EmblemHealth™

55 Water Street, New York, New York 10041-8190 www.emblemhealth.com

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Re: CMS–4182-P

On behalf of EmblemHealth and our partner organizations ConnectiCare and AdvantageCare Physicians, we are writing in response to the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) entitled "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" published in the *Federal Register* on November 28, 2017 (82 FR 56336). 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 160,000 Medicare Advantage enrollees in New York and Connecticut who rely on our innovative approach to providing high quality health care services.

GENERAL COMMENTS

The proposed rule suggests a number of significant changes to the Medicare Advantage and Part D programs. We strongly support many of these ideas and have specific suggestions where we believe the proposed rule could be refocused to ensure Medicare Advantage enrollees are best served by the program.

For example, the agency's proposal to provide Medicare Advantage Organizations (MAOs) with additional flexibility to establish value-based insurance designs is an important step in support of health plan activities targeted to individuals with chronic conditions. The rule's willingness to allow Part D plans to quickly offer generic options at preferred cost-sharing if the product is introduced during the plan year will make prescription drugs more affordable for beneficiaries. We also greatly appreciate CMS's proposal to permit Medicare Advantage plans to modernize the delivery of the Evidence of Coverage and its new, commonsense approach to the oversight of marketing activities, which we are convinced will allow MAOs to provide more usable information to beneficiaries to help them better understand their benefits and rights.

Below, we provide detailed comments on many of CMS's proposals, including recommendations to ensure MAOs can continue to be a positive force for change in the Medicare program.

DETAILED COMMENTS

- **Part D Management Programs to Address Overutilization of Frequently Abused Drugs (§§423.100, 423.153(f); Preamble, pp. 56342-56360)** – CMS proposes to implement provisions in the Comprehensive Addiction and Recovery Act of 2016 (CARA) that permit plans to assign at-risk beneficiaries to specific prescribers and pharmacies (also known as "lock-in" provisions). We strongly support CMS's activities in this area. CARA provides Part D sponsors with new clinically-based tools to address and prevent the abuse of prescription drugs that have proven effective in state Medicaid programs and other areas. Congress's support and CMS's adoption of these techniques in this proposed rule are necessary to reduce opioid dependence among Medicare beneficiaries.

  While we are continuing to evaluate the required implementation steps in the proposed rule, we greatly appreciate the agency's thoughtful approach to implementing the CARA reforms. Specific issues we have identified include:

  - We support permitting plans to begin lock-in activities when the beneficiary is first determined to be potentially at-risk. CMS's proposal to require beneficiaries to be notified they are "potentially" at-risk while receiving care management for six months without prescriber and pharmacy lock-ins is inconsistent with our state's Medicaid program and may delay sponsors from using all necessary tools to treat an individual's condition.

  - We are also considering the implications of relying on beneficiary choice for the identification of lock-in prescribers as proposed in the rule and would suggest a stronger plan role in identifying the clinician who can best provide the care an enrollee needs. Such an approach would better sync up with ongoing care coordination activities.

  - We support expanding the list of frequently abused medications to benzodiazepines and other controlled substances. We believe these new tools will be effective in treating all areas of potential abuse.

- **Value-Based Insurance Designs (V-BID) (Preamble, pp. 56360-56361)** – CMS has historically interpreted the Social Security Act[1] to prohibit plans from offering tailored benefits to individuals within a plan benefit package (PBP) that are not offered to all enrollees. The preamble notes CMS's intent to re-interpret the statute to permit plans to "reduce cost sharing for certain benefits, offer tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees… are treated the same." CMS notes this new interpretation would take effect in 2019 but would not apply to Part D benefits offered by an MA-PD plan.

[1] See section 1852(d)(1)(A) of the Social Security Act requiring Medicare Advantage plans to make "benefits available and accessible to each individual electing the plan within the plan service area"

EmblemHealth strongly supports the agency's new approach. A recent *Health Affairs*[2] study found V-BID strategies improve compliance with preventive services and significantly reduce medical trend. The V-BID Center at the University of Michigan projects these approaches in the Centers for Medicare and Medicaid Innovation's ongoing demonstration will lower out-of-pocket costs for Medicare Advantage enrollees with chronic conditions while reducing federal spending.[3]

However, there are three areas where we believe the CMS proposal could be strengthened.

- It will be important for enrollees and MAOs to ensure the agency's new understanding of the uniformity clause remains stable. We therefore recommend CMS add regulatory text to §422.100(d) making it clear that plans are permitted to vary benefits and cost-sharing within a plan benefit package (PBP) to individuals with chronic conditions provided that the plan's benefits meet CMS's antidiscrimination test.

