details of any manufacturer-sponsor pricing relationship.	PerformRx believes it would be extremely difficult to operationalize the rule because rebates are not received for all drugs. This would be especially true because of the potential of a manufacturer rejecting a rebate at the end of the year. For example, the pharmacy is a 340B pharmacy, but that is not known until the end of the year. These rejections would make POS estimates difficult. Further, the coverage determination process may result in POS for a non-rebatable product. All of this would provide for inaccurate weighted estimates. That is precisely why sponsors report DIR at the end of the year. Reconciliation would be complicated because manufacturers do not pay pharmacies. The pharmacy would still need to be paid the full cost of the drug. So, sponsors would have to pay pharmacies the full cost of the drug. This would mean that the sponsor subsidizes the reduction in cost sharing at the pharmacy. Sponsors would thus bear the risk of reconciliation and of being made whole at the end of the year. Premiums would have to be adjusted upward to account for losses incurred at POS. CMS agrees that the rule would result in plan premium increases. The proposed rule would also result in excessive PDE adjustments. Because of the inability to estimate accurately, sponsors would need to engage in extensive PDE adjustment. This would also cause an administrative burden on CMS.
17.d.(1) All Pharmacy Price Concessions	56426 (PDF 91)	We are considering revising the definition of negotiated price at § 423.100 to remove the reasonably determined exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy.	As explained above, PerformRx also has serious concerns about this part of the proposed regulation. We are concerned that this part of the proposed regulation also would interfere with private contracts between the PBM and pharmaceutical manufacturers. We again ask CMS to please reconsider this rule in light of the aforementioned Presidential Executive Orders.
B. Improving the CMS Customer Experience			
10. Part D Prescriber Preclusion List			
10.(3)b.(2) Targeted Approach to Part D Prescribers	56443 – 56444 (PDF 108 – 109)	The process we envision and propose, which would replace the prescriber enrollment requirement outlined in § 423.120(c)(6) with a claims payment-oriented approach, would consist of the following components: . . . We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of prescribers in the Medicare Part D program . . . We thus propose to revise § 423.120(c)(6), as further specified in this proposed rule, to require that a Part D plan sponsor must reject, or must require its PBM to reject, a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug prescribed by an individual on the preclusion list.	First, PerformRx is concerned that the proposed rule would result in additional regulation contrary to Presidential Executive Order # 13771 on Reducing Regulation and Controlling Regulatory Costs and Presidential Executive Order # 13777 on Enforcing the Regulatory Reform Agenda. Even though CMS proposes to eliminate part of the prescriber enrollment requirement, we see increased regulation through the proposed rule. We ask CMS to please reconsider this rule in light of the aforementioned Executive Orders. PerformRx agrees, however, that if CMS implements this program, it should not be retrospective, to avoid complications in PDE reconciliation.
10.(3)b.(2)(ii) Updates to Preclusion List	56444 – 56445 (PDF 109 – 110)	The preclusion list would be updated on a monthly basis. Prescribers would be added or removed from the list based on CMS' internal data that indicate, for instance: (1) Prescribers who have recently been convicted of a felony that, consistent with § 424.535(a)(33), CMS determines to be detrimental to the best interests of the Medicare program, and (2) prescribers whose reenrollment bars have expired. As a particular prescriber's status with respect to the preclusion list changes, the applicable provisions of § 423.120(c)(6) would control . . . [We] propose to keep an unenrolled prescriber on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber had he or she been enrolled and then revoked . . .	PerformRx is concerned that CMS' preclusion list would not be aligned with state lists. Impact on the beneficiary at POS would not be aligned between state and federal processes. This would be particularly relevant for an MMP beneficiary. The 21st Century Cures Act now requires prescriber enrollment for Medicaid providers. States are phasing in the requirement.