January 16, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via www.regulations.gov

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)

Dear Administrator Verma:

The Alliance of Community Health Plans (ACHP) is pleased to submit comments in response to the proposed rule on Medicare Advantage and Part D, published in the *Federal Register* on November 28, 2017.

ACHP is a national organization bringing together innovative health plans and provider groups to improve the health of communities. Members are non-profit organizations or subsidiaries of non-profit health systems and are among the highest-performing plans in the nation. They provide coverage and care for more than 19 million Americans, including 2.5 million Medicare beneficiaries. ACHP members offer eight of the sixteen 5-star rated Medicare Advantage (MA) plans. Overall, 34 MA contracts offered by ACHP members received 5, 4.5 and 4-stars in the 2017 star ratings.

We applaud CMS' work and support the overall direction of this proposed rule towards regulatory flexibility and relief from outdated or burdensome requirements. The rule reflects recommendations that ACHP has previously offered and facilitates the ability of plan sponsors to strengthen benefits that reflect the needs of their enrollees and administer coverage efficiently. We would highlight the following:

- ACHP appreciates CMS' commitment to the star ratings system and proposed changes for updating measures. We agree with the steps outlined for calculating star ratings when contracts are consolidated. We offer a number of recommendations for further development of the ratings system; provide a comparison to NCQA data on cut points for our recommendation that CMS cap year-to-year changes; and suggest further work to report measures and compare performance at the state level. We urge CMS to diminish the weight

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given to improvement measures, which are redundant of the overall thrust of the star ratings system and distort the ratings.

- ACHP appreciates the discussion that CMS has initiated on drug rebates and beneficiary costs at the point of sale. The proposed policies fail to address the real problem, which is the prices set by manufacturers for their drugs. We suggest this problem should be addressed more directly and effectively – for example, by requiring transparent justification for prices – than by requiring Part D plans (and their PBMs) to pass along manufacturer rebates at the point of sale. The potential financial impact combined with administrative complexities, operational burdens on our member plans and other potential consequences of the point-of-sale approach lead us to urge CMS not to move forward with these proposals.

- ACHP supports exceptions to uniformity requirements in order to tailor benefits to segments of the enrolled population and promote informed consumer choice.

- We support and appreciate changes that will allow Part D plans to better manage formularies, including updating drugs to account for new generics and other clinical or pricing developments.

- ACHP offers additional recommendations that we urge CMS to address in the final rule or in the 2019 Advance Notice and Call Letter. These include: restoring quality payments that have been eliminated under the MA benchmark cap; improving the accuracy of county benchmarks by excluding Part A-only enrollees from the calculation of underlying FFS costs; allowing telehealth-based services in the MA bid for basic benefits; eliminating the coding pattern adjustment after the statutory mandate expires in 2018; reducing multiple plan audits and requirements; and reducing unnecessary communications.

Our detailed comments follow.

Section A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

A.1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

ACHP supports the implementation of the statutory provisions of CARA in order to strengthen drug management programs designed to limit access to opioids. Specifically, CMS is requesting information on plan sponsors' systems capabilities and whether such systems can account for group practice prescribers or pharmacies with multiple locations.

Currently, plan sponsors have the capability to account for prescribers by practice group (TIN). Pharmacy Benefit Managers are able to account for pharmacies by their corporate affiliation. Neither entity possesses both pieces of information, so in order to build an effective system, a multidirectional exchange of information with better end-to-end visibility is needed. We ask that CMS take these operational challenges into account when finalizing the rule.

A.2. Flexibility in the Medicare Advantage Uniformity Requirements

ACHP supports CMS' proposal to enable MA plans to vary supplemental benefits as well as premium and cost sharing and allow MA plans flexibility on the uniformity requirements within each segment of a MA plan. We believe that this flexibility will encourage value-based benefit designs, allowing plan sponsors to offer MA plans that meet the targeted needs of different Medicare populations and promote informed consumer choice when comparing plans. When implementing the proposal, we ask CMS to develop and implement clear and distinct medical criteria, including eligible conditions, that MA plans may utilize to determine eligibility for enrollees to obtain tailored supplemental benefits. For similar reasons, we also support the proposal in A.3 to allow MA plan segments to vary by benefit *in addition* to varying by premium and cost sharing.

A.4. Maximum Out-of-Pocket Limit (MOOP) for Medicare Parts A and B Services

ACHP supports CMS' proposal to establish its authority to set annual MOOP limits in the Call Letter and other subregulatory guidance, using Medicare FFS data. ACHP believes that MOOP is an effective tool that protects plan enrollees from unforeseen costs. We appreciate CMS' flexibility in this regard and support the implementation of two or more levels of MOOP. This would enable MA plans to offer lower MOOP limits with different cost-sharing. In order to provide greater consumer choice, we further recommend that CMS consider reducing cost sharing amounts for plans that implement mandatory MOOPS.

A.6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review

ACHP supports the proposal to eliminate the meaningful difference requirements. We believe CMS' existing requirements for marketing materials and nondiscriminatory benefit designs are sufficient consumer safeguards.

A.7. Coordination of Enrollment and Disenrollment through MA Organizations and Effective Dates of Coverage and Change of Coverage

ACHP supports CMS' proposal to codify modified requirements for default enrollments upon conversion to Medicare. While CMS points to the example of dual eligibles converting to special needs plans (D-SNPs), we believe that widespread experience with managed care among the general population warrants a simplified election of the MA plan for an individual aging into Medicare who has been enrolled in health coverage provided by the same parent organization.

A.8. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries

ACHP supports CMS' proposal to allow passive enrollment for full-benefit, dually eligible beneficiaries from a non-renewing integrated D-SNP to another comparable plan. This important change would help reduce disruptions in integrated care coverage for these beneficiaries, many of whom have complex and chronic conditions. We recommend that CMS require written notices be sent to affected beneficiaries, backed up by telephonic outreach when appropriate.

A.11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

Commitment to quality has been a defining characteristic of ACHP member plans. Our organization developed the clinical quality indicators that later became the HEDIS measures under NCQA and were incorporated into Medicare's star ratings. Given that long commitment, it is not surprising that ACHP member plans dominated the quality ratings well before any financial rewards were attached. We have been and remain strongly supportive of the star ratings system and the quality incentive payments.

