Proposed Rule 4182-P Comments: MII Life, Incorporated

| 1. ***Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability*** | | |
| --- | --- | --- |
| **Section** | **CMS Proposal** | **Comments** |
| Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions *Pg. 56340-60* | **Frequently Abused Drug** *Pg. 56343*  CMS proposed that for plan year 2019, consistent with current policy, opioids are frequently abused drugs. | We encourage CMS to consider the addition of Gabapentin to the list of frequently abused drugs. This drug is already being identified by some states as a potential drug of abuse. It can be used to potentiate the euphoric effects of opiates or fend off withdrawal symptoms. |
|  | **Clinical Guidelines and Program Size**  **At-Risk Beneficiaries & Those Potentially At-Risk** *Pg. 56345*  The clinical guidelines for use in drug management programs that CMS is proposing for 2019 include… Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies *OR* 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. | We believe that CMS’ proposed guidelines do not go far enough to support efforts to decrease doctor and pharmacy shopping. We recommend identifying at-risk beneficiaries using the 90 mg MME and either: a guideline of 2 or more opioid prescribers and 2 or more opioid dispensing pharmacies **OR** 3 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. We would support CMS discussing elimination of the MME altogether if the number of unique prescribers reached 5. This could help identify potential at-risk utilizers before a high MME threshold is reached. |
|  | **Chain Pharmacies** *Pg. 56345*  CMS proposes that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines. | We recommend that CMS not consider multiple locations as one pharmacy. The standard of care and interpretation of utilization between pharmacies can vary widely, even within pharmacy chains. Medical providers can establish and share a care plan, whereas pharmacists don’t have a similar tool nor access to the medical providers’ documentation. We can’t assume different pharmacy locations have similar information. |
|  | **Exempted Beneficiaries** *Pg. 56346-7*  An exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long- term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or (3) Has a cancer diagnosis. | We support CMS’ proposed list of exempted beneficiary categories, however, please clarify that LTC facilities means those staffed with medical personnel. Group homes and other assisted living facilities with non-medical staff should not be exempt as this status is not readily available to plans. We recommend that CMS specify “active” cancer diagnosis in exemption (3). |
|  | **Sponsor Requirements** *Pg. 56349*  CMS proposes that the sponsor must first obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management, in light of the risk to the beneficiary’s health. | We ask that CMS consider making prescriber agreement highly recommended rather than required. This would allow plans to move forward with restrictions, even if prescribers are non-responsive or that perhaps are prescribing in ways that may be contributing to a beneficiary’s at-risk status.  This is particularly important for stand-alone Part D plans that do not have contractual relationships with prescribers.      In addition, we ask that CMS look at ways to address how care management is impacted by varying state laws. For example, the Minnesota Privacy Rule does not allow health plans to share drug information prescribed by Doctor A with Doctor B, and vice versa, without patient consent. Instead we are expected to refer doctors to a state-sponsored opioid utilization database to review prescriptions prescribed for their patients (prescribers aren’t required to use this database). This slows down how quickly information can be shared and acted upon and can result in prescribers that have incomplete information on which to base their opinion. In addition, these extra steps in the process only increase the likelihood of inaction on the prescriber’s part. |
|  | **Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s)** *Pg. 56354*  A sponsor may not limit an at-risk beneficiary’s access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. | We believe the 6-month timeframe is too long to wait before beginning the process of prescriber lock-in, considering that CMS has already done some analysis to identify the beneficiary in OMS. The process to implement lock-in, including prescriber lock-in if appropriate, should begin as soon as possible after member notification requirements are met. This would allow sponsors to intervene early against misuse or abuse of opioids. |
|  | **Selection of Pharmacies and Prescribers** *Pg. 56356*  Under CMS’ proposal, the beneficiary could submit preferences for in-network prescribers and pharmacies from which to obtain frequently abused at any time. | We recommend that CMS place limits on beneficiary preference changes, since having no limitations would defeat the purpose of the lock-in. We suggest an allowance of one change per calendar year at the member’s discretion and additional changes if there is a material address change. This would establish a base number of changes allowed industry-wide, but allow Plans to be more generous if they so choose. We also recommend that the pharmacy lock-in should be to a single location, not the whole chain. |
