

CMS-4182-P (Medicare Program; 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)

January 16, 2018

The Pennsylvania Department of Aging and Pennsylvania Department of Human Services offer the following comments on CMS's proposed changes and updates for Medicare Advantage and the Prescription Drug Benefit Program. Specific interest is given as it relates to individuals dually eligible for Medicare and Medicaid and Pennsylvania's Pharmaceutical Assistance Program for the Elderly (hereinafter called the PACE Program).

CMS Proposed Provisions	State Comment
Section I. Subsection 3: Revisions to Timing and Method of Disclosure Requirements CMS proposes to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC).	What if the beneficiary does not have access to either a computer or Internet access? While the proposed rule highlights the national percentage (67%) of Medicare beneficiaries that prefer "use of the internet vs hard copies," though implied, the proposed rule does not clearly specify what the requirements are for plan sponsors to ensure that the remaining 33 percent receive information via hard copy.
Section I. Subsection 4: Preclusion List	The Preclusion List is a good idea, and CMS has explained its rationale well. If it maintains the list monthly, this will remove much uncertainty in PACE contracting.
Section II. Subsection A(1)(a): Medicare Part D Drug Management Programs	The proposed rule speaks at length about the criteria that plan sponsors will use for identifying at-risk beneficiaries for inclusion in the drug management program and favors a uniformed approach over allowing flexibility for plans to adopt their own internal criteria. However, how will CMS determine equitable application of the opioid use criteria with beneficiaries?
Section II. Subsection A.1.c.(2)(1)(B)(vii)(A): Initial Notice to Beneficiary and Sponsor Intent To Implement Limitation on Access to Coverage for Frequently Abused Drugs	A concern related to restricting access to "select prescribers/pharmacies" has to do with whether or not prescribers/pharmacies are "in-network." This concern would also be impacted by what is decided in the final rule on the "any willing pharmacy" provision. The Centers for Medicare and Medicaid Services (CMS) appeared to have largely addressed this concern in the proposed rule and have clearly outlined the requirements of plan sponsors to ensure beneficiary access, both in situations

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	<p>involving Medicare Advantage Plans with networks and stand-alone Part D plans without networks. The rule also provides guidance in respect to beneficiary preferences. However, while the proposed rule describes how the plan sponsor will be required to communicate with the prescriber the clinical guidelines for prescribing frequently abused drugs, the rule did not appear to indicate any intention on CMS' part to approve the language and messaging of the notices plan sponsors are required to provide to beneficiaries regarding the restrictions.</p> <p>Requirement (2) seems vague and thus will lead to inconsistencies in the information provided to beneficiaries by different Medicare Advantage plans. It may be beneficial if CMS lists specific resources they want all plans to include.</p> <p>If under Requirement (4), the beneficiary does not offer a preference as to prescribers or pharmacies, and they will subsequently be chosen for the beneficiary, then this should be made clear in the notice so that the beneficiary is aware of the consequences of inaction.</p> <p>In general, is the identification of at-risk beneficiaries for this "lock down" program a potential violation of HIPAA requirements because it involves sharing individual identifying health information among multiple providers, prescribers and pharmacies without the beneficiary's consent?</p>
Section II. Subsection A.2: Flexibility in the Medicare Advantage Uniformity Requirements	<p>This appears to allow for different deductibles and supplemental benefits both among MA plans and related to beneficiaries who meet specific medical criteria. It is already challenging to assist beneficiaries in understanding the different MA plan choices available to them. The "flexibility" advocated by this proposal would appear to make it even more difficult.</p>

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Section II. Subsection A.6: Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review	While CMS' rationale for eliminating the "meaningful difference" requirement sounds plausible, there is no guarantee the "competition and 'innovation" CMS anticipates will result from the change and more choices are not necessarily better for the consumer. There is already a full breadth of choices available to beneficiaries, and it takes considerable time to evaluate and cross-compare plans adequately.
Section II. Subsection A.7: Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage	<p>The enrollment and transfer rules should specifically require PACE to be offered as an option, where available, and a detailed overview provided in sufficient time for the person to be assessed and make an informed choice. The PACE option is often overlooked or underemphasized during all types of enrollment discussions. Default or passive enrollment procedures initiated by the state or an MA plan might provide an unintentional incentive to avoid the PACE option.</p> <p>The default and passive enrollment may potentially have an impact on certain Community HealthChoices enrollees. Depending on whether a CHC plan fits the CMS requirements, especially that it be a qualified D-SNP, a CHC plan could see an advantage or disadvantage. Additionally, MA plans and D-SNPs not participating in CHC might not have the same opportunity to be presented with the incoming Duals population.</p> <p>With respect to (2), as a state, we support seamless conversion and default conversion makes sense to us from a Medicare-Medicaid coordination of benefits effort. However, we do have the following concerns/questions:</p> <ol style="list-style-type: none">1. We are wondering the exact mechanism CMS has in mind for us to provide Medicare eligibility for members to their Medicare Advantage organization. Currently, we are made aware of Medicare eligibility in a variety of ways, such as through client

