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Submitted electronically at www.regulations.gov.

March 5, 2018

CMS-2017-0163

On behalf of EmblemHealth and our partner organizations ConnectiCare and AdvantageCare Physicians, we are writing in response to the Advance Notice of Methodological Change for Calendar Year 2019 and 2019 Draft Call Letter issued by the Centers for Medicare & Medicaid Services (CMS) on December 27, 2017 and February 1, 2018. EmblemHealth is the largest community-based nonprofit health plan in the country, and with our partner ConnectiCare, serves approximately 3.1 million individuals who live in New York, Connecticut, New Jersey, and Massachusetts. The issues addressed in this proposed rule are of critical importance to the more than 160,000 Medicare Advantage enrollees in New York and Connecticut who rely on our innovative approach to providing high quality health care services.

ADVANCE NOTICE PART 1

- **Taking Into Account the Number of Conditions of an Individual (p. 13)**

  EmblemHealth supports the adoption of the 2019 Payment Conditions Count Model according to the phase-in schedule proposed in the Advance Notice. CMS is proposing to adopt changes to the CMS-HCC model required by the 21st Century Cures Act, which incorporate new HCC codes and establish a conditions counting factor. The agency puts forward two alternatives to address the Congressional requirement for the conditions counting factor – one which would determine a beneficiary's number of chronic conditions based on his/her total number of documented HCCs (the "Total Conditions Count Model") and the second counting only those conditions used in the CMS-HCC model ("Payment Conditions Count Model"). The law requires these changes to be phased in over a "three year period" from 2019 – 2022, which the agency notes provides it with some flexibility whether to begin the transition to the new model starting 2019 or 2020.

  We support CMS's decision to use the Payment Conditions Count Model. These conditions are those the agency has determined to be influential in differentiating beneficiary health status to determine appropriate payment. Including conditions outside the model would also count conditions that are not as influential, which is contrary to the model's purpose. We also support initiating the transition in 2019 to provide greater lead time for plans to consider any uncertainty that could arise because of this fundamental change in the model.

- **Encounter Data as a Diagnosis Source for 2019**

  EmblemHealth strongly opposes increasing the percentage of the risk score tied to encounter data and using encounter data as the sole source for determining risk scores under the 2019 model. CMS's encounter data system remains a work in progress. The agency continues to make changes to the MAO-004 report, the agency's primary output file to allow plans to determine which diagnoses will be accepted and to correct errors. There also continue to be concerns that the agency uses filtering logic to determine which diagnoses it will accept using encounter data that is significantly different from that used under the Risk Adjustment Payment System (RAPS). These concerns are validated by CMS's recent estimate that the increased encounter data phase-in percentage would reduce program funding[1] and the Department of Health and Human Services description of a related Administration budget proposal to "Eliminate ***Excessive*** Payment in Medicare Advantage by Using Claims Data from Patient Encounters"[2]. (emphasis added)

  This characterization is both inappropriate and untrue. It had been our understanding that CMS initially viewed the transition to encounter data to be funding neutral to RAPS for each plan because the information submitted through both systems reflects the same experience. Medicare Advantage Organizations (MAOs) and CMS have expended a significant amount of resources to make the system work. Still, after more than six years of intense effort, it remains flawed.

  It is time to pause and reevaluate whether moving towards an encounter data based system has been worth the considerable effort. It is our understanding that the agency's original goals to collect encounter data were connected to its plan use in a revised CMS-HCC model and to respond to researchers' concern that the Medicare Advantage program is a "black box". While these aims may be laudable, the concept is flawed. Medicare Advantage is meant to be different from Original Medicare. At its best, our program is reliant on outcomes, not claims, to determine payment. Yet in the midst of the growing understanding that claims-based care is the wrong type of care, the encounter data system has forced health plans to direct its energy toward creating systems that meet all of the agency's collection standards instead of managing care. This defeats a primary purpose of the Medicare Advantage program.

  It is now time to recognize that the encounter data system is counterproductive. CMS should roll back the percentage of risk scores based on encounter data to 0 and work with health plans to develop a better way. EmblemHealth welcomes the opportunity to participate in this process.