|  | **Confirmation of Pharmacy and Prescriber Selection** *Pg. 56357*CMS proposes that plan sponsors can obtain a network provider’s confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries’ selected prescriber or pharmacy, as applicable. In these cases, the network provider would agree to forgo providing specific confirmation if selected under a drug management program to serve an at-risk beneficiary. …Absent a provision in the network contract, however, the sponsor would be required to receive confirmation from the prescriber(s) and/ or pharmacy that the selection is accepted before conveying this information to the at-risk beneficiary. | The requirement to get confirmation from prescribers would create additional barriers and administrative burden for stand-alone Part D Plans, since they do not hold contracts with prescribers. Furthermore, it is unclear how this process would work if the prescriber was non-responsive in earlier phases of the review process.  We suggest that CMS consider a modified approach and recommend that this confirmation be required only in instances where the Plan Sponsor chooses to restrict a beneficiary to a pharmacy or prescriber without regard to the beneficiary’s preference. |
|  | **Initial Written Notice** *Pg. 56350*  CMS would require that the notice use language…that provides the following information…(2) A description of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits);  (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… | We believe the initial letter, sent upon determination that prescriber involvement is warranted, should serve only as notification of interaction with prescribers which could lead to a drug utilization management program based on the findings.   We ask CMS to consider whether or not this initial notice is the appropriate point at which to offer additional resources to beneficiaries.  At this point in the process the beneficiary has been determined to be potentially at-risk, but the assumption that there is an issue of misuse or abuse is premature, and could impede our ability to work collaboratively with the beneficiary.  As such, we recommend that offering of resources and counseling services should wait until the second letter when the beneficiary has been determined to be at-risk. We also ask CMS to provide additional detail as to what specific additional resources CMS is referencing.  Furthermore, we believe that since this initial letter should serve only as a notice, it should not include rights to a *Coverage Determination* or *Redetermination*, since neither would apply based on HPMS memo dated 9/6/2012 titled “*Related to Improving Drug Utilization Review Controls in Part D*”.  Page 8 of this memo indicated that “…Opioid overutilization programs created by the sponsor are to fit within existing coverage determination, appeal, and grievance rules, as set forth at 42 CFR 423 Subpart M and Chapter 18 of the Medicare Prescription Drug Benefit Manual. If a sponsor determines that a beneficiary is overutilizing an opioid and implements a beneficiary-level edit to prevent overutilization, the beneficiary will have a right to request a coverage determination. Imposing an edit in this case does not constitute a coverage determination, but the plan must process the beneficiary or a prescriber dispute of the edit as a coverage determination. All such coverage determinations should be handled as exceptions requests.”  As such, we ask that CMS align this guidance with the previously issued guidance, so that second notice, not the initial notice, would provide the beneficiary with the right to request a *Coverage* *Determination*. |
|  | **Second Written Notice** *Pg. 56351*  …also includes: Explanation of the beneficiary’s right to a redetermination, description of standard and expedited redetermination process, including beneficiary’s rights to and conditions for obtaining an expedited process | Previous guidance provided by CMS (see HPMS memo dated 9/6/2012 titled “S*upplemental Guidance Related to Improving Drug Utilization Review Controls in Part D*”) indicated (PG. 8) that “…Opioid overutilization programs created by the sponsor are to fit within existing coverage determination, appeal, and grievance rules, as set forth at 42 CFR 423 Subpart M and Chapter 18 of the Medicare Prescription Drug Benefit Manual. If a sponsor determines that a beneficiary is overutilizing an opioid and implements a beneficiary-level edit to prevent overutilization, the beneficiary will have a right to request a coverage determination. Imposing an edit in this case does not constitute a coverage determination, but the plan must process the beneficiary or a prescriber dispute of the edit as a coverage determination. All such coverage determinations should be handled as exceptions requests.”  As such, we ask that CMS align this guidance with the previously issued guidance, so that the second notice would provide the beneficiary with the right to request a *Coverage* *Determination*, rather than a *Redetermination*.  We also ask that CMS clarify whether these are required to be handled based on the timeframes for a *Request for Benefit* or *Request for Payment*, and whether or not these are subject to the *Expedited* timeframes.  Lastly, we ask CMS to provide Plans and IREs direction as to what documentation will be required to support these appeals at the IRE level. |