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	<p>provided documentation entered by the County Assistance Office (CAO), our Third-Party Liability vendors, CMS, and most often through electronic data verification from the Social Security Administration (SSA). How quickly we receive this information is based on the way it is received. Medicare Part A and B information is received on nightly files from the SSA or the CAO enters this information in the case record when the information is received from the beneficiary. However, in contrast, Medicare Part D information is only received monthly from CMS. An individual may be enrolled in a D-SNP once Medicare Part D information is entered on the case record in our MA eligibility system.</p> <ol style="list-style-type: none">2. Has CMS considered the political ramifications of default enrollment from the perspective of non-affiliated D-SNPs?3. Does CMS believe this supports beneficiary freedom of choice on the Medicare side?4. Is it possible that CMS can develop a process by which the affiliated Medicaid managed care plan could share with the Medicare Advantage plan when their members are nearing Medicare eligibility as they should have this information readily available and it would not require relying on state data that may not be timely as discussed under point (1) above? <p>Based on our experience with the seamless conversion process thus far, we are proposing, to be codified at § 422.66(c)(2), requirements for seamless default enrollments upon conversion to Medicare. As proposed in more detail later in this section, such default enrollments would be into dual eligible special needs plans (D-SNPs) and be subject to five substantive conditions: (1) The individual is enrolled</p>
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	in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization.
Page 56367- “Lastly, we propose that CMS may suspend or rescind approval at any time if it is determined that the MA organization is not in compliance with the requirements. We request comment whether this authority to rescind approval should be broader; we have considered whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization under this proposed regulation in order to assure that the regulation requirements are still being followed.”	Because this default conversion is a new process and option for Medicare Advantage plans, it seems reasonable to set a time limit in the beginning, two years seems appropriate, as it should allow for collection of data for CMS to evaluate.
Page 56368- “We solicit comment on these coordinated proposals to implement section 1851(c)(3)(A)(ii) in general as discussed below and in two particular ways: (1) To permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and to permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan.”	<p>It is not readily clear from reading pages 56366 through 56368 what the difference is between default conversion and seamless continuation and to whom each process applies. On page 56367, at the top of the third column it says “affirmative elections would be necessary for individuals not enrolled in a Medicaid managed care plan, consistent with § 422.50.” but later in the same column it says “and to establish, through subregulatory guidance, a new and simplified positive (that is, “opt-in”) election process that would be available to all MA organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members.”</p> <p>Can the opt-in option be used under the default conversion process, meaning before the default conversion is done, the same opt-in option is granted to beneficiaries in the Medicaid managed care plan?</p>