ADVANCE NOTICE PART 2

[1] CMS Fact Sheet, "2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter". Found at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-02-01.html
[2] See U.S. Department of Health and Human Services FY 2019 Budget in Brief, p. 68.

- **MA Employer Group Waiver Plans (p. 25)**

  EmblemHealth continues to believe funding reductions to Medicare Advantage Employer Group Waiver Plans (EGWPs) are unjustified and urges CMS to reverse cuts put in place in 2017. Unfortunately, the Advance Notice proposes to continue phasing in EGWP funding reductions paused last year. CMS directs readers to its reasoning for EGWP cuts described in the 2017 Final Rate Notice to understand why it is moving in this direction. Below we summarize those arguments and provide our response.

  1. CMS notes that prior to 2017, it had allowed EGWPs to submit "composite" bids, which organizations could customize for employer and union customers. This approach reduced administrative burdens for plans and the agency but meant a "lack of transparency (which) has significantly impaired CMS' ability to comprehensively review and assess the reasonableness of the underlying actuarial assumptions and projections included in the bids submitted for EGWPs and to trace how federal funds, in the form of the capitation payments and the rebates, are spent for beneficiaries in specific EGWPs."

     - Response: EmblemHealth understands the agency's concerns but believes its solution is counterproductive. Other steps could improve the transparency and plan accountability for the soundness of these bids. For example, CMS could require EGWPs to certify the reasons why the bid may differ from the MAO's non-EGWP bids in the same service area and establish penalties for plans found to be misrepresenting these factors. The agency could then review historical data plans submit during the annual bid and medical loss ratio (MLR) processes to determine if an organization's EGWP bids should be subject to further review.

  2. CMS further cites 2012 data from the Medicare Payment Advisory Commission (MedPAC) which found EGWP margins were significantly higher than other plans.

     - Response: Our analysis of 2014 CMS MLR data indicate very different results. We compared adjusted MLRs for contracts categorized by the percentage of EGWP enrollment based on September 2014 CMS data. Note that EGWPs continued to submit composite bids in 2014, which is prior to the implementation of the 2017 cuts. Our results indicate contracts with a higher percentage of EGWP enrollment generally reported ***higher MLRs*** than other plans.

% of Contract Enrollment in EGWPs	Average MLR
50% +	92.5%
20% - 49%	101.5%
10% - 19%	90.5%
1% - 9%	91.0%
None	91.0%
All Plans	92.6%

In fact, our findings indicate the average MLR among contracts with above average EGWP enrollment (the first two categories above) in 2014 was 97% compared to 91% for other plans. Therefore, these findings would not justify targeting EGWPs for cuts under the new methodology.

3. CMS cites MedPAC data that EGWP bids were generally higher than non-EGWPs in the same service area. According to CMS and MedPAC, "the nature of the MA bid process and the ability to access federal funds creates incentives for these plans to bid as close to the benchmark as possible."

    - Response: The differences in EGWP and non-EGWP bids are a function of the greater likelihood that EGWPs operate as PPOs or are HMOs in which enrollees are more likely to receive benefits outside the plan's network. MedPAC continues to find PPOs bid about 9% higher on average than HMOs. CMS acknowledged those concerns in the 2017 Final Rate Notice but continued to support funding EGWPs based on non-EGWP bids due to "the small number of PPO plans in the individual MA market (which) could introduce significant year-over-year instability in future EGWP payment rates." We understand that CMS may be rethinking its position and requests comments on a PPO adjustment to account for the differences between EGWPs and other plans.

We appreciate these considerations and agree a PPO adjustment would mitigate some of the cuts that have already increased costs for our EGWP enrollees. At the same time, the rationale for targeting these plans for funding cuts is not substantiated by the data, and we urge the agency to return to the pre-2017 bid-based funding system. EmblemHealth stands ready to work with CMS to make adjustments to the bid submission and review process that would increase transparency, mitigate operational burdens, and do not continue to deleteriously affect the 4 million Medicare beneficiaries enrolled in EGWPs.