- The agency should permit MAOs to target approaches to increase medication compliance to individuals with chronic conditions. The preamble limits V-BID strategies to Part C benefits. Recently, CMMI announced an expansion of its V-BID demonstration in which MAOs in 25 states may apply V-BID strategies to Part C and D benefits. We strongly believe enrollees in all states, including New York and Connecticut which are not included in the expanded demonstration, should be able to take advantage of the full range of permissible V-BID approaches.

- We strongly recommend that CMS should prohibit MAOs from marketing V-BID strategies to potential enrollees. EmblemHealth views the new strategies as integral to disease and care management techniques that improve the lives of enrollees with chronic conditions. Permitting MAOs to market these approaches to prospective enrollees could run the risk of organizations targeting enrollment activities to beneficiaries with specific chronic conditions to maximize funding under the agency's risk adjustment system, creating a potential black eye for the program. Instead, considering V-BID as a key component of disease and care management will allow MAOs to further demonstrate important innovations we bring to the program without creating these threats.

- **Meaningful Differences Test: Part C (§§422.254(a)(4), 422.256(b)(4); Preamble, pp. 56363-56365)** – CMS proposes to eliminate the "Meaningful Differences" test for Part C benefits in 2019. **We strongly support this proposal.** As we have previously noted, the

[2] Hirth, Richard A., et. al, "Connecticut's Value-Based Insurance Plan Increased the Use of Targeted Services and Medication Adherence." Health Affairs, 35 No. 4 (2016). See also V-BID Center brief "V-BID in Action: A Profile of Connecticut's Health Enhancement Program." (Feb. 21, 2017) Found at http://vbidcenter.org/v-bid-in-action-a-profile-of-connecticuts-health-enhancement-program-2/

[3] University of Michigan Center for Value-Based Insurance Design, "Incorporating Value-Based Insurance Design to Improve Chronic Disease Management in the Medicare Advantage Program" (August 2016). Found at http://vbidcenter.org/wp-content/uploads/2016/08/MA-White-Paper_final-8-16-16.pdf

meaningful difference test often has had the unintended consequence of requiring plans to be forced to increase beneficiary cost-sharing or reduce benefits. Moreover, it 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.

Though not a subject of this proposed rule, **we also recommend CMS eliminate the Total Beneficiary Costs (TBC) test.** The agency's reliance on this test takes the decision to remain enrolled in a plan out of the beneficiary's hands. 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[4] and urge it to do so.

- **Special Enrollment Periods (SEPs) for Dually Eligible Beneficiaries (§423.38(c); Preamble, pp. 56373-56375) –** Federal regulations currently provide individuals who are dually eligible for Medicare and Medicaid unlimited SEPs that allow them to change, disenroll, or enroll in a Medicare Advantage Prescription Drug (MA-PD) plan at any time during the year. CMS is proposing to limit dual eligibles to one change during a calendar year, with the exception of individuals who experience a modification to their Medicaid or Part D low-income eligibility (LIS) status (who may enroll or disenroll in an MA-PD plan within two months of the status change) and those deemed to be "potentially at risk" or "at risk" of using frequently abused prescription drugs, who may not change plans.

  We do not support these new limits on SEPs for dual eligibles except as described below and strongly suggest CMS maintain existing opportunities for most dual eligibles to switch plans on a monthly basis. While we understand the agency's goal to promote care management for dual eligibles, we are concerned fewer dual eligibles will choose to enroll in a Medicare Advantage plan if their options are limited. Enrollment in Medicare Advantage Dual Eligible Special Needs Plans (SNPs) increased by almost 11% from December 2016 – December 2017 and by more than 60% since December 2012.[5] Locking in dual eligibles with limited opportunities to switch plans during the year may have the unintended consequence of jeopardizing the continued enrollment growth of dual eligibles into coordinated care options offered by MAOs that are improving health outcomes. The proposed approach also would limit beneficiary choices, which is especially important to low-income individuals experiencing life changes (e.g., housing, health) that make care less affordable without the opportunity to select the plan option that works best for them.

[4] Section 1854(a)(5)(c)(ii) states CMS "may deny a bid… if it proposes significant increases in cost sharing or decreases in benefits offered under the plan". The law does not define "significant" or require the agency to use the TBC test.

[5] EmblemHealth analysis of CMS data found at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html

We do support CMS's proposal to prohibit plan changes by dual eligibles determined to be potentially at risk or at risk for abuse of prescription drugs from changing plans unless they experience a Medicaid/LIS status change. EmblemHealth agrees that acting otherwise would undermine new authority granted by the Comprehensive Addiction and Recovery Act (CARA) to CMS and Part D plans to implement proven practices that prevent and treat prescription drug abuse.