|  | **Termination of a Potential At-Risk or At-Risk Status** *Pg. 56359*  The identification of an at-risk beneficiary as such shall terminate as of the earlier of the following—…(ii)The end of a 12-calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section. | The 12-calendar month period seems arbitrary. This should instead be a decision based in case management and specific to each beneficiary’s unique situation.  We recommend that, prior to the expiration of the 12-month period, the sponsor would evaluate whether the status should continue. If the sponsor determines that the beneficiary’s status remains “at-risk”, the designation would continue for another 12-month period or sooner based on sponsor determination. |
| 9. Part D Tiering Exceptions *Pg. 56371-73* | Proposes several clarifications to the tiering exception process:   * Approved tiering exceptions for a brand or biologic product would be assigned to the lowest applicable cost-sharing associated with alternatives that are brands or biologics, respectively * Approved tiering exceptions for a generic drug would be assigned to the lowest applicable cost-sharing for a brand or generic alternative * Sponsors are not required to apply lower cost-sharing tiering exceptions to Part D drugs, including biologics, placed in a sponsor’s specialty tier (unless the specialty tier drug is the lower cost alternative of a higher cost drug) * If a drug has alternatives on multiple lower cost-sharing tiers, then an approved tiering exception would be assigned to the lowest cost-sharing level for those alternatives   1. An “alternative drug” available as a tiering or formulary exception is a drug “for treatment of the same condition of the enrollee.” This, the drug must be an appropriate alternative therapy taking into consideration the individual’s specific clinical condition | Please provide additional clarification on CMS’ expectation in this area as it relates to coinsurance cost-sharing.  Would a plan be expected to determine if the coinsurance on the Specialty tier results in a lower cost-sharing than the copay on any other tier (which would vary depending on the drug cost, pharmacy pricing and day supply)?  Would the same evaluation be expected for other copay vs. coinsurance tiers? We recommend that CMS include language in this section which clearly indicates that, for purposes of Part D tier-exceptions, a flat copay is always assumed to be a better benefit when compared to coinsurance, since a flat copay is known and predictable to the beneficiary while coinsurance will vary based on multiple factors (such as drug cost, pharmacy pricing and days supply).  Although the existence of a biological on a tier other than the specialty tier is unlikely due to cost, CMS notes that tier exceptions should be assigned to the lowest tier containing biological alternatives.  Earlier in this section, CMS states, “eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug(s) **for treatment of the enrollee’s health condition**” (emphasis added).  CMS has previously clarified that “alternative” drugs do not need to be in the same class of drugs, yet this language seems to imply that **only** biological alternatives should be considered as alternatives. Biologicals as a category do not exist in the formulary structure today.  We recommend adding clarifying language to the definition of “alternative drug” including how to address biologicals. We also ask that CMS consider adding a drug’s mechanism of action in determining an appropriate alternative. |
| 10. Establishing Limitations for the Part D Special Election Period for Dually Eligible Beneficiaries  *Pg. 56373-75* | Proposes to change the current continuous SEP rules for dually eligible beneficiaries to a more limited set of rules that would apply to both PDP and MA-PD plans. | How will a new plan know that the beneficiary has the SEP available to them? Please clarify whether the information needed to implement will be in BEQ. |
