**Advance Notice of Methodological Changes for CY 2019 for Medicare Advantage, Part D and 2019 Call Letter Draft**

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| **Section/Page #** | **CMS Proposal** | **Comments** |
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| 1. **Parts C and D** |  |  |
| **Enhancements to the 2019 Star Ratings and Future Measurement Concepts** | |  |
| Removal of Measures Pg 112 | Retire current BAPP for 2019 star ratings. Modify to only include Compliance Activity Module (CAM) data and be on display page for 2019 star ratings. | We recommend retiring this measure permanently in a move toward separating auditing and enforcement activities from STAR ratings. Inconsistencies in notices of non-compliance and warning letters amongst different organizations are cause for concern when considering impact to STARs. |
| Data Integrity  Pg 113 | Propose to define a contract as non-compliant if it either receives a “No” or a 1, 2, or 3 on the 5-point Likert scale in the specific data element’s data validation. | There are hundreds of data points in data validation. Receiving a ‘no’ on any one element would not necessarily mean an entire contract is non-compliant.  Please clarify that the proposal is to define a specific data element for a contract as non-compliant if it scores 3 or less, as opposed to the entire contract being non-compliant. |
| **Validation Audits** | |  |
| Threshold for Requiring an Independent Validation Audit Pg. 160 | Change threshold from >5 program audit conditions to >5 non-CPE conditions cited in final audit report. | We support this change and thank the agency for addressing this issue. |
| **Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice** | |  |
| Pg. 164 | Starting with 2019 AEP, CMS intends to display icon on Plan Finder for organizations that have received a CMP in 2018 (or receives a CMP for a 2017 Program Audit.) | This provision raises numerous concerns.   * It is not clear how this information would be helpful to beneficiaries. The icon itself would not provide useful information as the reasons for CMP can vary widely. * The CMP letters CMS suggests would be linked to the icon do not use beneficiary-friendly language and would be very difficult for them to fully understand. The letters include Federal Register and CMS Manual references that most beneficiaries wouldn’t know where to locate. * The link doesn’t provide any context for beneficiaries as to how common a finding may be across contractors. * Beneficiaries have no knowledge of how the dollar amounts for CMPs are determined. Amounts that are calculated on a per beneficiary basis will appear more serious in a larger plan than a small plan. * This again raises the issue of fairness in that many CMPs are based on audit findings and not all plans are audited every year.   In addition, it is not clear how long the icon would be displayed or what would happen if the CMP were in the appeal process. |
| **Audit of the Sponsoring Organization’s Compliance Program Effectiveness** | |  |
| Pg. 166 | Considering allowing sponsoring organizations that have undergone a program audit to count it as meeting the annual compliance program audit requirement for one year from the date of the CMS program audit. How would this impact burden for organizations undergoing a program audit? | We strongly support this provision. It is a more efficient use of resources for plans and CMS. |
| 1. **Part D** |  |  |
| Improving Drug Utilization Review Controls in Medicare Part D | |  |
| Retrospective DUR  *OMS Metrics*  Pg. 205 | Propose to report a second Opioid Daily Dose rate with a 90 MME threshold  Therefore, in the April 2018 OMS reports, CMS will report:   * 90 MME Opioid Daily Dose rate: # opioid days > 90 MME/1000 Opioid utilization days during the last 6 months. * 120 MME Opioid Daily Dose rate: # opioid days > 120 MME/1000 Opioid utilization days during the last 6 months.   Propose to discontinue reporting the 120 MME Opioid Daily Dose rate in the 2019 OMS reports. | We recommend discontinuing reporting the 120 MME Opioid Daily Dose rate for 2018 as it is no longer relevant to the OMS targeting and is not in alignment with CDC recommended maximum MME of 90 mg/day. |
| Cumulative MME Daily Safety Edits for High, Chronic Prescription Opioid Users Pg. 209-12 | Propose that all sponsors should implement a hard edit in 2019 triggered when cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME). Sponsors should not include multiple prescriber or multiple pharmacy criteria in these edits. Continue to apply specifications to account for known exceptions. Don’t impede access to medication-assisted treatment (buprenorphine).  CMS generally expects coverage determination requests seeking exceptions to the MME edit to meet criteria for expedited review (24 hours) | We do not support this change because the 7-day supply presents challenges, including the following:  A prescription written for more than 7-day supply would require the beneficiary to return to their prescriber for a new prescription for the 7-day supply for schedule II drugs, and again for subsequent fills. We believe this may inadvertently drive patients to emergency departments.  The expedited review period may result in requests being denied due to lack of information as this may not provide enough time to reach a prescriber and get a response, particularly on weekends/holidays. We recommend that CMS not require all coverage determination requests for a rejected POS edit be treated as expedited (unless requested by the beneficiary or the prescriber). |