- **Adding, Updating, and Removing Measures (§422.164(c) – (e); Preamble, pp. 56382-56385)** – CMS proposes to establish a new process for adding, updating, and removing measures from the Star Ratings system. Starting 2022, the agency would add measures or implement "substantive changes" to measures after receiving comments through both the Call Letter and rulemaking processes. Non-substantive changes and the removal of measures could occur after appearing in the Draft Call Letter but would not be subject to rulemaking. All substantive changes would be prospective to the data collection year.

  EmblemHealth strongly agrees with this approach. As noted above, we support additional transparency in the Star Ratings selection process. Allowing plans sufficient time to work with providers and others to ensure plans are meeting CMS's goals is critical to improving plan performance. The process the agency is proposing will permit plans to do so.

- **Proposed Measure List – Beneficiary Access and Performance Problems (BAPP) Measure (Preamble, pp. 56385-56393) –** CMS includes a proposed list of measures for the 2022 Star Ratings system in the preamble to the proposed rule. This list is unchanged from the 2018 measure set with three exceptions – CMS proposes to add a new Statin Therapy for Patients with Cardiovascular Disease Part C measure, add a new Statin Use in Persons with Diabetes Part D measure, and eliminate the BAPP measure.

  It had been our understanding that CMS had decided to remove the BAPP measure from the 2019 Star Ratings due to a change in the calculation and planned to restore it as a single-weighted measure subsequent to appearing on the Display Page pending a comment opportunity. As the agency stated in the 2018 Final Call Letter, "We will continue our dialogue with stakeholders and examine the interplay between audits, compliance/enforcement actions, and the Star Ratings, as well as further specification changes to the BAPP measure and the role it should play in Star Ratings."[6] However, we are unaware of when that dialogue will take place because there is no mention of the measure in the preamble.

  We urge CMS to restore the BAPP measure in its latest form into the 2019 Star Ratings with at least a 1.5 weight and maintain it on the measure set through 2022 and beyond. As we stated in our comments to the 2018 Draft Call Letter, we strongly disagree with those who believe Star Ratings and the agency's compliance activities are unrelated. Star Ratings have been developed to provide beneficiaries with an assessment of the care they would likely receive if enrolling in a plan. A plan that fails to be compliant with CMS requirements, which have been developed to ensure beneficiaries

[6] See page 86.

are well served by the program, is not providing high quality care in areas where it is deemed to be non-compliant. A well-functioning marketplace ensures consumers have the information they need to fully evaluate their choices. Eliminating the BAPP measure from Star Ratings keeps this key information from beneficiaries when making the important decision of whom to entrust with their health care, which is inconsistent with the agency's overall approach to improve transparency and support beneficiary choice as the primary engine for moving the program forward.

We also continue to strongly oppose removing the BAPP measure from Star Ratings for 2019 and believe it should maintain at least a 1.5 weight. While we agree that measures undergoing specifications changes should be implemented using a phased-in process consistent with CMS policy, we view CMS's 2017 proposals for the BAPP measure as alterations in the *calculation* of the measure score and not a change to its specifications. The proposed changes do not require MAOs to establish new data collection processes or put systems in place with providers to promote high performance. MAOs are already working to comply with CMS requirements and the agency has the data it needs to evaluate performance on the BAPP measure as proposed. The agency's phased-in approach to adapt the changes put in motion in 2017 is therefore unnecessary.

- **Data Integrity (§422.164(g); Preamble, pp. 56394-56397) –** In general, CMS proposes to continue its policy to reduce a contract's measure score to 1 Star when it finds data reported by the MAO or PDP "are inaccurate, incomplete, or biased". The exception to this rule is a new scaled reduction for Part C and Part D appeals measures.

  We support the agency's proposed phased approach for the appeals measures. Our contracts have been affected by CMS's previous unwillingness to consider scaled reductions to appeals measures in the past when we have made honest and correctible mistakes that did not warrant a reduction to 1 Star. 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.

  We also continue to believe CMS should offer MAOs an opportunity to correct errors without facing rating reductions. One way to identify when these errors are occurring is for CMS to provide MAOs and PDPs with a preliminary view of performance midway through each data reporting year, which would allow organizations to closely examine if data reporting mistakes are causing unexpected results and correct these errors before the end of the reporting year. We strongly urge the agency to work with MAOs to consider if a preliminary review period is feasible and could be implemented quickly.

- **Star Ratings: Calculating Individual Measure Scores (§422.166; Preamble, pp. 56397-56399) –** CMS proposes to incorporate its existing methodology for calculating individual measure scores into regulatory text. This methodology includes the clustering approach the agency uses to determine individual star thresholds or cutpoints for most

measures. In the preamble, CMS acknowledges plan concerns about this methodology and solicits comments to create more stability in these cutpoints.