| 11. MA and Part D Prescription Drug Plan Quality Rating System  *Pg. 56375-407* | **Stakeholder Feedback on Specific Topics** *Pg. 56377*  Whether CMS’ current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality. | We do not feel that the existing cut points accurately reflect plan quality. For measures such as those from the CAHPS results and Complaints, it appears that most plans are performing well, moving cut-points in a way where plans that are performing adequately are being identified as “poor” performers. Further, the narrowness of rating levels from 5 Star to 1 Star calls to question the accuracy of the rating system overall, e.g. 7% for Rating of the Drug Plan, 5% for Getting Needed Prescription Drugs, 0.26 points for Complaints, and others. At a minimum, CMS should eliminate the lowest Star ratings for measures in which plans are all performing at a level that in any other situation would be considered at least good (and we feel that would include a positive rating of over 75% by members in any “satisfaction” category – especially give the overall inaccuracy of member survey responses which may be influenced by issues not related to plan operations or performance (e.g. prescriber issues or failure to make informed decisions due to not reviewing one’s Annual Notice of Change)).  We believe that the following measures have issues which result in inaccurate reflections of plan performance:   * Measure D05: Members Choosing to Leave the Plan * Measure D08: Rating of the Drug Plan * Measure D09: Ease of Getting Needed Prescriptions * Measure D04: Complaints * Measure D01: TTY/Foreign Language Call Center Accessibility * Measure D03: Appeals Upheld: Fairness of Plan’s Denial * Measure D07: Quality Improvement * Measure D14: Medication Therapy Management   We are in favor of CMS re-implementing use of pre-determined cut points for CAHPS measures and other select measures, so that the result is both logical and statistically valid when translated to a Star rating level. |
|  | **Stakeholder Feedback on Specific Topics** *Pg. 56377*  Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted. | We recommend that CMS conduct analysis on how plan size impacts ratings for individual measures. Our data is showing geographic variation in plans that are running on the same platform (particularly related to CAHPs scores). Given that we have both a large multi-state plan and a small, single state plan running on exactly the same operational platforms, with support provided by the same personnel, and offering similar product designs, we find it difficult to reconcile the radical differences in CAHPS and other measure scores between the plans and believe it to be the impact of geography and/or LIS membership levels, depending upon the measure. We recommend that these differences be examined and addressed in order to produce a more accurate rating for plans.  We also believe that there may be some influence on adherence rates for border states where certain members are, for instance, obtaining their medications in Mexico due to pricing. While these members are adherent in taking their prescribed medications, they are not having claims run through the plan and therefore, are underrepresented in the Acumen adherence reporting. We would like CMS to investigate this issue and propose an equitable solution for rating plans impacted by this behavior. |
|  | **e. Contract Ratings** *Pg. 56380*  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 support continuation of calculating the Star Ratings at the contract level and all PBPs under the contract having the same overall and/or summary ratings. |
|  | **f. Contract Consolidations** *Pg. 56380* | We support CMS’ proposal to base Star Ratings on the enrollment-weighted mean of the measure scores of the surviving and consumed contracts. |
|  | **Table 2: Proposed Individual Star Rating Measures for Performance Periods Beginning on or After January 1, 2019** *Pg. 56393* | Medication adherence measures:  Stand-alone part D plans have very little influence over beneficiaries’ medication adherence, because we do not contract with prescribers. As such, we can be penalized for a prescriber’s decision to not follow prescribing guidelines or to discontinue therapy. We ask CMS to create a reporting mechanism that allows plans to identify for removal from the measurement data, those beneficiaries who are “non-adherent” due to documented therapy changes.  In addition, we recommend that CMS require beneficiaries to provide a contact phone number at the time of enrollment in order to assist plans in reaching members to impact adherence.  We recommend weighting MAPD and PDP measures differently based on the plans ability to influence outcomes on a measure (statin use in persons with diabetes for example). PDPs should have less weight placed on measures that largely depend on prescriber behavior over which stand-alone part D plans have very little influence. |
|  | **j. Improvement Measures** *Pg. 56394* | We recommend that CMS modify the current methodology related to how QI measures are calculated to include measures for which plans achieved and maintained at least 4 Stars in the “held harmless” category.  We recommend that CMS remove the CAHPS survey and HOS measures from the improvement factor calculation given their subjectivity. |