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<p>Section II. Subsection A.8: Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries</p>	<p>This section of the rule proposes to allow for passive enrollment of an individual into a new D-SNP when disruptions that may affect continuity of integrated care occur; such as when an individual’s Medicaid managed care plan is lost due to reprourement or when their D-SNP’s contract is not renewed. Passive enrollment would be in consultation with the state Medicaid agency.</p> <p>As noted above, this would currently have no effect on Pennsylvania. However, in the situations described in the proposed rule, DHS supports this provision under CHC. Freedom-of-choice is not effected since individuals are given advanced notice of the change, as well as a special enrollment period during which they may choose to opt-out of the change.</p> <p>However, Pennsylvania Medicaid allows individuals to change their managed care plans as often as they wish. The proposed rule is silent regarding this situation and as such, DHS is concerned that there would be a disruption in care if the individual is required to stay in the D-SNP until the Medicare open-enrollment period.</p> <p>The proposed rule’s “SEP” that is distinct from other SEPs and relates specifically to individuals designated as “at-risk.” Later the rule speaks of an “SEP” that is more broadly applied to LIS and Duals. However, it is not clear whether situations related to auto-enrollment were addressed. Furthermore, it is not clear if the new SEP, which takes into account when a beneficiary has a gain, loss or change in Medicaid or LIS eligibility, also includes consideration for new to Medicaid or LIS enrollees auto-enrolled in plans for which a change might be necessary. Moreover, if the change in Medicaid/LIS status occurs more than once during the calendar year, will the beneficiary be able to utilize the SEP each time? How will the limited SEP apply in these</p>
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	<p>situations? The descriptions in the proposed rule was not entirely clear, making it difficult to maintain a distinction between the two SEPs. Sometimes the language seems to relate to at risk beneficiaries and other times it seems to reference duals, which may include those deemed “at risk.” Addressing the SEP topic wholly in one area of the proposed rule would minimize the confusion. Finally, why is the SEP restriction being imposed at all, since CMS as already determined that less than 10% elect the SEP option? Medicare beneficiaries struggle with understanding Medicare rules and it is doubtful that they would pursue this avenue to avoid the drug management program. It seems more appropriate to delay implementation of this requirement until after CMS has observed patterns of utilization following the implementation of the drug management programs.</p>
<p>Section II. Subsection A.10: Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries</p>	<p>This section of the rule proposes to limit the Part D special election periods (SEP) for dually eligible individuals from monthly to once per year, with additional SEPs made available under certain circumstances such as a change in Medicaid eligibility or as a result of passive enrollment. Limiting the number of times an individual may change their Part D plan will allow for better care management.</p> <p>While DHS agrees that choice is important, we feel that limiting that choice to once per year is in keeping with Medicare’s annual open enrollment period. Moreover, given that individuals are given two months to choose a Part D plan, as well as other opportunities to change the plan under certain conditions, OMAP feels that an individual’s freedom-of-choice will not be affected.</p> <p>The rule also proposes to limit the SEP for at-risk duals in an effort to combat opioid misuse. Once a plan determines that an enrollee is at-risk, they will be limited to the drug plan they are in until such time as they are no longer considered at-risk or once</p>

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	every 12 months. This is similar to Pennsylvania Medicaid's Restricted Recipient, or "lock-in" program, so DHS is supportive.
<p>Page 56377- "As we continue to consider making changes to the MA and Part D programs in order to increase plan participation and improve benefit offerings to enrollees, we would also like to solicit feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We welcome all comments on those topics, and will consider them for changes through this or future rulemaking or in connection with interpreting our regulations (once finalized) on the Star Rating system measures. However, we are particularly interested in receiving stakeholder feedback on the following topics:...</p> <ul style="list-style-type: none"> • 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." 	<p>We encourage CMS to develop a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services. We believe this will add behind the scenes information about the administrative processes of health and drug plans and could shed light on areas such as: appeals, benefit limit exceptions, capitation payments, grievances, and prior authorization which all impact beneficiary health outcomes.</p>
<p>Page 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 ask for</p>	<p>As a state, it would be beneficial for us to have quality data and Star Ratings at the individual Plan Benefit Packages (i.e., D-SNPs), because as CMS noted previously in the column, it would give states specific information on the performance of D-SNPs and provide the public with data specific to the quality of care for dual eligible (DE) beneficiaries</p>

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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. In particular, we are interested in feedback on the best balance and whether changing the level at which ratings are calculated and reported better serves beneficiaries and our goals for the Star Ratings System.”	<p>enrolled in these plans. While we understand this may increase the data burden on the D-SNPs and that small sample sizes would mean the data in some cases would be unreliable and could not be used, we still support quality data at the PBP level.</p> <p>CMS indicated that a significant number of D–SNP plans would not be rated and in lieu of a Star Rating, Medicare Plan Finder would display that the plan is “too small to be rated”. Perhaps, as an additional piece of information in this field, the Star Rating for the overall contract number (or parent organization) could be listed. Also, where data size is limited, perhaps several years could be combined.</p>
Section II. Subsection B.1 Restoration of the Medicare Advantage Open Enrollment Period	Restoration of the Medicare Advantage Open Enrollment Period at pages 5-6 to permit beneficiaries to select a different MA plan or move to Original Medicare from January 1 through March 31. This is helpful in giving beneficiaries the opportunity for a "do over" of the MA plan they chose during Annual Open Enrollment.
Section II. Subsection B.2 Reducing the Burden of the Compliance Program Training Requirements	CMS proposes to eliminate the CMS Compliance Training requirement, believing that the standing compliance obligations of the MA plan sponsors are sufficient for themselves and their downstream providers. CMS provides sufficient evidence for doing so. Please clarify how this will affect PACE organizations.
Section II. Subsection B.4 Revisions to Timing and Method of Disclosure Requirements Requirements Sections 422.111(d) and 423.128(g)(2) require MA organizations and Part D sponsors to provide the ANOC to all enrollees at least 15 days before the AEP. The ANOC is intended to convey all of the information essential to an enrollee’s decision to remain enrolled in the same plan for the following year or choose another plan during the AEP. CMS’s research and experience have	It is not clear from this whether the ANOC will continue to be mailed or posted to the plans’ websites. Also, although CMS requires plans to send hard copies of EOCs, provider and pharmacy directories, and formularies when requested, we recommend that a notice to beneficiaries explaining that they can request these items in hard copy format if they are unable to access them on the internet be sent out in advance of the Annual Coordinated Election Period so that these items are received on the first day of the period. This would alleviate any discrepancies in timing of information