EmblemHealth agrees that changes in the clustering methodology are necessary and continues to believe stability is best achieved by announcing thresholds before the measurement year. While CMS has described predetermined cutpoints as potentially "mischaracterizing" plan performance, we strongly disagree. There are other CMS practices in the threshold-setting process that more likely lead to any mischaracterization that occurs. For example, cutpoints may be extremely narrow such that variation of 2-3 percentage points from year to year can lead to significant rating reductions in many measures.

Instead, we strongly advise CMS to predetermine thresholds that it anticipates will determine high performance on a prospective basis. This may lead to the establishment of 4 Star cutpoints that are more demanding than would otherwise be the case. Establishing predetermined thresholds is also consistent with the agency's overall approach to Star Ratings in this rule, which recognizes the importance of stability and predictability in ensuring Medicare Advantage and Part D plans are providing the highest quality care. CMS's proposals to apply changes to measures prospectively and add new measures or make substantive changes only after a rulemaking process (discussed above) are representative of this approach. We strongly suggest the agency bring this same perspective to the establishment of Star Ratings thresholds.

CMS suggests two alternatives to improve the predictability of 4 Star thresholds. We believe either of these ideas – calculating cutpoints based on the weighted average in earlier years or limiting the growth of the thresholds – is superior to the existing system. An MAO's work to address deficiencies in Star Ratings performance requires specific investments. As indicated above, more stability and predictability in the cutpoints allow organizations to target activities in deficient areas while also ensuring levels of performance determined at least at the 4 Star level in earlier years will not be undermined.

- **Measure Weights (§422.166(e); Preamble, pp. 56401-56402) –** The proposed rule would incorporate existing measure weights into regulatory text, including the 1.5 weights for measures in the Patient Experience and Complaints and Access domains. The preamble notes CMS is "considering increasing the weight of the patient experience/complaints and access measures" and requests input on this proposal.

  We strongly oppose increasing the weights of measures in these domains. While we are constantly working to ensure our members receive the highest levels of care, the survey measures are extremely subjective and may be affected by factors beyond the health plan's control such as social determinants of health, chronic disease, or health care disparities. We have found that beneficiary survey measures may not be an accurate reflection of satisfaction. For example, EmblemHealth historically has among the lowest disenrollment rates in the country and our number of beneficiary complaints has also generally been below our competitors. Yet our CAHPS scores seem inconsistent with

these results. This suggests that the existing methodology to case-mix adjust CAHPS scores may be inadequate.

Instead, we believe the measures in these domains should be de-weighted to 1x. Doing so would not affect our continuing efforts to attract and retain our enrollees and would mean the Overall Rating provides a more accurate account of plan performance.

- **Any Willing Pharmacy (§§423.100, 423.505; Preamble, pp. 56407-56411) –** CMS is proposing several "clarifying" changes to the any willing pharmacy regulations. These include new definitions of retail and mail-order pharmacies, requirements to make standard contract terms available to requesting pharmacies within two business days and at least 15 days prior to the AEP, and prohibitions of new credentialing requirements within standard contracts that are not endorsed by state or nationally recognized sources. The changes are intended to ensure pharmacies able and willing to participate under standard contract terms are permitted to do so in compliance with the statutory requirements.

  We have concerns with several of these proposals. Part D sponsor pharmacy network techniques have been critical components in ensuring prescription drugs remain accessible, affordable, and safe for plan enrollees. We are unaware of ***enrollee*** concerns about the accessibility of Part D benefits. In fact, beneficiaries have reported high levels of satisfaction with the program,[7] which suggests these changes are unnecessary and could only reduce the affordability of prescription drugs without increasing enrollee access to the medications they need. Our specific concerns include:

  - New Limits on Participation Standards: Establishing reasonable standard contracting terms is one way in which Part D plans ensure their enrollees are safely and effectively taking their medications. As the preamble notes, Part D plans may create terms in standard contracts to promote safety by establishing additional standards for pharmacies and pharmacists. This includes making sure pharmacies that dispense complex medications have been determined to improve compliance and beneficiary understanding of how to use these drugs. Part D plan activities to protect beneficiaries should not be prohibited, and we urge CMS to take another look at the proposed ban of plan credentialing requirements that promote better outcomes.

  - Definition of Retail Pharmacy: We are also concerned the agency's revised definition of retail pharmacies could allow network access to organizations that are not appropriate for the sponsor's enrollees. For example, plans should be permitted to limit participation by retail pharmacies that do not have physical establishments within the plan's service area under standard contracts for retail pharmacies. For this reason, we suggest an adjustment to the revised retail pharmacy definition so it reads "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public **in the sponsor's service area**

[7] For example, see the 2017 Medicare Today survey finding 88% of Part D enrollees are satisfied with their coverage and 92% who find their plan "convenient to use."

from which Part D enrollees could purchase a covered Part D drug at retail cost sharing..." This clarification would not change existing Part D requirements to make medications available out-of-network or when an enrollee is not in the sponsor's service area.

