Amy Sawyer
Director Health Policy
120 Fifth Avenue Place
FAP 2628
Pittsburgh, PA 15222
(412)544-2455

January 16, 2018
VIA ELECTRONIC SUBMISSION at www.regulations.gov
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: **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, CMS-4182-P**

To the Centers for Medicare & Medicaid Services:

Highmark Inc. ("Highmark") is one of America's leading health insurance organizations and an independent licensee of the Blue Cross and Blue Shield Association. Highmark, together with its Blue-branded affiliates, collectively comprises the fourth-largest Blue Cross and Blue Shield-affiliated organization and one of the nation's 10 largest health insurance organizations. Highmark and its affiliated health plans work passionately to deliver high-quality, accessible, understandable, and affordable experiences, outcomes, and solutions to customers. Highmark and its Blue-branded affiliates proudly cover the insurance needs of nearly 5 million members in Pennsylvania, Delaware, and West Virginia.

Highmark is invested in the success of the Medicare Advantage program and is committed to working to improve the total health care experience and to improve the health of the communities we serve. We thank the Centers for Medicare and Medicaid Services ("CMS") for the opportunity to offer comments on the 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.

First and foremost, we are responding with great thanks to a number of the provisions set forth in this proposed rule:

- Highmark applauds the steps that CMS has taken to enable plans to be more responsive to beneficiaries' unique needs and greater opportunity to provide value including the introduction of more flexibility within uniform benefit requirements, elimination of meaningful difference requirements, and more flexibility to offer segmented benefits.

- We are also supportive of the changes that have been made to improve the customer experience and reduce the amount of paper mailed to beneficiaries. We believe that enabling electronic EOC delivery will improve beneficiaries' satisfaction and help make care more affordable by reducing administrative spending.

- Highmark is also supportive CMS' proposal to codify the MA and Part D Star Ratings System, and Highmark agrees with CMS' vision to improve transparency and predictability in the Star Ratings System. Ultimately, this will ensure better alignment across health plans and providers to ensure all parties are appropriately coordinated to deliver high quality care and services to Medicare Advantage beneficiaries. Highmark remains committed to this program and stands ready to work with CMS on initiatives that further enhance the Star Ratings System.

- Additionally, with regard to the Star Ratings System, Highmark supports both CMS' proposal to calculate the quality bonus payment for consolidated contracts based on the enrollment-weighted mean of the quality bonus payment rating of the surviving and consumed contracts and the development of limits of cut point fluctuations on a year-over-year basis.

- We thank CMS for the revision to the definition of generic drug to include follow-on biologic products to allow a lower cost-sharing option to LIS beneficiaries and non-LIS beneficiaries during catastrophic coverage. We believe that this will reduce marketplace confusion about what level of cost sharing Part D enrollees should be charged for follow-on biological products and by allowing for a lower cost sharing, this will improve Part D enrollee incentives to use follow-on biological products.

Second, we would like to take this opportunity to ask for clarification regarding several of the proposed provisions:

- We first seek clarification with regard to the implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA), under proposed Reasonable Access (§§ 423.100, 423.153(f)(11), 423.153(f)(12)), CMS proposes sponsors provide reasonable access to frequently abused drugs and take into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time. Highmark requests clarity on CMS expectations for provision of coverage for emergency overrides and special accommodations.

- Additionally, while overall we are supportive of the proposed changes in the Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (MLR) (§§ 422.2420 and 423.2430) provisions, we seek clarity around what type of activity should be included or excluded from fraud activities. Highmark is also seeking confirmation as to whether CMS will still be providing a detailed template for sponsors to complete as support for the streamlined data being requested.

- We also appreciate the codification of changes to the enrollment period as required by the 21st Century Cures Act and hope that further clarification will be offered about the marketing guidelines during that timeframe. Specifically, the 21st Century Cures Act prohibits unsolicited marketing and mailing marketing materials to individuals who are eligible for the new OEP. However, the comment solicitation in the proposed rule asked how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as through mailing campaigns aimed at a more general audience. If CMS is going to allow some form of marketing during the OEP, Highmark asks that the rules regarding this marketing be explicitly established as we fear that any grey area with regard to those rules could lead to confusion among both payers and beneficiaries.