We appreciate CMS' commitment to quality improvement and recommend the gradual evolution of the star ratings system to better distinguish superior and sustained performance, especially by focusing on accountability for health plan functions (see comments on sec. 11.h). Also, we urge CMS to restore quality payments that have been denied to 4- and 5-star plans, an issue addressed under "Additional Recommendations."

11.c. *Basis, Purpose and Applicability of the Quality Star Ratings System*

ACHP supports CMS' plan to codify the star ratings system including its methodology, measures and data collection. Codification brings a measure of stability that is important. The transparency required of notice-and-comment rulemaking is a significant gain, while CMS retains the flexibility to introduce changes through annual rule-making and subregulatory guidance. We agree that current procedures should remain in place through the 2020 star ratings.

11.e/f. *Contract Ratings* and *Contract Consolidations*

CMS requested feedback on additional adjustments to the star ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance. Currently, CMS calculates Star Ratings at the contract level, which allows for statistically reliable measures while reducing administrative burden. However, contract consolidation has resulted in some contracts having disjointed market areas and artificially inflated star ratings.

In its March 2017 report, the Medicare Payment Advisory Commission stated: "The cross-state consolidation of MA contracts that we have seen over the past several years has eroded our ability to evaluate quality in the program and lessened the utility of star ratings as a plan comparison tool for beneficiaries. In many cases, star ratings do not reflect the quality of care in the local market area."

The effects of consolidation are particularly egregious when contracts are in distinct geographic areas and have different star ratings. When contracts are combined, the surviving contract determines the star rating of the new single contract, regardless of its enrollment size. For example, if two contracts each with 3.5 stars and 100,000 members are consolidated into a surviving contract with 5 stars and only 10,000 members, the newly formed single contract will be designated as having a rating of 5 stars. This means all 210,000 members are now enrolled in 5 star plans for purposes of bidding, quality comparison, and quality bonus payments. The MA plans offered under these contracts can be in different and noncontiguous states.

This practice not only costs the Medicare program, it reduces plan comparability related to quality and undermines the quality system by sending inaccurate signals to beneficiaries on which to base plan selections. Contract consolidation has made it increasingly difficult for community-based health

plans to benchmark their performance against competitors and differentiate to consumers their sustained and superior performance.

ACHP thanks CMS for recognizing this problem and proposing a revised calculation of star ratings when a consolidation involves the same parent organization and plans of the same type. ***We support CMS' proposal to mitigate the "cross-walking" of star ratings by assigning ratings based on the enrollment-weighted mean of the measure scores of the surviving and the consumed contract(s), for the first two years after consolidation***. This will provide a more accurate picture of the performance of the underlying contracts both for beneficiaries when they evaluate choices and for the calculation of quality incentive payments.

We also suggest that CMS consider as an alternative MedPAC's proposal to calculate star ratings based on the pre-consolidation configuration. In a sense, the MedPAC approach is more conservative; it would "freeze" star ratings of consolidated contracts at the rating of each contract before they were combined, whereas CMS' model could potentially change star ratings, depending on the results of averaging. MedPAC recommends using star ratings of October 2017 to determine quality payments in 2019, projecting a savings of $1 billion to $5 billion over five years. Their approach would affect 17 consolidations effective January 1, 2018 in which a contract below 4 stars was consumed by a contract at or above 4 stars. All but one of these consolidated contracts were in distinct geographic areas.

ACHP believes that additional policies are required to address the underlying problem of comparing geographically dissimilar MA contracts. ***In the near term, we recommend that CMS limit contract-level star ratings to the state level***. For MA contracts that span multiple states, those with sufficient enrollment to calculate a star rating in a particular state (e.g., 1,500 enrollees) would be required to report measure scores separately for those states. Until CMS develops more refined market areas for star rating comparison, this proposal would limit administrative burden on most health plans while substantially improving the comparability of star ratings. We believe that star ratings reported at the state level would provide a particularly meaningful comparison for consumers, who are not likely to recognize that the quality ratings of a plan they are considering are affected by ratings under a contract that crosses state lines. We recognize that our proposal would have to take into account plans servicing major metropolitan areas that cross state lines.

11.h. *Adding, Updating and Removing Measures*

Consistent with our comments above on codification, ACHP supports the proposed rules for adding, updating and removing measures. While we agree that CMS should work closely with measure developers in the private sector, we also recognize that CMS may develop its own measures for the Medicare Advantage program. Doing so through rulemaking will provide opportunity for a broad array of stakeholder input. We also support putting new measures on the star ratings display page before they are incorporated into the ratings. Finally, to the extent possible, we recommend that new measures be claims-based rather than require chart review.

CMS has asked whether there are "additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans." ACHP offers the following recommendations which we believe reflect accountability for health plan functions.

MA plans should be expected to play a significant role coordinating care and promoting value-based care delivery. Addition of the measure for all-cause readmissions was an important step in the

direction of evaluating the coordinating role of MA plans, although we recognize that it has limitations and that it (and similar measures) is also subject to factors beyond the plan's control. Especially in settings that are not fully integrated, it is more necessary than ever that quality measures and value-based payments for hospitals and physicians in traditional Medicare be aligned with Medicare Advantage so that they do not work at cross purposes in meeting readmissions and other targets.

We recommend the addition of a measure of emergency department visits for "ambulatory care-sensitive conditions," or what some have called "preventable" emergency visits, once the measure has been validated. This indicator reflects the responsibility of health plans to ensure that enrollees receive primary care, coordinate care among providers and offer or arrange for appropriate treatment in the outpatient setting.

Another indicator reflecting health plan accountability is the number of days before a patient has a follow-up visit after discharge from an inpatient setting. While the optimal time from discharge to follow-up visit (which may be a telehealth-based visit) is likely to vary by condition, a validated measure would be an indicator of superior care coordination and appropriate planning for the transition from hospital to home.