- **Formulary Changes and Transition Process (§423.120(b)(3),(5); Preamble, pp. 56411-56416)** – CMS is proposing several constructive changes in these sections that will allow Part D sponsors to reduce costs for enrollees and taxpayers. These proposals include changing beneficiary notice requirements during the transition and formulary change process that permit sponsors to more quickly ensure enrollees are receiving the most clinically appropriate, cost-effective medications. CMS also proposes to permit Part D sponsors to add generic drugs and eliminate or change the tier placement of brand-name drugs midyear without preapproval from the agency when a new, therapeutically equivalent generic product enters the market.

  We strongly support these proposals. As we describe in more detail below, Part D sponsor management techniques have been responsible for partially insulating beneficiaries from recent drug manufacturer pricing practices that jeopardize the affordability of this extremely successful program. The elimination of existing barriers to permit our use of these techniques in combination with commonsense approaches to ensure drug companies are held accountable for their pricing practices is the key to keeping the Part D program affordable for beneficiaries and taxpayers in the future.

- **Meaningful Differences Test: Part D (§423.265; Preamble, pp. 56417-56419) –** CMS is proposing to limit the meaningful differences test in Part D to require enhanced options to be meaningfully different from basic Part D plans offered by the sponsor in a service area. The agency would no longer apply the test to two enhanced options offered by a Part D sponsor.

  We support the proposal. EmblemHealth has raised concerns that this test may limit choices by applying a regulatory evaluation instead of the market to determine what components of a Part D plan are of value to beneficiaries. We would prefer the test be eliminated for all products and plans but appreciate the agency's proposal to encourage more enhanced options.

- **Request for Input – Direct and Indirect Remuneration (DIR) (Preamble, pp. 56419-56426) –** In the preamble, CMS requests comments to proposed approaches to ensure rebates negotiated by Part D sponsors with drug manufacturers are passed on to beneficiaries at the point of sale. The agency cites evidence of "cost shifting" in support of pursuing these ideas, which includes higher federal spending for reinsurance and reduced transparency for beneficiaries at the point-of-sale.

  We appreciate that CMS is taking a deliberative process in implementing this proposal. **Although we believe that these proposals will not achieve the agency's desired results, we are committed to working with the agency to implement a workable**

approach that continues to allow Part D plans to negotiate discounts and rebates with pharmaceutical manufacturers.

The complexity of issues that must be overcome is evident in the number of questions raised in the preamble. For example:

- It remains unclear how plans would reflect performance-based agreements at the point of sale. Under the existing DIR framework, Part D sponsors may incorporate these performance-based rebates into lower premiums, and the data described below demonstrate that is exactly what is taking place. Requiring plans to reduce prices at the point of sale without first demonstrating we have met the performance terms could make these arrangements less attractive to drug manufacturers and plans and therefore limit the amount of savings plans can pass on to their enrollees.

- Part D plan rebate agreements focus on medications where it is clinically appropriate to negotiate discounts among products with similar therapeutic attributes. However, many rebates agreements (including the performance-based agreements described above) may mean discounts vary from quarter to quarter. The variability of these discounts could create perverse incentives for beneficiaries to request switching from drug product to drug product to receive the largest discount without regard to clinical efficacy or overall program cost.

- The generic drug dispensing rate in Medicare Part D is 87%.[8] These data demonstrate that Part D plans are effectively encouraging beneficiaries to use clinically appropriate, cost-effective generic drugs even though the plan may not have negotiated a rebate. The agency's consideration of a mandatory rebate pass-through approach would likely undermine these efforts and unnecessarily increase costs in the program.

We are concerned that these proposals are diverting focus from drug manufacturer pricing policies that continue to put the program in jeopardy. While some are continuing to allege Part D plan practices are causing costs by the government and enrollees to increase, the facts tell a very different story. It is only lately with the introduction of high-cost drugs that analysts are raising concerns about Part D expenditure growth and the future viability of the program.

The evidence of the real cause of higher federal reinsurance costs is clear.