- **Medicare Advantage Coding Pattern Adjustment (p. 35)**

EmblemHealth supports CMS's decision to apply the statutory minimum coding pattern adjustment to Medicare Advantage risk scores. However, CMS also notes it may be considering other methods for calculating the adjustment for 2019. We oppose moving forward with these other methodologies. Although CMS provides citations to descriptions of these other ways of calculating the adjustment, it does not offer additional detail to determine what the impact would be next year. A decision by CMS to calculate the adjustment using one of these other methodologies in the 2019 Final Rate Notice would be inconsistent with the increased transparency the agency is moving towards in its operations (for example, the revised process for adding, removing, or making significant changes to Star Ratings described in the recent proposed rule) and demanding of plans.

- **Normalization for the CMS-HCC Model (p. 38)**

  EmblemHealth remains concerned about the recent trend toward higher annual increases in the FFS Normalization Factor. The new proposed factor is about 2.3% higher than 2018, which follows a 1.9% increase from 2017 – 2018. We understand the purpose of the adjustment and appreciate that the agency provides a detailed analysis of the trends in FFS risk coding which provide the basis for the calculation. A key element in the calculation is CMS's proposed recalibration of the model based on 2014 diagnosis data used for 2015 payment. The agency explains in Part 1 of the Advance Notice that more recent data are available but "we elected not to update the data years to 2015/2016, because we did not expect the diagnosis coding pattern in 2015, which was the first year ICD-10 diagnoses were implemented, to be sufficiently stable for use in model calibration."

  We continue to try to better understand these findings. While it makes sense that coding practices in FFS have improved as Medicare Advantage plan efforts to work with providers to better document and treat conditions spill over into the FFS program, some have suggested there may be independent effects of the transition to ICD-10 that may also factor into this analysis. In that case, it would seem these factors should somehow be addressed in the FFS Normalization calculation. We recommend CMS consider these issues when finalizing the final factor.

DRAFT CALL LETTER

- **Star Ratings -- Enhancements to the 2019 Star Ratings and Future Measurement Concepts (p. 106)**

  EmblemHealth requests meetings of the new Technical Expert Panel (TEP) be open to the public and made available electronically with opportunities to provide live feedback. The Draft Call Letter announces a new TEP to be "comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures." It is our understanding that CMS is already making appointments to the TEP. We have concerns that due to the broad range of views on Star Ratings issues and their critical importance to each and every organization participating in the program, important positions on key issues will not be adequately represented on the TEP.

  For example, as we describe in detail below, EmblemHealth's perspective on the interplay between Star Ratings and compliance diverges from the positions advanced by national trade associations. We believe there are unintended consequences deleterious to beneficiaries if health plans invest in mechanisms to do well on Stars but, at the same time are not similarly strong on compliance with key program requirements. If the agency is interested in taking a position that compliance is subordinate to Stars, then the public should be told that and told why.

The Draft Call Letter lists this issue as one which the TEP will address. We are concerned that our views will not be represented there. While we fully support opportunities for health plans and other stakeholders to be involved in the development of CMS proposals, any process to do so should be completely transparent to allow input from those with knowledge of the program who have perspectives that differ from those serving on the panel. We strongly urge CMS to consider how it will operate the TEP, including the application of federal Open Meetings requirements and other rules, to ensure transparency and the sharing of views.

- **Changes to Measures for 2019 – MPF Price Accuracy (p. 110)**

  EmblemHealth continues to have concerns with the Part D Medicare Plan Finder (MPF) Accuracy measure. While we appreciate the detail CMS provides in explaining its changes and the transparency with which the new changes are phased in, the sample of drug prices the agency uses to assess performance is still subject to outliers that may not reflect plan efforts to ensure enrollees have the information they need. Drug prices often change on a day-to-day and hour-to-hour basis. MAOs are constantly working to ensure these price changes are accurate. The fluidity of these changes may mean an MAO is working to update its systems as plan performance is being assessed.

  Moreover, the narrow cutpoints and generally high level of performance among plans make every point count. For example, EmblemHealth's two primary Medicare Advantage contracts scored 98 on this measure yet that was only good enough for 4 Stars. A different sample taken on a different day may have led to a different result. We recommend the agency take these views into account as it makes changes to the measure.