We urge CMS to work actively with measure developers and stakeholders to develop additional measures reflecting the contributions that health plans make to efficient and effective care. The provider-aligned community health plans that are ACHP members are eager to share their deep experience with the agency. We suggest the following aspects of care coordination and plan responsibilities as illustrative of indicators that could be developed:

- Making complete patient information available to providers at the time of the visit
- Providing actionable data to practices on gaps in care across their patient population
- Promoting continuity and coordination of care between medical and behavioral health providers
- Expanding advance care planning and assuring that patients admitted to ICUs have care preferences documented
- Structuring payment models that promote value-based delivery of care

Patient-Reported Outcomes Measures: Patient experience is a critical dimension of health plan performance. While ACHP believes the CAHPS measures remain an important component of the star rating system, ***we recommend that CMS encourage and support the development, testing and refinement of reliable patient-reported outcomes measures***. One potential metric that MedPAC suggested – if validated – is "healthy days at home," reflecting the number of days a MA member does not have an ED visit or inpatient admission. We believe these measures may better reflect patient experience and changes in health outcomes over time than the Health Outcomes Survey.

The Health Outcomes Survey (HOS) does not provide a reliable evaluation of patient experience, as it is subject to variables such as timing, memory and patient physical and mental status when completing the survey. ***We recommend elimination of the HOS-based measures on improving or maintaining physical and mental health***; these measures are too generic for use in the star ratings and few plans have demonstrated that they can consistently improve performance over time***. If they are retained, we urge they be weighted as process measures at 1.5***.

11.j. *Improvement measures*

ACHP opposes the codification of improvement measures and urges CMS to discontinue use of the improvement measures for Part C and D. The improvement measures are unnecessary and distort the star ratings for both health plans and consumers. ACHP believes that CMS can best encourage organizations to strive for the highest quality with a graduated system of quality incentive payments that provides greater rewards for higher levels of achievement. The entire thrust of the star ratings system and the quality incentive payments is to incentivize improvement. It is a striking indicator of success of the star ratings that more than 70 percent of enrollees are now in contracts of 4 stars and above.

A separate measure of improvement blurs the distinction between high-performing plans and others. We would argue that consistency and stability in performance over time should be rewarded more than improvement in any given year compared to the previous one. ACHP believes that star ratings are more appropriately based on performance across the entire range of clinical, patient experience and administrative/compliance measures. We are concerned that the improvement measure may lead to misclassification of plans in the ratings. Plans that obtain high scores in the improvement measure one year may not maintain that improvement in a subsequent year. Therefore, a higher rating obtained by improvement would misclassify the underlying performance to consumers, who may inadvertently purchase a lower performing plan than they intended.

If the improvement measures are retained, we strongly recommend that they be reassigned a weight of no higher than 3. The "super weighting" of 5 that CMS created for these 2 measures alone introduces significant distortion in the weightings. The higher weighting of improvement measures diminishes the importance of clinical measures and misleads Medicare beneficiaries about which are the highest quality health plans. Consider, for example, the distinction between a "most improved" physician and the "highest quality" physician. We urge CMS to weight all measures within the 1/1.5/3 weighting system that it originally established. (See additional comments on this issue in sec. 11.q. below.)

11.k. *Data Integrity*

ACHP recognizes the importance of accurate and reliable data for measures reported in the star ratings. ***We continue to have concerns, however, about CMS' approach which duplicates HEDIS auditing of measures***. If a sponsor meets HEDIS requirements for accuracy of reported data, we do not think it necessary for CMS to duplicate the review of the same data reporting.

We also believe that the reductions in star ratings for data integrity errors blur the distinctions between quality measurement and compliance and audit activities. Except to the extent to which compliance issues are already a component of the star ratings metrics, we believe that CMS should maintain the focus of the star ratings on clinical quality and beneficiary satisfaction. CMS' approach to data integrity reductions exposes MA plans to the double jeopardy of being penalized through audits and penalized again through the star ratings.

If CMS maintains its data integrity review, we support the proposal to scale the reductions for Part C and D appeals measures. Instead of an automatic reduction to 1 star, data from the Timeliness Monitoring Project and audits would be used to determine the scaled reductions, from 1 to 4 stars, and calculated separately for Parts C and D.

11.l. *Measure-level Star Ratings*

CMS requested feedback on "whether the current process for establishing the cut points for star rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality." ***ACHP recommends that CMS place a cap on cut point changes in any given year based on the maximum change in relative distribution of scores***.

For most outcome and process measures, CMS determines cut points using a clustering hierarchy that distinguishes numerically similar groups in the distribution of scores. However, the current methodology allows for large year-over-year changes in cut points when there is relatively little change in the distribution of scores. This limits CMS in achieving its goals of (1) making star ratings stable over time and (2) putting improvement in ratings under the control of the health plan.

To illustrate the problem of changes in star rating cut points when the relative distribution of scores changes very little, we benchmarked the changes in cut points against the National Committee for Quality Assurance (NCQA) change in cut points. NCQA determines measure ratings (1-5) based on percentile cut points (10, 33.3, 66.7, and 90). The table below demonstrates that the change in 2018 star rating cut points in some instances was far larger than the change in the relative distribution of scores. Consequently, the scores of relatively few contracts for those measures drastically changed the cut points for all contracts. This raises a significant concern for health plans that improve their clinical quality relative to their peers but see a decrease in their rating under the methodology.

	2018 Star Cut Point Change (Clustering Methodology)				2018 NCQA Cut Point Change (Relative Distribution Methodology)			
Measure	**2-Star**	**3-Star**	**4-Star**	**5-Star**	**10th (Rating =2)**	**33rd (Rating = 3)**	**67th (Rating = 4)**	**90th (Rating = 5)**
Controlling Blood Pressure	+17	+11	+11	+11	+4	+2	+2	0
Breast Cancer Screening	+13	+7	+9	+8	+1	+1	0	0
Diabetes Care - Blood Sugar Controlled	-9	-2	-3	-4	+4	+2	+2	0
Improving/Maintaining Physical Health	-1	0	-3	-12	0	-1	0	0

In the near term, ACHP recommends that CMS place a cap on cut point changes based on the maximum change in relative distribution of scores. This would allow CMS' clustering methodology to move cut points (e.g., moving the 4 and 5 star cut points up) without extreme changes based on the movement of relatively few MA contracts. The cap also would allow changes to occur because of measure specification updates or a general trend in plan improvement.