- According to a January 2017 report from the Office of Inspector General (OIG),[9] total spending (includes beneficiary and government costs) on medications with monthly costs of more than $1,000 in the catastrophic phase of the Part D benefit grew from $5 billion in 2010 to more than $33 billion in 2015. However, as

[8] 2017 Medicare Trustees Report, footnote 66 on page 143

[9] Department of Health and Human Services Office of Inspector General, "High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage," (OEI-02-16-00270, January 2017).

competitors for many of these high-priced drugs have been introduced (most notably, those treating Hepatitis C), the rate of increase of federal reinsurance costs has declined, from an average annual growth rate of about 25% from 2010 – 2015 to under 5% in 2016.[10]

- The Medicare Trustees have found Part D prescription drug costs have increased annually by 8.3% during the past five years, much faster than Part A (2.1%) and Part B (5.4%). While average Part D expenditures were increasing by over 8% annually from 2012-2016, the average Part D premium was increasing by just more than 1%.[11] These findings demonstrate how Part D plans are passing on negotiated rebates to beneficiaries.

- The American Association of Retired Persons (AARP)[12] has found retail prices for the 268 brand name drug products most widely used by older Americans rose 15.5% in 2015 or over 150 times the rate of general inflation. The study also finds the average cost of brand-name drugs commonly used by older adults to treat chronic conditions almost doubled from 2011 – 2015, from $2,995 to over $5,800.

Any cost-shifting that is occurring is therefore not from plans to the government but from drug manufacturers to the government, which recognize that Part D will pay for these drugs without regard to price. Given these factors, we are unsure how the rebate pass-through proposal will have any real effect other than to increase premiums. Several new drugs cost more than $10,000 for a course of treatment, far higher than the point at which the catastrophic threshold kicks in. Even requiring a 50% pass-through on these drugs will still leave unsubsidized beneficiaries and the federal government with considerable costs. We also view the proposed concept as inconsistent with the agency's market-based philosophy, the value of which Part D program demonstrates, and which has kept premiums in Part D low and beneficiary satisfaction high throughout its history. Instead, this approach would have CMS more directly dictate the ways in which the market requires Part D sponsors to achieve savings for beneficiaries.

Other solutions are necessary to achieve the program's goals. We recognize that many of these ideas are likely not within CMS's authority without Congressional action (e.g., instituting a federal Research-to-Profit ratio for drug companies, extending the Coverage Gap Discount Program into the catastrophic phase of the benefit). However, there are additional steps the agency could have proposed that would have more directly addressed rising Part D costs. These include reevaluating the agency's two-drugs per class policy or permitting Part D plans even greater flexibility to make midyear formulary changes for therapeutically equivalent brand-name drugs when recommended by the sponsor's Pharmacy & Therapeutics Committee.

[10] EmblemHealth analysis of data in the 2017 Trustees Report. See Table IV.B10 on page 146.
[11] EmblemHealth analysis of data in the 2017 Trustees Report.
[12] AARP Public Policy Institute, "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015" (December 2016)

EmblemHealth has first-hand knowledge of efforts by Part D plans to make the program work, both during the first days of its implementation in 2006 and through the years. We remain committed to this practical hands-on, problem-solving attitude that has made the program such a success and will continue to work with the agency to consider how it can ensure the long-term viability of the program. For example, we have considered whether requiring a minimum percentage pass-through should apply only to drugs with monthly costs above the specialty tier threshold, which could mitigate premium increases while focusing efforts on products that have been responsible for recent Part D spending growth. However, we also believe it is time for drug manufacturers to come to the table in a similar spirit. We urge CMS and federal policymakers to turn their attention to real solutions that will address the root causes of high Part D spending increases without adversely affecting beneficiaries.

- **Open Enrollment Period (OEP) (§§422.62(a), 422.2268(b)(9), 423.2268(b)(9); Preamble, pp. 56428-56429, p. 56436)** – The proposed rule would implement a change recently enacted by Congress to replace the Medicare Advantage Disenrollment Period with a revamped Open Enrollment Period (OEP) that closely resembles the opportunity for beneficiaries to change Medicare Advantage plans during the first three months of the year that was in effect prior to the Affordable Care Act (ACA). The new OEP differs from the previous version in that beneficiaries would now be permitted to change their Part D election during this period and individuals in fee-for-service (FFS) Medicare would no longer be permitted to enroll in a Medicare Advantage plan.

  The preamble notes another important difference from the pre-ACA OEP is the authorizing legislation's prohibition of "unsolicited marketing and mailing marketing materials to individuals ***who are eligible*** for the new OEP." (emphasis added) Since the law no longer permits individuals in FFS Medicare to enroll in a Medicare Advantage plan during this period, this prohibition of unsolicited marketing activities would apply only to Medicare Advantage enrollees.