- **Removal of Measures from Star Ratings -- Beneficiary Access and Performance Problems (BAPP) (Part C & D) (p. 112)**

  EmblemHealth urges CMS to reconsider the changes to the BAPP measure and restore it to the Star Ratings with a minimum 3 weight in 2019. CMS is proposing to weaken this measure and put it on the Display Page in 2019 with no indication whether it could ever be restored to the Ratings in future years. The agency notes arguments made by commenters about "the differences in methodologies and goals, the subjective nature of audits, and the absence of audit information for each plan each year" to support these changes. We strongly disagree with those arguments and remain perplexed why they would drive a change that has such important implications for beneficiaries.

  - We see the goals of Stars and compliance as one in the same. Each assesses the likelihood that a Medicare beneficiary will have a positive experience if s/he enrolls in a plan. To suggest otherwise is a misstatement of what CMS rules are intended to do. For example, if a plan fails to comply with Part D transition rules, enrollees are more likely to experience medication adherence problems when they change plans or their plan changes

its formulary. Rules established by Congress and the agency do not exist in a vacuum. They are intended to ensure beneficiaries receive the treatment they deserve.

- The differences in methodologies argument is also difficult to understand. Star Ratings consists of over 40 measures, each with its own separate calculation methodology that the agency makes clear in the Call Letter and Technical Notes. Similarly, CMS has established audit protocols and provides other materials to assist plans in understanding how plan performance will be assessed.

- We also continue to be puzzled by concerns about "the subjective nature of audits". Beneficiary experience measures in CAHPS are also subjective, yet despite concerns being advanced, CMS recently proposed to ***increase*** the weight of these measures. However, in contrast to CAHPS, a plan's compliance record is directly within its control.

- A recent industry document states "these audits are qualitative assessments of Medicare Advantage plan and Part D sponsor processes and protocols… In some cases, a single incident can result in an audit finding."[3] This statement undermines the important role that program audits play in ensuring beneficiary protections are respected. Organizations are rarely subject to CMS compliance actions. Those that are not subject to compliance actions do not achieve these results by chance. We urge the agency to send a strong signal that compliance matters and not the opposite.

- Finally, many have argued that the BAPP measure is somehow unfair because not all plans are subject to program audits every year. However, each plan is subject to program audits every three years. We all operate on a level playing field in that respect. Moreover, plans may be subject to compliance actions outside of program audits, whether assessed as a result of annual financial audits, beneficiary complaints, or its other dealings with the agency.

EmblemHealth realizes that our history of high performance on the BAPP measure is in no way assured into the future. However, we understand the degree to which Medicare Advantage plans are held accountable through both the compliance and Star Ratings systems sets our program apart. To somehow disassociate compliance from Star Ratings, which has become the primary means by which beneficiaries and other analysts evaluate plan performance, seems to both undermine the importance of compliance and is inconsistent with the signal that the ratings are intended to provide and the types of plan behaviors they are intended to encourage. We urge CMS to reevaluate recent decisions and restore the BAPP measure to its rightful place within the Star Ratings system.

[3] America's Health Insurance Plans, "Medicare Advantage: Star Ratings, Audits, and Compliance Findings" (February 2017)

- **Star Ratings -- Data Integrity**

  EmblemHealth supports the agency's proposed phased approach for the appeals measures. CMS is proposing to adopt a scaled reduction for findings of mistakes in plan data submission for Part C and D appeals measures. The agency also put forward this approach in its recent proposed rule. As we noted in our comments, we believe the scaled approach based on the severity and size of the error is a step in the right direction and we strongly urge CMS to finalize this proposal. We suggest CMS consider expanding the scaled reduction to other measures with special consideration for organizations demonstrating a commitment to compliance.