|  | **l. Measure-Level Star Ratings** *Pg. 56397*  **l. Measure-Level Star Ratings (continued)** *Pg. 56397*    **l. Measure-Level Star Ratings (continued)** *Pg. 56397*  **l. Measure-Level Star Ratings (continued)** *Pg. 56397* | Appeals Upheld: IRE overturns incorrectly penalize plans as they do not always equate to the plan having made an incorrect decision. In many instances, cases are overturned based on more current and complete information being provided to the Independent Reviewer than was available to the plan. A mechanism for removal of cases where such information was provided to the IRE that was not available to the plan should be part of the measure methodology.  Disenrollment Rate: We believe that results for this measure are heavily influenced by the pricing strategies that plans use as a competitive advantage to attract membership during the AEP and by demographics of plan membership rather than the actual patient experience provided by the plan. We recommend that CMS revise this measure’s specifications to accurately capture the member experience to ensure that the voluntary disenrollment was the direct result of the inadequate/unsatisfactory services and care delivery provided by the plan and not due to the PBP components such as cost and coverage.  CAHPS Survey Measures: We believe that CMS needs to consider alternative CAHPS survey questions that will provide member responses that more closely reflect their experience with the drug plan and the plan’s ability to provide the necessary and timely service and care needed by the beneficiary, as well as to provide information which is actionable to the plan in cases of actual performance issues. Given the subjectivity of surveys in general and the amount of money spent by the collective plans on these surveys annually, allowing plans to pose additional questions, the answers to which can be used to both validate and clarify the reasons for members’ responses, seems a reasonable improvement. Use of such questions have historically been denied as creating too much of a time burden for beneficiaries, however, we believe that those types of questions are critical to the accuracy of outcomes for these Star measures. Until new methods are implemented and tested, we believe that CMS should reduce the weighting or move these measures to the display page.  Complaints about the Drug Plan: In addition to certain operational issues that we have seen with the CTM system, we would like CMS to revisit the scoring methodology which we believe unduly penalizes plans with very small membership.  Foreign Language Interpreter and TTY Availability: We recommend that CMS revise the languages included and the testing frequency to ensure that the testing results accurately reflect the Medicare beneficiary experience. The current methodology should be revised to ensure foreign language testing volumes align with languages most commonly spoken by Medicare beneficiaries; and CMS should also consider aligning foreign language testing volumes to the demographics served by each contract.  Drug Plan Quality Improvement: While we support inclusion of the Quality Improvement (QI) measure as a part of the Star Ratings System, we are very concerned about the underlying methodology flaws that do not allow equitable opportunity for both the high and low performers, given there is limited room for improvement for high performers compared to their low performing counterparts. We also urge CMS to review the measures that are included as a part of the QI measure calculation to ensure that, performance improvement on these measures is under the control of the plan and that the measures included are not those for which virtually all plans have achieved peak performance since there is then little to no opportunity to improve performance for those measures.  MTM Program Completion Rate for CMR:  We would like CMS to consider replacing the current process measure with outcome-based and/or patient-experience based MTM measures, such as those that are currently under development by the Pharmacy Quality Alliance (PQA)’s MTM task force.The two measures under development are:   * Next Generation MTM Measure: Diabetes (an Outcome-based measure) * MTM: Medication Therapy Problem Resolution (A Patient Experience-based measure).   We recommend that CMS partner with PQA to develop and understand the feasibility of implementing the outcome and/or patient-experience based MTM measures, especially related to the Next Generation MTM Measure: Diabetes, given the increasing prevalence and downstream impact of this disease state. We strongly feel that outcomes measures such as the above are better aligned with the quality of care provided to beneficiaries through an MTM interaction and overall impact on health outcomes. Until outcomes based MTM measures are adopted, we recommend CMS consider adjustment to the measure to evaluate true differences in plan performance. CMS could consider adjustments based on contract size, targeting criteria, overall health of the population, and geographical location to solve for differences in number of members who qualify for the measure and a plan’s ability to complete the CMR.  Adherence Measures: We are seeing a very significant negative impact by LIS members on adherence measures, which is exacerbated for a plan with relatively small (under 15,000) membership. In one case, the difference in adherence between LIS and non-LIS was approximately 20%, dragging the score for the plan for the measure down dramatically. Due to the difficulty contacting LIS members (lack of phone numbers, etc.) and influencing member adherence behavior, we believe that additional adjustment (in addition to the CAI) should be considered by CMS for plans showing this type of disparity. |