  The preamble acknowledges that compliance with the marketing requirements could be complicated as MAOs conduct permissible activities directed towards all Medicare beneficiaries. In response, CMS would prohibit MAOs from "knowingly" targeting or sending materials to Medicare Advantage enrollees during the OEP. **We agree with this approach.** MAOs that intentionally target marketing activities to Medicare Advantage enrollees during the OEP would clearly be in violation of the law. The agency's proposed standard would focus enforcement on activities tailored to these individuals without implicating organizations that unknowingly reach OEP-eligible beneficiaries with otherwise permissible activities.

  We also request additional guidance to define "unsolicited marketing". The Medicare Advantage Marketing Guidelines currently describe "unsolicited contacts" as including but not limited to door-to-door solicitation" and "approaching potential enrollees in common areas" and excludes "conventional mail and other print media (e.g., advertisements, direct mail)". While we understand that mailing materials during the OEP to eligible beneficiaries will be prohibited pursuant to the enacting legislation and

that unsolicited contacts will also not be permitted, it will be important to know what other activities constitute "unsolicited marketing" for compliance purposes.

- **Beneficiary Materials (§422.111; Preamble, pp. 56431-56433)** – CMS proposes to change its requirement that MAOs send hard copies of the Evidence of Coverage (EoC) to all enrollees at least fifteen days prior to the start of the Open Enrollment Period (OEP). Instead, under the agency's proposal, MAOs would send hard copies only upon request and otherwise make the EoC available on its website and/or via email no later than the start of the OEP. MAOs would continue to provide the Annual Notice of Change (ANOC) in hard copy to enrollees at least fifteen days prior to the start of the OEP.

  EmblemHealth strongly supports this proposal and greatly appreciates CMS's willingness to put it forward. While the EoC provides very important information, we have found beneficiaries are not often comfortable receiving a document of this length, and the process of preparing and mailing a 200+ page document to 160,000 enrollees has proven to be a significant burden. We also strongly support the additional fifteen days to ensure the information in the EoC is accurate for our enrollees. The agency's proposal is an important step forward in improving the usability of the document and reducing costs for beneficiaries and taxpayers.

- **Medicare Advantage Communication Requirements (§§422.2260 – 422.2268, §§423.2260 – 423.2268; Preamble, pp. 56433-56436) –** The rule suggests significant changes to the way Medicare Advantage and Part D plan materials would be regulated. The agency proposes to differentiate between "communications" and "marketing". Marketing would be defined as the subset of communications involving the use of materials to "draw a beneficiary's attention to a MA plan or plans" and "(i)nfluence a beneficiary's decision-making process when making a MA plan selection or influence a beneficiary's decision to stay enrolled in a plan." Communications would encompass marketing and all other beneficiary materials. Marketing activities would continue to be subject to the existing Marketing Guidelines and materials review processes. Communications activities that are not marketing would be subject to certain basic standards and be auditable but would not need the agency's preapproval.

  EmblemHealth strongly supports this CMS proposal. We appreciate the crucial role the agency's oversight plays to ensure all materials MAOs provide to beneficiaries, marketing or otherwise, are accurate, translatable, and do not provide the false impression of the agency's endorsement. We also recognize that additional scrutiny of marketing materials is important to promote a more competitive marketplace and address concerns raised by members of Congress and others about the Medicare Advantage program prior to the adoption of the current requirements. We believe that the agency's proposal strikes the right balance of ensuring beneficiaries are safeguarded and the program's reputation is protected while also providing MAOs with additional flexibility in developing information that is more usable for enrollees.

We suggest the agency issue specific sub-regulatory guidance clarifying exactly which materials will be considered communications/non-marketing and which are marketing in support of this approach. The preamble includes helpful examples of each and it will be important to develop an itemized list of where existing materials fall to ensure plans are fully in compliance with the new processes.

- **Preclusion List (§§422.2, 422.222, 422.224, §§423.100, 423.120(c)(5),(6); Preamble, pp. 56441-56454)** – CMS is proposing to replace Part C and D provider enrollment requirements with new "preclusion lists" of providers from whom plan sponsors may not cover prescribed services. **We support the agency's proposal.** The Part D provider enrollment requirements have proved extremely challenging. This preclusion list, which will be generated by CMS, is a practical solution to ensure Medicare funds are not used to support individuals found to be behaving in a fraudulent manner. We understand there are ongoing issues with the development of a preclusion list (e.g., how it is to coordinate with the OIG's exclusion list, the appropriate terms of the provisional coverage period) and request the agency continue to work with MAO and Part D sponsor representatives to address these issues.