| Days Supply Limits for Opioid Naïve Patients  Pg. 212 | Expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain.  Would a days supply limit with or without a daily dose maximum (e.g., 50 MME per day) be more effective?  Request information on both inclusions and exceptions for specific clinical situations (i.e., whether and to what extent a supply limit could be based on specific indications or other criteria) and other parameters and what safeguards should be in place to protect appropriate beneficiary access. | Plans need clarification as to how “acute pain” and “opioid naive” would be defined.  We do not recommend adding an MME limit in addition to the 7 days’ supply. This would make the development of the edit more complex and not realistic for 1/1/19 effective. It would also be difficult to explain the complexities to beneficiaries.  Beneficiaries in LTC facilities should be exempt from the initial fill for acute pain requirement.  Please provide guidance as to what plans should do when there is no prior claims history (new to plan).  See also the comments above related to Cumulative MME Daily Safety Edits. They would also be of concern with this provision. |
| Opioid Duplicative Therapy Safety Edits  Pg. 215 | Expect all Part D plan sponsors to implement a soft POS edit for duplicative LA opioid therapy beginning in 2019, with or without a multiple prescriber criterion.  We also recognize that multiple opioid POS edits could potentially  generate a combination of messages and soft or hard rejects that may cause confusion. Therefore, we recommend that contracts create a hierarchy for the opioid POS edit messaging in an effort to reduce confusion. | Multiple opioid edits could create confusion at POS. It will be important for all plans to utilize the same hierarchy for edits. We recommend that CMS develop a standard hierarchy list with input from PCMA and NCPDP. |
| Access to Medication-Assisted Treatment  Pg. 216 | Benefit designs that would substantially discourage enrollment by beneficiaries who need these therapies will not be approved.  Avoid placing generic drugs indicated for MAT in brand tiers. CMS will not approve PA criteria that requires a beneficiary to  need an authorization any more frequently than once during a plan year. Further, when a sponsor has authorized MAT for a beneficiary in the prior plan year, we expect that the sponsor would carry that authorization through to the next plan year. | The highlighted text indicating CMS expects a sponsor to carry an authorization through to the next plan year is inconsistent with current guidance in Chapter 18 of the Prescription Drug Benefit Manual Section 30.2. |
| Using the Best Available Information when making B vs. D Coverage Determinations for Immunosuppressants and Inhalation DME Supply Drugs | | |
| Immunosuppressants Used to Prevent Transplant Rejection  Pg. 218-20 | *No Prior Part D Claims History for Immunosuppressants*  - plans are expected to rely on CMS information and cannot cover immunosuppressants under Part D even if information is also provided by the prescriber that indicates that the transplant was not Medicare covered  -if plan has not received info from CMS or from a prescriber, default to covering under Part D (no longer have to reach out to prescribers) | We appreciate CMS’ efforts to improve accuracy and efficiency in the B vs. D decision process. However, the recommended changes will require plans to continue accepting information from multiple sources and overriding system functionality to apply the expected result. For example, information from the prescriber that the transplant was not Medicare-covered is often “unreliable” per the draft Call Letter language. But information from the prescriber that indicates the transplant *was* Medicare-covered should be used to prevent Part D payment. We recommend CMS allow plans to rely on a single source of truth (MARx) in processing immunosuppressants. In the instance where CMS confirms a Medicare-covered transplant during an audit, we would recommend that CMS initiate the change in MARx so that claims can begin rejecting under Part D going forward. |
| *Prior Part D Claims History AND MARx currently indicates that Medicare covered transplant*  -Sponsor must now rely on MARx going forward and notify enrollee that plan can no longer cover |
| *Prior Part D Claims History, no MARx indicator BUT Part D sponsor receives info from CMS that transplant was covered by Medicare*  -Sponsor must now rely on CMS information going forward and provide notice to the enrollee that the plan will no longer cover |