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<p>indicated that the ANOC is particularly useful to and used by enrollees.</p> <p>Drawing on nationally representative surveys, the Pew Research Center found that 67 percent of American adults age 65 and older use the internet.</p> <p>Under this proposal to permit flexibility for us to approve non- hard-copy delivery in some cases, we intend to continue requiring hardcopy mailings of any ANOC or EOC errata.</p>	<p>being available on the website but at a later date for a mailed hard copy.</p> <p>While the proposed rule highlights the national percentage (67%) of Medicare beneficiaries that prefer “use of the internet vs hard copies,” though implied, the proposed rule does not clearly specify what the requirements are for plan sponsors to ensure that the remaining 33 percent receive information via hard copy.</p> <p>We agree that the use of the Internet has increased over time; however, this still means 33 percent do not use the Internet and we are concerned about their access to documents on websites.</p> <p>Since CMS allows the EOC to be posted to the plans’ websites and not mailed unless requested, we believe it would be confusing to beneficiaries to continue requiring hardcopy mailings of any EOC errata.</p> <p>It is unclear how the new Marketing rules affect PACE. Since PACE organizations are Part D providers, the rules would appear to cover them. But, since the PACE Provider Organization as a whole is not a “plan” under Medicare, and PACE falls under independent authorization, there is uncertainty. Please clarify how a PACE program is impacted by the new Marketing rules, or restate the rule to cover or exclude a PACE program as a whole.</p>
<p>Section II. Subsection B.5.a Revising the Scope of Subpart V To Include Communications and Communications Materials</p>	<p>This is confusing in the way it is written. Could CMS possibly revise the language? As a suggestion, “For markets with a significant non-English speaking population, materials, as defined by CMS, must not be provided in a language other than that spoken by the population.”</p>
<p>Section II. Subsection B.12 Removal of Quality Improvement Project for Medicare Advantage Organizations</p>	<p>CMS proposes to eliminate the Quality Improvement Project (QIP) requirement, and offers good reasons for doing so. It retains the requirement for a Quality Improvement Program. PACE requires a Quality Assessment and Performance Improvement (QAPI)</p>

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Page 56455- Therefore, we believe the removal of the QIP and the continued CMS direction of populations for required CCIPs would allow MA organizations to focus on one project that supports improving the management of chronic conditions, a CMS priority, while reducing the duplication of other QI initiatives. We propose to delete §§ 422.152(a)(3) and 422.152(d), which outline the QIP requirements.	<p>program. Are there intentions to make Medicare and PACE quality initiatives more comparable?</p> <p>We agree with this decision and support it for the reasons CMS identified. Additionally, we have had feedback from the D-SNPs that operate in our state that they found the requirements for the QIPs and CCIPs overlapped and were burdensome. They believe this change will better allow them to concentrate on improving quality.</p>
Section III. Subsection B.1	<p>Please reiterate that PACE is not subject to enrollment windows or other constraints not specifically stated in PACE regulations. Clarify how a Dual wishing to disenroll from PACE would be able to enroll in a D-SNP or other Medicare program without the constraint of enrollment windows.</p>
Section III. Subsection B.8 ICRs Regarding Revisions to Parts 422 and 423, Subpart V, Communication/ Marketing Materials and Activities	<p>Please include a count of PACE marketing materials in the analysis.</p> <p>Is it possible that during the Open Enrollment Period a beneficiary may request marketing materials from different plans if they were unhappy with their plan and wanted to switch? This information would inform them about their choices. Would this be possible, as it would seem that CMS wants to support informed choice?</p>

General observations:

- The CMS provisions related Marketing, Medical Loss Ratio, enrollment and transfer, quality programs, qualified vendors, and customer choice and experience are likely to spread to other programs.
- Some of the CMS requirements for better information about choices might affect the Community HealthChoices Managed Care Organizations (CHC-MCOs) and the Pennsylvania's approach to covering Duals.