Finally, while we were mostly supportive of the provisions of this proposed rule, there are several areas on which we would like to voice our concerns:

- Our first concern surrounds the implementation of CARA. While Highmark is supports the overall approach, given the severe health risks that this issue represents for millions of beneficiaries, we suggest CMS reconsider their proposed effective date and instead propose that this change be implemented in mid-year 2018. Additionally, CMS proposes that before a sponsor can limit access it must conduct case management, obtain the agreement of all prescribers of frequently abused drugs that the limit is appropriate, unless the prescriber is nonresponsive, and provide notice to the potential at-risk beneficiary. Highmark does not believe prescriber agreement is needed to lock-in members. In this process, prescribers were consulted by case management and given the opportunity to change prescribing behavior. Therefore, they should not be able to prohibit a lock-in approach.

- Our second concern regards the changes to the Any Willing Pharmacy Terms and Conditions. CMS clarifies that the "any willing pharmacy" requirement applies to any "similarly situated" pharmacy that, "…has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy." Highmark recommends CMS consider the subjectivity of the assessment and whether this is executable. We are concerned the assessment, being subjective, might influence medications normally dispensed in less expensive distribution channels to be diverted to more expensive distribution channels.

- Our third concern relates to the Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale. CMS is considering setting the minimum percentage of manufacturer rebates that

must be passed through at the point of sale at a point less than 100 percent of the applicable average rebate amount for drugs in the same drug category or class. For operational ease, CMS is considering setting the same minimum percentage, for all rebated drugs in all years- that is, the minimum percentage would not change by drug category or class or by year. There are significant concerns with this proposed approach. Operationally, the cost of this provision is substantial. Maintaining an up-to-date price list, which would have to reflect the proposed methodology of passing on a part or all of the rebates, would create a large administrative burden and operational cost, which would ultimately need to be passed on to the members or the federal government. Plans would have extreme difficulty making mid-year updates to manufacturer rebate contracts that would reflect changes in available and clinically superior drugs on the market. However, drug manufacturers will benefit through reduced liability for the gap discount, but at the expense of the beneficiary and government plan premiums, around tens of billions of dollars. According to tables 10A-C, the reduced cost for drug manufacturers is roughly equal to the increased premiums members would pay. Furthermore, of the increased cost to the government, drug manufacturers are projected to receive approximately a third under all four scenarios presented. Additionally, applying rebates as average percentages across drug classes or at fixed dollar amounts will result in inadvertent cross-subsidizations across drugs. This will result in prices at the point of sale not proportionate to true cost. Lastly, we believe this action will impair rebates in the aggregate as lower performing plans have the ability to self-correct and high performing plans have had their competitive advantages made public. Said differently, we believe this action will cause rebates to be more tightly clustered around a lower mean on any given drug. Consequently, we do not support any approach where rebates are made part of the point of sale discount; however, average rebates at least preserve competitive advantages a strong rebate performing plan might have.

- Our final concern relates to the comment solicitation regarding Reducing Provider Burden. To address concerns from providers about burdensome requests from MAOs for their patients' medical record documentation, CMS is soliciting comment from stakeholders to more fully understand the issue and for ideas to accomplish reductions in provider burden. While we are sensitive to the time and effort that providers spend fulfilling medical records requests, we want to ensure that the Plans' access to medical records whether through automated electronic channels or through manual retrieval, is of utmost importance. Many times, membership is large and diverse, and it is quite common for beneficiaries to have seen numerous practitioners over the years. A health plan has the unique ability to maintain comprehensive line of sight into beneficiaries' care and serve as the hub from which a panel of providers may coordinate care.

However, in order to execute effectively, plans must have access to medical records and associated medical data. Furthermore, both CMS and accrediting bodies require plans to demonstrate their overall quality (e.g., Medicare Star Ratings, HEDIS scores, etc.). The only means to objectively measure quality is to leverage the data found in medical records. Many performance measures, of which plans are held accountable, require plans to demonstrate that an activity occurred in the past. This retrospective review can be up to 10 years prior, before a beneficiary was eligible for Medicare Advantage and/or was affiliated with his/her current health plan. Therefore, in order to ensure plans have the ability to maintain quality care, and also objectively demonstrate that standard of quality, full and timely access to medical records is a necessity.

We thank the Department for its consideration of these comments.

Respectfully,

Amy M. Sawyer
Director, Health Policy
Government Affairs
Highmark, Inc.