- **Enforcement Actions for Provider Directories (p. 165)**

  EmblemHealth urges CMS to recognize the shared responsibility between plans and providers when considering appropriate enforcement actions. CMS notes that in response to inquiries, "Civil Money Penalties (CMPs) and other enforcement actions may be imposed against MAOs that have received a compliance notice or notices for violations that have gone uncorrected" and that "CMS has the discretion to take enforcement actions when egregious instances of non-compliance are discovered." However, as CMS knows, ensuring the accuracy of provider directories is a two-way street. While we are very focused on developing innovative tools to ensure our directories provide beneficiaries with accurate information, we remain extremely dependent on receiving data from our providers when there is a change in their status.

  This process can create enormous burdens as the physicians and other clinicians in our network face numerous requests in varying formats from health plans to ensure provider directories are accurate and accreditation information is up to date. These different formats add burdens on physicians and their staffs that may contribute to inaccuracies in provider directories and frustration for beneficiaries. We strongly suggest CMS establish a national database for physicians and other clinicians to submit information for provider directories (e.g., addresses, office hours) and accreditation status. This national database would reduce burdens by allowing physicians and other clinicians to submit required information including changes to a single source and be accessible to health plans to update without contacting their offices.

- **Audit of the Sponsoring Organization's Compliance Program Effectiveness (p. 165)**

  EmblemHealth supports CMS's proposal to allow sponsoring organizations that have undergone a CMS program audit to treat it as meeting the annual compliance program audit requirement. As noted above, we take the agency's oversight role seriously. For this reason, we support proposals that eliminate duplication and reduce burdens on the agency and plans while maintaining the integrity of the audit process. We strongly recommend CMS finalize this proposal.

- **Meaningful Difference (Substantially Duplicative Plan Offerings) (p. 170)**

  EmblemHealth strongly supports CMS's proposal to eliminate the Medicare Advantage Meaningful Difference test. As we have previously noted, the meaningful difference test has often had the unintended consequence of requiring plans to be forced to increase beneficiary cost-sharing or reduce benefits. Moreover, the test has not historically considered variations in plan networks or other strategies to provide beneficiaries with choices that meet their needs. Eliminating the standard will allow market forces to play a greater role in the composition of the options available to Medicare Advantage beneficiaries.

- **Total Beneficiary Cost (TBC) (p. 170)**

  EmblemHealth supports eliminating the TBC test. CMS is proposing to increase the TBC threshold for 2019. On page 173 of the Draft Call Letter, the agency states it is "considering the elimination of the current TBC evaluation in future years, subject to statutory and regulatory limitations or changes." According to the Draft Call Letter, "we interpret the statutory provision as one ***granting authority*** for us to deny bids on these grounds." (emphasis added) We also understand that the law permits but does not require CMS to apply the test as currently established or as broadly as has been the case. Eliminating the test would further empower beneficiaries to determine what they like or don't like about Medicare Advantage plans. Medicare Advantage plans provide enrollees significant amounts of information through the Annual Notice of Change and Medicare Compare website to evaluate their choices during the Annual Enrollment Period (AEP). We believe CMS has the statutory authority to move away from the TBC requirement and urge it to do so.

- **Cost-Sharing Limits (p. 180)**

  EmblemHealth requests additional information before responding to CMS's request for input on the impact of its cost-sharing limits. On page 180 of the Draft Call Letter, the agency requests comments from plans "on whether CMS's interpretation of the cost sharing limits is impacting plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options." EmblemHealth strongly supports additional flexibility to allow plans to consider benefit designs that meet enrollee needs. However, our understanding is the agency's existing limits most affect benefits that are implicated under its antidiscrimination authority. It would be useful to understand if CMS's analysis of plan benefit designs suggests areas in which cost sharing limits appear to be hampering the development of valuable options without raising concerns it would normally address during the bid review process.

- **Employer Group Waiver Plans (p. 180)**

  EmblemHealth supports reinstituting the Employer Group Waiver Plan bid process for 2019. The agency ended this process in 2017 when it established the new payment methodology addressed above. EmblemHealth strongly supports reversing the agency's new approach for calculating payments to these plans, which would reinstitute the EGWP bid process to serve as the basis for plan funding. As noted above, we also support changes to the bidding process to provide CMS with additional tools to enforce its oversight without adding significant burdens to its review process.