- **Provider Burden (Preamble, pp. 56455-56456)** – CMS requests information on reducing burdens on providers "arising from (MAO) requests for medical record documentation" to comply with risk adjustment validation requirements. **We share the concerns underlying this request.** CMS's Medicare Advantage risk adjustment model depends upon diagnosis data to predict the costs of enrollees and calculate appropriate payment to plans. MAOs rely upon diagnoses reported by physicians and other clinicians in the beneficiary's medical record. Oftentimes, a clinician may not report an individual's diagnoses with each visit and MAOs must then contact the physician's office to ensure the medical record is complete. This can create additional burdens on physicians who may participate in multiple plan networks and for MAOs seeking to be reimbursed appropriately for the costs of treating a beneficiary's conditions. More importantly, these contacts between MAOs and clinicians divert resources, both personal and financial, that are better spent addressing beneficiary needs.

  One potential solution is for CMS to consider changes to its risk adjustment documentation requirements. We and others have been longstanding proponents of permitting MAOs to use chronic condition diagnoses reported on medical records from previous years or data from sources other than the individual's medical record (e.g., prescription drug claims) that provide evidence supporting the submitted diagnoses. Accepting this information would likely reduce the need for MAO outreach to clinicians to confirm a beneficiary's condition. We believe CMS has the statutory and regulatory authority[13] to permit MAOs to use these other data sources to validate diagnoses,

[13] Section 1853(a)(3)(C)(iii) states the risk adjustment methodology "shall be based on data from inpatient hospital and ambulatory settings" which seems to include prescriptions ordered in these settings and other similar data from prior years. Similarly, 42 CFR §422.310(d)(3) states MAOs must obtain the risk adjustment data required by CMS from the provider, supplier, physician, or other practitioner that furnished the item or service.

although the agency would likely need to make changes to the Medicare Advantage manual[14] and other sub-regulatory guidance.

However, we recognize that permitting MAOs to use additional sources of data to substantiate risk adjustment diagnoses will not significantly alleviate provider burdens and refocus resources to address beneficiary needs. **These concerns have led us to consider whether there are alternatives to the agency's diagnosis-based model that provide appropriate incentives for MAOs to enroll and manage care for high-needs beneficiaries.** In general, we believe the model should be more directly related to the costs of treating individuals in the previous year. Changing the model to depend more on experience would significantly reduce provider burdens by relying on Medicare Advantage encounter data (once it is fully reliable) and other information collected by MAOs instead of diagnosis reporting and validation to determine appropriate plan payments.

However, we realize that there could be unintended consequences for MAOs and clinicians to stop managing care in ways that would increase risk scores under this framework. We are continuing to think through this approach and welcome the opportunity to discuss it or other alternatives with CMS.

- **Medical Loss Ratio (§§422.2420, 422.2430, 423.2420, 423.2430; Preamble, pp. 56456-56459)** – CMS is proposing significant changes to the Medicare Advantage and Part D minimum medical loss ratio (MLR) formula. If finalized, starting the 2018 plan year, MAO and PDP costs for conducting fraud prevention activities and providing medication therapy management (MTM) services would be considered quality improvement activities (QIA) in the MLR calculation. The agency is also proposing other changes to simplify the MLR reporting process.

  We strongly support these proposals. Fraud prevention activities are fundamental to the Medicare Advantage value proposition. MAO activities to detect and deter fraud reduce taxpayer costs throughout the program by identifying providers and suppliers who are creating unnecessary and unlawful expenses in Medicare Advantage, FFS, and Part D. Although not a subject of this regulation, we strongly suggest CMS make these changes to the MLR calculation for Qualified Health Plans participating in commercial health exchanges in addition to the other constructive changes recently proposed by the agency in the 2019 Notice of Benefit and Payment Parameters.[15] We also strongly support the agency's clarification for how MTM activities are treated in the MLR calculation, which has not been clear since the start of the Part D program.

- **Changes to the Medicare Advantage Risk Adjustment Model (§422.308(c))** – As noted above, CMS is proposing significant changes to the process in which it makes substantive changes to the Star Ratings system. **We support CMS putting a similar process in place for substantive changes to the agency's risk adjustment system.**

[14] For example, Section 40 of the Medicare Advantage manual specifically requires "All diagnosis codes submitted must be documented in the medical record and must be documented as a result of a face-to-face visit."
[15] See 82 FR 51052.

These changes have a significant and material effect on plan operations and more transparency is needed when the agency proposes substantive changes. We would define "substantive" to mean either structural changes in the model (e.g., the agency's recent adoption of a six-segmented model, the agency's planned switch to calibrating the model on Medicare Advantage plan encounter data) or additions or removals of HCC codes. Changes to HCC coefficients due to updating the model calibration year and normalization factors would be considered "non-substantive" under our proposal and would continue to be addressed through the Advance Notice and Final Notice process.

We appreciate this opportunity to respond to this proposed rule. Please contact Howard Weiss at 646-447-1074 or hweiss@EmblemHealth.com if you would like to discuss the issues we have raised.