|  | **q. Measure Weights** *Pg. 56401*  We are considering increasing the weight of the patient experience/complaints and access measures and are interested in stakeholder feedback on this potential change in order to reflect better the importance of these issues in plan performance. | We do not support an increase in weights to the patient experience set of Star measures. CMS has indicated that the Star measures should be selected based on plans’ ability to influence them. Given that context, contracts have little control, if any, over the patient experience measures performance and increasing their weight will adversely impact plan performance with little added benefit to the beneficiaries. These include: Members Choosing to Leave the Plan, Rating of the Drug Plan or Getting Needed Prescriptions, and Complaints, which we do not believe are accurate reflections of a member’s experience with the plan’s quality of services.  We further recommend that CMS weight certain measures differently for MAPD and PDP plans, based on the plan’s ability to influence outcomes on a measure (statin use in persons with diabetes for example). PDPs should have less weight placed on measures that largely depend on provider behavior, which they have very little ability to impact. |
|  | **t. Categorical Adjustment Index** *Pg. 56404* | We recommend that CMS revisit how the CAI is developed for each plan and normalize measure performance disparity in LIS vs non-LIS plan populations. Small plans, in particular, are in need of adjustments for differences in these populations which impact Star measure performance. In particular, we are seeing a very significant negative impact by LIS members on adherence measures, which is exacerbated for a plan with relatively small (under 15,000) membership. In one case, the difference in adherence between LIS and non-LIS was approximately 20%, dragging the score for the plan for the measure down dramatically. Due to the difficulty contacting LIS members (lack of phone numbers, etc.) and influencing member adherence behavior, we believe that additional adjustment, in the CAI or by some other method, should be considered by CMS for plans showing this type of disparity. |
|  | **u. High and Low Performing Icons** *Pg. 56406* | We recommend that CMS include a full explanation for beneficiaries, in easily understandable language, when a low-performing icon is assigned to a plan. This explanation should include measures where the individual plan fell short and factors that may have influenced the result that are not within the control of the plan. |
|  | **v. Plan Preview of Star Ratings** *Pg. 56407* | We recommend that CMS release data on individual measures (for instance, the disenrollment score) as the final data becomes available rather than releasing the majority of data during the plan preview periods. By doing this, plans can better identify issues with the scoring data in a timely manner. When data is released en masse and so late in the process, it is very difficult for a plan to gather the documentation in a timely manner in order to provide CMS with the information needed to correct an erroneous measure result. |
| 12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types  *Pg. 56410-11* | **c. Treatment of Accreditation and Other Similarly Any Willing Pharmacy Requirements in Standard Terms and Conditions** *Pg. 56410* | Please clarify CMS does not intend to extend the any willing pharmacy (AWP) requirements to preferred pharmacy networks. We do not believe it is in the best interests of the Part D program to extend AWP rules into preferred pharmacy networks. These networks incent high-performing pharmacies to offer deeper discount pricing which in turn results in decreased costs to members and the Part D program. |
|  | **d. Timing of Contracting Requirements** *Pg. 56411*  Standard terms and conditions must be provided to requesting pharmacies within 2 business days of receipt of request | A 2 business-day timeframe does not allow plans sufficient time to process and act upon a request for terms and conditions or confidentiality agreement. We recommend a 14-calendar day requirement for provision of terms and conditions and confidentiality agreements. |
| 13. Changes to the Days’ Supply Required by the Part D Transition Process *Pg. 56411-12* | * Proposes to change the transition days’ supply for long term care (LTC) setting from 91+ days to the same as in the outpatient setting * Proposes to change the outpatient days supply from “30 days” to “a month’s supply” | We recommend leaving the outpatient days supply at 30 days with usual exceptions based on packaging size. |