  We have also been thinking about the appropriateness of establishing a three-year bidding cycle for EGWPs to further reduce CMS resource needs. Under this approach, CMS would require EGWPs to submit bids once every three years instead of every year as was true before 2017 and rotate MAOs so that CMS is reviewing 1/3 of all EGWP bids each year. In years when an EGWP does not submit a bid, the agency would base payment on the previous year's bid increased by the national fee-for-service (FFS) growth rate announced by CMS each year. We are hopeful that this idea in combination with the attestation and oversight proposal described above will allow CMS to address its concerns while reinstating a payment system that does not unfairly target EGWP enrollees for funding reductions.

- **Tiered Cost Sharing of Medical Benefits (p. 181)**

  EmblemHealth supports CMS's proposal to permit MAOs to propose tiered cost sharing arrangements in bids without first seeking approval from the agency to do so. Tiered cost-sharing arrangements are a proven technique to encourage enrollee use of providers meeting health plan quality criteria. We agree that the bid process ensures CMS has the opportunity to review these arrangements to ensure compliance with program requirements.

- **Health Related Supplemental Benefits (p. 182)**

  EmblemHealth supports the additional flexibility for Medicare Advantage plans to provide health related supplemental benefits starting 2019. These changes would mirror those recently enacted by Congress, effective 2020. Expanding the definition of health related supplemental benefits recognizes the value of services and supports that have been offered in state Medicaid programs and demonstrated to improve the lives of beneficiaries with high health care needs. The recent authority granted by Congress for all Medicare Advantage plans to provide these benefits is long overdue and we appreciate the agency's proposal to move up implementation by one year.

- **Special Needs Plan (SNP)-Specific Networks Research and Development (p. 185)**

  EmblemHealth supports CMS's decisions not to establish separate SNP network adequacy requirements in the areas we serve. The agency notes that it has determined CMS's existing network reviews are adequate to ensure SNP enrollees have access to the services they need. We agree with that assessment, especially in the urban areas we serve. EmblemHealth's service area includes very diverse populations that are served by our network providers. Our networks therefore do not differ in our SNPs from those offered in our other Medicare Advantage products. We recommend that further consideration of the appropriateness of establishing separate SNP network adequacy requirements be mindful of the unique circumstances of plans operating in similar areas.

- **Rewards and Incentives for Completion of a Health Risk Assessment (HRA) (p. 186)**

  EmblemHealth supports the agency's proposal to permit Medicare Advantage plans to offer rewards and incentives to beneficiaries for completing health risk assessments (HRAs). HRAs are valuable tools to assist plans in developing treatment plans that meet each enrollee's unique needs and detecting warning signs for diseases. Permitting Medicare Advantage plans to offer rewards and incentives meeting the agency's requirements should increase completion rates, which will allow plans to better serve our enrollees.

- **Encounter Data Listening Forums, Monitoring and Compliance Activities (p. 191)**

  EmblemHealth does not believe CMS should move forward with encounter data compliance measures. As noted above, we strongly support eliminating the role of encounter data in calculating risk scores. If CMS moves forward, we continue to believe the agency should be careful to establish compliance measures that take into account the continued challenges CMS and plans are facing, despite the additional agency outreach noted in the Draft Call Letter that we very much appreciate. For example, we provided comments to the CMS request cited in the call letter emphasizing the importance of applying these measures only to extreme outliers based on thresholds that plans know beforehand and are not determined in relation to peer performance. We hope CMS will accept these comments.

- **Transparency & Timeliness with Prior Authorization Processes (p. 193)**

  EmblemHealth understands its responsibilities and strongly urges CMS to remind others of theirs to effectively manage and treat the enrollees we serve. The Draft Call Letter includes several reminders to plans about the implementation of management programs in recognition of "the burdens imposed by coverage restrictions such as prior authorizations (PA) in the Part C program". These provisions are directly related to provider noncompliance with national treatment standards and health plan programs designed to ensure health care is delivered in the right place at the right time. For beneficiaries to receive the best care, it is crucial that the safety and efficacy of proposed treatments be evaluated.