Capping changes in star ratings cut points so that they are not larger than the change of the relative distribution of scores would be relatively simple to implement. Using NCQA's cut points as an

example, because the 10th percentile for Controlling Blood Pressure moved up by 4 percentage points (the largest change among all NCQA cut points for this measure), the CMS star thresholds for 2, 3, 4, and 5 stars could not individually move up or down more than 4 percentage points each for that measure. To allow for the phase-in of large changes that become stable over time, after the first year of implementation, that cap would be the larger of: (1) the prior year cap and (2) the current year cap.

Variations on capping changes in star ratings are also possible. Rather than benchmarking against NCQA's cut point changes, CMS may use other measures of relative distribution such as quintiles or deciles. In addition, since large changes to cut points in the current year sometimes offset large changes to cut points in the prior year, the cap could be limited to cut points that move away from the relative distribution of scores. For example, 5-star cut points that move in the direction of the 90th percentile could be exempt from the cap.

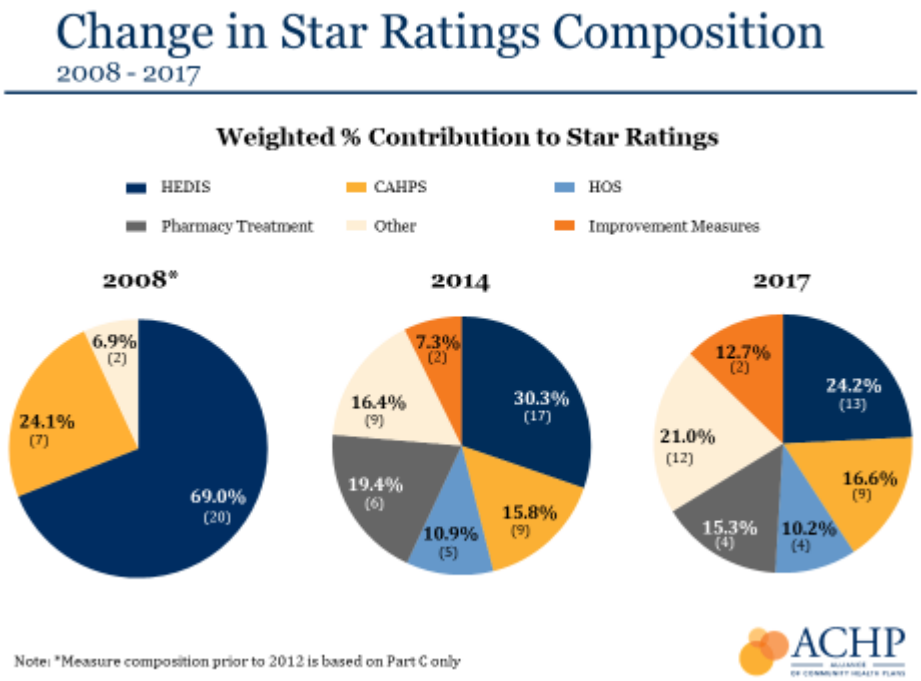
In the long term, we request that CMS develop an alternative to its clustering methodology that provides greater stability in the ratings, a CMS goal which we share. CMS' clustering methodology is difficult to model from year-to-year, which in turn makes it difficult for health plans to align performance and financial targets. A methodology that provides more predictability would also help health plans and providers better identify gaps in quality and appropriately target resources. We would be happy to contribute analysis and recommendations to this work.

11.q. *Measure Weights*

We noted above our strong belief that CMS should continue to weight all measures within the 1/1.5/3 weighting system that it originally established. We believe the Part C and D improvement measures are unnecessary and, especially at the assigned weight of 5, distort the ratings. They should be eliminated or, if retained, reassigned a weight of no higher than 3.

ACHP urges CMS not to increase the weight of the patient experience/complaints and access measures beyond 1.5. While patient experience and satisfaction should (and do) play a significant role in the star ratings, a change in the weights would further reduce the utility of the star ratings to consumers as a tool to evaluate the *clinical* quality of MA plans – that is, the ability of plans to keep them healthy and treat their illnesses.

The changing composition of the star ratings is displayed in the graphic below, clearly indicating the already diminished role of clinical quality measures. In the past three years along, HEDIS measures have been reduced from 17 to 13 measures and from 30 percent of the weighting to 24 percent of the weighting. In the same period, pharmacy treatment measures have been reduced from 6 to 4 measures and from 19 percent to 15 percent of the weighting.



ACHP believes that CMS should not take further steps that would diminish the role of clinical quality measures in the composition of the star ratings.

A.12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types

CMS proposes to clarify and modify its current interpretation of existing regulations to ensure that plan sponsors can continue to develop and maintain preferred networks while fully complying with the Part D Any Willing Pharmacy (AWP) requirements. CMS is addressing concerns that the terms and conditions that Part D plan sponsors use to establish their preferred pharmacy networks are in some cases circumventing the AWP requirements and inappropriately excluding pharmacies from network participation. We understand the concerns, but ***recommend that CMS not limit the ability of sponsors to exclude, when necessary, a pharmacy that may have questionable motives or a unique business model that does not fit a commercially or community acceptable practice***.

CMS also proposes to require a plan sponsor to provide a copy of a standard contract to a requesting pharmacy within 2 business days after receiving such a request from the pharmacy. ACHP believes that the 2-day timeline is not feasible for most plans who contract with PBMs to meet network and contract administration requirements. ***We ask CMS to expand the number of business days required for providing a copy of a standard contract***.

A.13. Changes to the Days' Supply Required by the Part D Transition Process

ACHP supports CMS' proposal to shorten the required transition days' drug supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. We also support CMS' proposal to make a technical change to the current regulatory text to provide that the

required supply in the outpatient setting be a one month supply. We believe that this change will significantly reduce waste in the Part D program.