| 14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes  *Pg. 56413-16* | Proposes to permit Part D sponsors to immediately remove or change the preferred or tiered cost-sharing of, brand drugs and substitute or add therapeutically equivalent generic drugs instead of, for example, in the next month, and permits implementation at any time of the year. | We support this change. |
| 16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences  *Pg. 56417-19* | Proposes to retain but modify the meaningful difference requirement for Part D plans.  Proposes to eliminate threshold differentials to distinguish two enhanced alternative plans offered by the same parent organization in the same region. | We support these provisions. |
| 17. RFI Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at POS *Pg. 56419-28* |  | As CMS outlines, manufacturer rebates are an integral part of the Part D program.  The current process of applying the rebates after the point of sale (POS) helps keep member premiums low and helps incentivize generic drug usage.  The application of manufacturer rebates at POS will increase premiums for all members.  We have conducted an analysis on our block of business and the only entity that always gains from this approach is the manufacturers.  Members using generic drugs will pay more in their member premiums. Manufacturers pay out less under this proposal, while CMS, plans and members all pay out more in total.  We would like to address two specific issues CMS raises in the proposed rule:   1. *CMS believes the current methodology promotes an incentive to under-forecast DIR*.  The under projection of DIR is not related to any incentive, rather the difficulty PBMs have in helping plans project their rebate levels. Furthermore, this trend has appeared to already have started change and the DIR used in bids we completed for 2016 and 2017 are close or have exceeded actual levels.  Given the issues with generic launches over the years and the difficulty projecting when the launch will ultimately occur, it can cause some year’s projections to be understated and others to be overstated.  As a health plan, we do not believe there is an incentive to under-project DIR.  The member premium is a key component for many purchasers and so plans have incentive to have the lowest premiums.  Therefore, plans are incented to accurately project the DIR levels to attract the maximum number of members to their plans. 2. *CMS believes plans prefer to have high cost drugs on their formularies*.  Plans focus on the total cost of the program and how to keep overall allowed trends low.  Overall allowed pharmacy trend levels (trends prior to inclusion of rebates) have remained consistently low over the past several years.  This reflects the plans focus on total costs, not only their ultimate plan liability net of rebates.  Plans and PBMs make decisions on how to reduce trends not increase trends by adding on high cost drugs.  If this were the case, CMS would see incredibly large unit cost trends in the bids.  This is not the case for the bids we submit.  If this is occurring in some plans bids, we would suggest CMS work with those specific plans rather than employ a strategy that will ultimately impact most stakeholders negatively. |

| Improving the CMS Customer Experience | |  |
| --- | --- | --- |
| **Section** | **CMS Proposal** | **Comments** |
| Reducing the Burden of the Compliance Program Training Requirements  *Pg. 56429-31* | Proposes to eliminate the requirements for first-tier, downstream and related entities (FDRs) compliance training. | We support this provision. |
| Revisions to Parts 422 and 423, Subpart V, Communication /Marketing Materials and Activities *Pg. 56433-37* | c. Prohibition of Marketing During the Open Enrollment Period  We welcome comment on how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as through mailing campaigns aimed at a more general audience. | We agree that it would be difficult for a plan to limit marketing to only those who have not yet enrolled in a plan during the OEP. The “knowing” standard seems to be a reasonable solution. We oppose applying an overly broad marketing prohibition to all potential beneficiaries during the open enrollment period. |
| Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations  *Pg. 56437-38* | Proposes to increase the timeframe for issuing decisions on payment redeterminations and independent review entity (IRE) reconsiderations from 7 to 14 calendar days from the date the plan sponsor receives the request | We support the increase in these timeframes. Additionally, we encourage CMS to consider increasing the timeframe for coverage determinations. |

| Implementing Other Changes | |  |
| --- | --- | --- |
| **Section** | **CMS Proposal** | **Comments** |
| Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements *Pg. 56456-60* | Reduces MLR reporting to four data elements: Organization Name, Contract Number, Adjusted MLR percentage, Remittance Amount (if MLR is under 85%) | We support the reduction of burden in the MLR reporting, however, we request that CMS continue to produce and make available form CMS-10476. This form is very useful in our calculations for the MLR. |