We do not support arbitrary standards around prior authorization. Instead, we hope the agency will recognize the serious issues that still exist around readmissions, treatment regimens that are not in sync with the latest research, and the continued existence of overutilization and inappropriate site of care treatment.

At the same time, we have suggested several ideas here and in other comments that would reduce provider burdens. EmblemHealth remains committed to developing tools and techniques that provide our enrollees with affordable access to the care they need. We hope that neither CMS nor others create additional barriers to the development of management programs that are consistent with our goals.

- **Expanding the Part D OTC Program (p. 193)**

  EmblemHealth opposes further expansions of the Part D OTC Program. CMS's current policy permitting use of OTCs in benefit management programs allows us to ensure enrollees are prescribed medically appropriate Part D medications. Additional expansion of the program may increase enrollee demand for less appropriate remedies to conditions that are best addressed with prescription drugs.

- **Tier Composition (pp. 198-199)**

  EmblemHealth opposes the proposed maximum 25% generic composition threshold for the non-preferred brand tier. The agency is proposing this threshold in response to longstanding concerns that tier labels may create confusion among beneficiaries. While we understand this concern, we are finding that the entry of several high-cost generic drugs in the marketplace does not accommodate the establishment of purely "generic" tiers (whether preferred or non-preferred) that best promote the use of clinically appropriate, affordable medications. In fact, with some generics now in the market costing in the hundreds if not thousands of dollars, the non-preferred brand tier has allowed plans to ensure medications that do not fit into that definition are also available to enrollees at their option. A strict 25% threshold may create obstacles for plans to develop formulary designs that are responsive to beneficiary preferences and best address their needs.

- **Improving Drug Utilization Review Controls in Medicare Part D (pp. pp. 202-217)**

  EmblemHealth supports CMS proposals to safeguard Medicare beneficiaries from misusing opioids. We are extremely focused on ensuring our enrollees are correctly taking their medications without going through the misery of abuse and addiction. CMS proposes several changes to existing requirements.

  - <u>New Hard Edits for Beneficiaries Who Reach a Cumulative Daily Dose of 90 MME:</u> CMS proposes to change the hard edit threshold from 200 to 90 morphine milligram equivalent (MME) standard. We have some concerns that the significant reduction in

the threshold may be disruptive to beneficiaries with legitimate needs, who will now be subject to the hard edit standard. For example, our data suggest the number of hard edits may increase by more than eight times (800%) by decreasing this threshold from 200 to 120 MME with an additional increase likely if the standard were to decrease to 90 MME. While that means we will be more likely to find cases where individuals are abusing their medications, Part D sponsors already have programs in place to ensure enrollees are receiving an appropriate dosage. This raises concerns that those most likely to be affected will have legitimate needs.

- New Hard Edits for Clinically Naïve Beneficiaries: We recommend the hard edit permit an initial 7-days' supply instead of a 3 or 5 days' supply as also suggested. This longer days' supply will better accommodate beneficiaries experiencing an emergency event requiring immediate pain relief over weekends, holidays, or when their mobility is significantly limited and reaching their physician may be difficult within a shorter time period.

- New Soft Edits for Duplicative Therapies: CMS notes circumstances when a beneficiary taking a long-acting medication may also be prescribed a shorter duration opioid. We do not object to the soft edit but note that there are often legitimate reasons for when individuals on long-acting medications may be prescribed other opioids to address short-term needs for additional relief.

- **Part D Mail-Order Refill Consent Policy– Solicitation for Comments (pp. 220-221)**

  EmblemHealth agrees that CMS should permit non-EGWPs to use mail-order auto-ship programs. These programs are proven to improve medication adherence, especially among beneficiaries facing barriers to receiving refills at community pharmacies created by difficulties with mobility or access to transportation. Our experience is that mail-order refills remain a significant minority of the total prescriptions dispensed to our enrollees, which should limit the potential for waste from expanding auto-ship programs.

We appreciate this opportunity to respond to the 2019 Advance Notice and Draft Call Letter. Please contact Howard Weiss at 646-447-1074 or hweiss@EmblemHealth.com if you would like to discuss the issues we have raised.