A.14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

ACHP appreciates CMS' responsiveness to our request that plan sponsors be given stronger tools and flexibility to manage their formularies. ***We support CMS' proposal to enable Part D plan sponsors to immediately substitute newly released equivalent generics for brand name drugs at the same or lower cost sharing, if they meet revised requirements***. There is no clinical or administrative reason to mandatorily require a delay for the substitution of equivalent generics for brand name drugs. At the same time, we believe that Part D sponsors should be afforded the opportunity and adequate time to evaluate the generic drug and consider cost, availability and other factors before substituting newly released equivalent generics. Plans should have the flexibility to add the generic to their formularies when they believe it is clinically appropriate and practicable.

A.15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost-Sharing

CMS proposes to revise the definition of a generic drug to include follow-on biologics approved under section 351(k) of the PHS Act solely for purposes of cost-sharing. CMS believes that this would improve enrollee incentives to choose follow-on biologics over more expensive reference biological products and will reduce costs to both Part D enrollees and the Part D program.

Biosimilars hold the promise of reducing costs, and ***ACHP supports the proposal to treat them as generics***. We ask that CMS accord Part D plans flexibility to make a decision on including them in generic cost-sharing tiers after careful evaluation of costs and quality, including rebate considerations. Currently, many follow-on biologic products have the potential to be rebate-eligible, which is especially important because their pricing may not be significantly lower than the reference product due to limited competition in the market. Because rebates are generally not available for generics, losing the rebate on biosimilars through designation as generic could result in higher costs to the beneficiary.

We also ask CMS to consider the administrative impact that the proposed rule may have on Part D plans. Our hope is that the revisions to the definition of generic drug encourage LIS users to select more cost effective agents, thereby saving the Part D program significant resources. However, before any savings can be realized, Part D plans would have to work with the relevant Pharmacy Benefit Manager to ensure that the changes are implemented seamlessly. Training, as well as coding and system changes, will be necessary.

A.17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

ACHP appreciates the discussion that CMS has initiated on drug rebates and beneficiary costs at the point of sale. The proposed policies, however, fail to address the real problem: the prices set by manufacturers for their drugs.

Our member Part D plans work very hard to ensure that their enrollees have access to affordable medications through the combination of low and stable premiums and their plan benefit and

formulary designs. Effective negotiation with drug and biologic manufacturers for price concessions through rebates plays an important role in enabling our plans to provide affordable Part D coverage.

If the central problem that CMS seeks to address is the high cost and increasing lack of affordability of many Part D drugs (especially specialty drugs) for enrollees, health plans and the federal government, then we suggest addressing it more directly than by requiring Part D plans (and their PBMs) to pass along manufacturer rebates at the point of sale. CMS' own projections of the financial impact of the point-of-sale policy include higher beneficiary premiums, increased government spending and increased revenues for drug manufacturers. ***The financial effects combined with administrative complexities, operational burdens on our member plans and other potential consequences of the point-of-sale approach lead us to urge CMS not to move forward***. Our more specific concerns follow:

Increased Part D Premiums

As CMS indicates, the outlined policy would alter the current rebate policy that has contributed to lower-than-expected Part D premiums, a policy that has benefitted both beneficiaries and the Medicare program. By incorporating rebates at the point of sale, plan premiums would instead increase over current policy projections (the magnitude would rise depending on the portion of the rebates incorporated – 33, 66, 90 or 100 percent). Premiums are a major driver of beneficiary Part D plan decisions, not only their choice of a specific Part D plan but whether to participate at all. Significant increases to Part D premiums, in the absence of other policy changes to reduce the impact on beneficiary out-of-pocket costs, would likely lead to fewer seniors enrolling, with the effect of reducing Medicare beneficiary access to prescribed medications. In addition, the resulting deterioration of the risk pool could erode the long-term sustainability of the Part D program.

Although CMS' impact analysis correctly anticipates a rise in premiums, we believe that it significantly understates the potential magnitude of that impact. If Part D plan sponsors are no longer able to retain some or all rebate dollars that they now use to hold down premiums – and their administrative costs also increase as a result of the numerous operational steps needed to pass along rebates in point-of-sale prices – premium increases could be significantly higher than CMS' projections. One ACHP member plan, for example, believes that with the addition of the higher administrative costs associated with the outlined policy, its monthly Part D premiums could increase 30 percent to 35 percent (compared with CMS' 10 year estimates of 4-11 percent).

Undermining Effective Formulary Design and Part D Plan Bids

ACHP is also concerned about less obvious but similarly consequential adverse effects on formularies of incorporating rebates at the point of sale. Member plans report an increasing trend of new products entering the market absent rebates (or with significantly reduced rebates); instead, those products have been priced by the manufacturers more competitively *up front*. Some of these lower-priced new products include treatments for osteoporosis, multiple sclerosis and hepatitis C. (In the case of treatment for hepatitis C, one of these products is driving expanded access for people in prisons and those covered by Medicaid.[1]) This promising trend toward lower introductory prices is

[1] Andrews, M., Hepatitis C Drug's Lower Cost Paves Way for Medicaid, Prisons to Expand Treatment, *Kaiser Health News*, October 3, 2017, https://khn.org/news/hepatitis-c-drugs-lower-cost-paves-way-for-medicaid-prisons-to-expand-treatment/

an indication that competitive market pressures are beginning to reduce the grip that rebates have on pharmaceutical pricing and formulary development.

Our plans are concerned that a CMS policy that would lock rebates into place at the point of sale would interrupt this trend and impede the ability of plans to incorporate new, lower-priced products into formularies. If beneficiaries expect lower prices reflecting the rebates at the pharmacy, pharmaceutical manufacturers would have the incentive of introducing drugs at higher prices, with rebates, rather than introducing products at a more reasonable starting price.

We also believe that a requirement to reflect manufacturer rebates in the point-of-sale prices of Part D drugs would affect enrollee utilization, making it less predictable for a plan sponsor to properly price its Part D products. CMS' possible approach to estimate rebates by using a weighted average across all products would raise an additional complication for estimating utilization changes because some products have a rebate and others do not.

Increased Operational Challenges and Administrative Burden

ACHP members have expressed significant concerns about the operational challenges and added administrative burden and costs of the CMS outlined policy. We suggest that the various alternative policy designs that CMS describes – related to the applicable average rebate amount, rebated drugs, weighting options and components – do not adequately take into account the complexities of the rebate process and the administrative challenges of applying rebates at the point of sale.

In deciding whether to move forward on the outlined policy, CMS would have to incorporate how the policy would interact with, and be affected by the fact that, Part D sponsors' contracts with pharmaceutical manufacturers are updated numerous times over the course of a plan year. Rebate amounts fluctuate and are far from stable; they can change significantly and sometimes dramatically. A policy of rebates at the point of sale does not easily accommodate this dynamic.

In addition, rebates are often applied across a group of drugs and generally are not applicable to any single claim – that is, rebate amounts that are provided to the plan sponsor may not be product-specific. A further major complication in requiring that rebate amounts be reflected at the point of sale is that rebates are not received by the Part D plan until six to nine months after the sale date. Thus, the Part D plan sponsor would be required to "front" those discounts (presumably using a proxy estimate of the discounts) to enrollees at the point of service and then later recoup their discounts from manufacturers.

We would underscore that rebates are very challenging to project accurately. They often depend on achieving certain manufacturers' product utilization targets which a plan sponsor or its PBM cannot forecast accurately. Moreover, the actual amounts are not known until after the manufacturers examine the claims. Although some manufacturers will inform the plan which claims were excluded from the rebate, many do not. (In the case of a contracted PBM, the Part D plan sponsor may not be able to ensure the accuracy of the amounts provided by that PBM since PBMs are not subject to transparency requirements and a plan would not be able to audit them.)

Certain plan or PBM system changes would also be needed and the associated costs would be significant. For example, these proposals would require modifications to a plan's drug claim adjudication system and its Medicare Plan Finder Price file. In the case of a PBM, it may need to create new functions so that its contracted plan sponsors could obtain their own manufacturer rebate data at the Plan Benefit Package (PBP) and National Drug Code (NDC) 11 level in order for the rebates to be applied at the point at which their enrollees fill their prescriptions. PBM contracts with both plans and pharmacies also would need to be amended.

Transparency

CMS indicates that one of the issues it seeks to address with the outlined policy is to improve price transparency. While that is a desirable goal, we would point out that Part D plan sponsors are already required to report to CMS very detailed, drug-specific information on Part D drug rebates and other components of the Part D Direct and Indirect Remuneration (DIR).[2] It is unclear what additional information CMS may gain from requiring the rebates to be passed through at the point of sale.

There are additional potential consequences as well. If the outlined policy did result in increased public accessibility of rebate information across Part D plans, drug manufacturers might use that information to reduce rebates. In addition, the proposed policy could undermine the existing confidentiality between Part D plan sponsors and their PBMs, with the effect of diluting Part D plan competition.

Taken together, the issues discussed above would place Part D sponsors in the position of taking on a level of risk that some may be unwilling to assume. This could discourage their participation in the Part D program, reducing competition and plan choices for Medicare beneficiaries. ACHP urges CMS not to pursue the point-of-sale policy change at this time, but to work with all stakeholders to craft alternatives that more directly address the cost challenge.

Section B. Improving the CMS Customer Experience

B.1. Restoration of the Medicare Advantage Open Enrollment Period

CMS proposes to codify a new open enrollment period that would take place from January 1 until March 1 of each year. During that time, individuals enrolled in an MA plan would be allowed to make a one-time election to switch MA plans or to disenroll from an MA plan and obtain coverage in original Medicare. ***ACHP supports additional flexibility for beneficiaries but believes that safeguards will be necessary***. We are concerned that an expanded enrollment period will encourage some brokers to aggressively market to beneficiaries who have already chosen a satisfactory plan.

[2] Specifically, Part D sponsors are required to report DIR data associated with the Part D benefit at the plan benefit package (PBP) level on the Summary DIR Report to CMS for the purposes of the Part D payment reconciliation. Part D sponsors are also required to report DIR data at the 11-digit NDC level in the Detailed DIR Report to support implementation of section 9008 of the Affordable Care Act (ACA), which imposes an annual fee on certain manufacturers based on their share of brand drug sales net of rebates, discounts, or other price concessions. See: Memo from CMS, Medicare Plan Payment Group, *Final Medicare Part D DIR Reporting Requirements for 2016,* June 23, 2017. Available at: https://www.healthlawpolicymatters.com/wp-content/uploads/sites/8/2017/06/Final-2016-DIR-Reporting-Reqs-Memo-06-23-2017.pdf.

In order to safeguard beneficiaries, ***ACHP recommends that beneficiaries have the choice of either returning to their plan from the previous year, if they have changed plans, or moving to traditional Medicare with Part D coverage during this period***. This approach will allow beneficiaries the option of correcting a coverage decision with which they are not satisfied and will reduce the opportunity for agents in search of increased commissions to market coverage that may not meet the needs of the beneficiary.

B.4. Revisions to Timing and Method of Disclosure Requirements

ACHP appreciates CMS' responsiveness to our recommendations for increased use of electronic communications to beneficiaries. ***We support CMS' proposals to change the timeline for disclosing certain types of information to MA and Part D enrollees and revised disclosure requirements*** that allow sponsors more flexibility to provide certain types of plan information electronically rather than in written form.

B.5. Revisions to Communication/Marketing Materials and Activities

ACHP supports CMS' proposal to incorporate the concept of "Communications Material" into MA guidance. This step promises to reduce the administrative burden associated with complying with the pre-approval process for marketing materials.

In the proposed rule, it is unclear as to what exactly would be considered communications material. ***We recommend that CMS provide expanded guidance on the information that qualifies as communication material***, and whether these materials require pre-distribution approval similar to marketing materials.

A.6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

ACHP supports CMS' proposal to change the adjudication timeframe for Part D standard redetermination requests for payment from 7 to 14 calendar days.

A.7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE

CMS proposes to eliminate the requirement that MA plans mail a notice to enrollees when they forward cases to independent review. ***ACHP members would prefer having the option to send a letter to the member advising of the case status***. In accordance with the Medicare Managed Care Manual, an untimely reconsideration affirms the adverse organization determination. Therefore, the plan should advise the enrollee of the affirmation of the adverse organization determination; the health plan would not have the opportunity to do this if a letter is not sent. Similarly, many of our plans provide enrollees with their next level appeal rights. ACHP believes that enrollees could be confused if plans inform them of appeal rights before they receive the notice from the IRE. This would increase member calls to plans, causing unnecessary burden.

B.9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations

ACHP supports CMS' proposal to reduce from 14 months to 12 months the period that CMS reviews when determining if an MA or Part D plan sponsor has failed to comply with contracting requirements.

B.10. Part D Prescriber Preclusion List

CMS plans to enforce a statutory provision requiring that prescriptions for covered Part D drugs be prescribed by a physician or eligible professional enrolled in Medicare beginning January 1, 2019. CMS also included beneficiary protections to ensure access to medicines when prescribed by a provider who does not meet the enrollment or opt-out requirements. The beneficiary would receive a 90-day provisional supply of the medicine and written notice that future prescriptions from the same prescriber would not be covered unless the prescriber is removed from the preclusion list.

The proposed 90-day provisional supply of medicine raises concerns about overutilization and cost. ***While patients must have access to critical medicines, dispensing a shorter supply, such as a month, can meet that need and allow them time to find an authorized provider***. We recommend that a longer supply be authorized on an exceptions basis if the beneficiary cannot obtain a prescription from an authorized provider.

In addition, we ask CMS to clarify who is responsible for notifying a plan member if their provider is included on the preclusion list. We also seek additional clarification as to how the preclusion list would intersect with the Office of Inspector General list, and what steps sponsors should take to ensure compliance with the relevant regulations.

Additional Recommendations

ACHP urges CMS to address the following additional issues in the final rule or in the 2019 Advance Notice and Call Letter:

Restoring Quality Incentive Payments

ACHP urges CMS to reverse the substantial losses affecting 2.5 million seniors from implementation of the benchmark cap that has reduced or eliminated quality incentive payments. The unintended consequence of the benchmark cap provision has been to undermine value-based care, disincentivize quality and diminish benefits to seniors worth tens of millions of dollars.

The previous administration interpreted the law in a way that is contrary to Congressional intent, denying Medicare benefits to seniors who enrolled in high quality plans specifically so they could take advantage of enhanced benefits. This decision has reduced or eliminated quality payments to plans in about half the nation's counties, affecting 2.5 million beneficiaries. In some areas, 4- and 5-star MA plans may receive the same payment as a 3-star plan, contrary to CMS' goal of paying for value. According to MedPAC's March 2016 Report to Congress, the cap reduced county benchmarks by an average of $480 annually – and that figure will be higher for 2018. The benchmark cap interpretation has also limited the effects of CMS' initiative to account for the effects of high

enrollment of dual eligibles on star ratings, as achieving a 4-star rating will do little if the plan with high numbers of dual eligibles is in a capped county.

We continue to believe that the statute allows the Secretary discretion to exclude the quality payments from the benchmark cap calculation, as is done in other Medicare programs. Please note that we do not support elimination of the benchmark cap, but rather removing the quality payments from the calculation in which pre-ACA benchmarks are compared to post-ACA benchmarks. We have previously shared our legal analysis with CMS and would be glad to provide another copy.

Improving the Accuracy of the MA Benchmark Calculation

ACHP urges CMS to improve the accuracy of MA county benchmarks by excluding the costs of the Part A-only FFS beneficiaries from the calculation. As MedPAC has pointed out, this population's costs are likely to be very dissimilar from the FFS population enrolled in both Parts A and B because of the higher cost sharing the beneficiary faces if he/she uses health care services that are not covered by Medicare. If a county has a disproportionate share of these beneficiaries, the FFS costs of the county – and therefore the MA benchmarks – are likely to be underestimated compared to the costs of the MA population which receives both A and B benefits. According to MedPAC's March 2017 Report to Congress, correcting the underestimation of benchmarks would increase benchmarks by about 1 percent in the average county and up to 3 percent in some counties.

We believe that the county benchmarks should be based on a population with similar characteristics to that of the MA population. It is often the case that FFS costs and MA payment rates are compared to each other when there is policy discussion of whether MA plans are paid "fairly." The proposed change would make this comparison fairer and more equitable.

MedPAC notes that Part A-only enrollees currently represent 12 percent of the FFS beneficiaries and that this population is increasing. The share of FFS beneficiaries varies by county, especially in counties with large numbers of Federal retirees, and could have a large impact on a county's benchmark in some instances. In addition, as MA penetration continues to increase, FFS costs in those counties will be based upon a disproportionate share of Part A-only beneficiaries. As a result, without a correction, the county benchmark calculation will be less accurate in representing the overall FFS population.

ACHP recognizes there are several issues which CMS will have to consider. Among them are: whether to recalculate the geographic indices of the past five years based on the new methodology; whether or not to phase-in the change and, if so, over what time period; the effect on the benchmark quartile into which the county falls; and the effect on "double bonus" counties.

Allowing Telehealth-Based Services in the MA Bid for Basic Benefits

ACHP believes that beneficiaries will welcome, and increasingly expect, services to be provided through telehealth modalities where appropriate. Congress is considering legislation that would allow MA plans to incorporate telehealth-based services in their bids to provide basic benefits. While the legislation has strong bipartisan support and a Congressional Budget Office estimate that it will reduce spending, passage is uncertain. Even if the bill passes, it may not be in time for CMS to incorporate in the 2019 Advance Notice and Call Letter. ***We urge CMS to use regulatory authority***

to allow MA bids that incorporate telehealth-based services, knowing that there is significant support in Congress for modernizing MA in this way.

In CMS' words, remote access technologies have the ability to "improve access to and timeliness of needed care, increase communication between providers and patients, and enhance care communication." ACHP members increasingly utilize remote access mechanisms to provide clinical care and strengthen coordination of services across settings; these efforts are enhanced by our members' reliance on an electronic medical record. Medicare leadership and support for innovative clinical approaches relying on remote access technologies would have a substantial impact on the entire delivery system.

CMS has considered remote access technologies to be a benefit. Under this approach, given the reduction in MA benchmarks and the negative update in capitated payments, MA plans are forced to reduce other supplemental benefits or increase premiums, potentially putting them at a disadvantage competitively. ACHP, MedPAC and other experts view remote access technologies as an alternative modality or complementary means of providing clinical services, not a supplemental benefit. Health plans are using remote access technologies, when clinically appropriate, to provide care for their enrollees, and ACHP members are finding very high member satisfaction and no degradation in the quality of care. Almost all state Medicaid programs recognize that telehealth is an appropriate way of delivering covered benefits, and thus provide reimbursement for telehealth, particularly for real- time interactive video visits. At least 35 states also require commercial health plans to provide reimbursement for some services provided via telehealth.

ACHP believes that CMS has the regulatory authority to recognize services provided by remote access technologies as covered services. The statute does not appear to limit covered benefits to those provided in person, nor does it prohibit covering services when the provider is remote from the patient. In addition CMS' regulations explicitly state that CMS may supersede Original Medicare coverage requirements for Medicare Advantage. As telehealth has the potential to be transformative in the delivery and accessibility of high quality care for Medicare enrollees, ACHP urges CMS to use its regulatory authority to allow MA plans to include telehealth-based services as part of their basic bid.

Eliminating MA Coding Pattern Adjustment

ACHP believes that the across-the-board coding intensity adjustment unfairly penalizes MA plans that code conservatively. Further, the adjustment does not take into account what the "right" level of coding is. Many MA plans may be coding more thoroughly and accurately than providers in traditional FFS, whose payment is tied to services and procedures rather than diagnoses. ***We recommend that there be no extension of the percentage reductions for coding differences beyond the 2018 plan year, the last year of a statutory requirement***.

We note CMS' projection in the fact sheet issued on Feb. 9, 2017 that MA plans on average would realize a revenue gain of 2.5 percent from coding trends. CMS has not shared the data for this projection and we would, in fact, expect downward trends in MA coding. After initial steps to improve the collection and reporting of diagnoses, including adoption of electronic medical records, and now with years of coding experience, mature MA sponsors have reached a "steady state" of accurate reporting of diagnoses for risk adjustment. We also expect downward pressures on future coding due to the growing enrollment of younger and healthier beneficiaries of the baby boom generation. Finally, a number of risk adjustment studies suggest that enrollees who switch from FFS

to MA tend to be healthier than their demographic cohort in FFS; that should drive coding down as well.

ACHP recommends that CMS initiate a dialogue with health plans by sharing its data on coding trends and variations in those trends by geography, plan type, newer v. older MA plans, and other factors. CMS should provide data on coding trends over the past five years and the methodology used to forecast the 2018 trend. It is especially important for stakeholders to review this data because 2018 is the last year of congressionally mandated coding adjustments. We also encourage CMS to share the raw coding data or a robust sample file. This would facilitate plans being able to assess whether they are experiencing material differences in health risks of their populations, or if they may have cause for concern on coding practices. Until data is available on coding pattern variations and there is an attempt to understand differences in coding between MA and FFS, ACHP believes there should be no extension of the coding adjustment beyond the 2018 plan year.

Reducing Multiple Plan Audits and Requirements

We recommend that CMS take appropriate regulatory or administrative action to address the problem of multiple, overlapping, and complex MA and Part D plan audits that present significant burdens and expense to plans.

ACHP recommends that audits be pared to no more than a small number per parent organization per year. In addition, audit activity should be coordinated across CMS divisions (including the Office of Financial Management (OFM)) so that any given parent organization is not undergoing more than one audit, monitoring or data validation activity at the same time. Associated data requests should be minimized and the same data requested for one purpose should suffice for other purposes – e.g., appeals monitoring data provides the same basic information as data for coverage determinations, appeals and grievances (ODAG/CDAG) but the specifications are different. In addition, for any given audit/monitoring activity, CMS agencies should request the minimum data or documentation required for the review, in a format as simple and straightforward as possible.

Audit and enforcement functions usually fall on a small group of individuals in the sponsor organization who also have significant program responsibilities. Data "universes" are highly prescriptive, complex and not always clear, even to auditors/contractors, and extraordinarily taxing to create and validate. Plan sponsors find that not all of the data are used and that the full universes do not produce any better or more accurate results than the statistically valid samples that were used a number of years ago. The "3 strikes" rule (sampling 5 cases within universe to validate the universe) is unduly punitive and burdensome. Changes in protocols can require IT and system updates, which adds time and costs.

ACHP urges CMS to work with MA and Part D plans on modifications that will increase the efficiency and effectiveness of audit and data reporting processes for both CMS and plans sponsors. Suggestions include:

- Plans should not have repeat financial audits if there are no problematic findings.
- CMS should accept the financials findings of the independent audit firms that MA plans are required to have annually.
- CMS should use results of a state's tri-annual financial audit, if current, adding areas as necessary such as prescription drug events.

Reducing Unnecessary Communications

Prior Authorization Approval Letters: MA plans are required to send notices of prior authorization to beneficiaries even though, in many cases, they are notified by their provider that the service has been approved; in fact, the patient often obtains the service shortly after that information is received from their provider. This situation arises for medical services, drugs, skilled nursing facility admissions and other services. As a consequence, the member often receives the notice from the MA plan after the visit or service, causing confusion and increasing costs for creating and sending the notifications. ***ACHP recommends that, when the prior authorization is the responsibility of the provider and they are communicating that approval to members, MA plans not be required to send a separate approval letter***.

Implementation of Section 1557 Non-Discrimination Provisions: ACHP member plans support the goals of the Affordable Care Act Section 1557, addressing language assistance for those with limited English proficiency and discrimination based on sex/gender, age, or disability. We hope that CMS will reconsider certain provisions of implementation that are burdensome to health plans and appear to be of little value to enrollees.

In order to inform members about their rights and how to communicate with plans, without generating member dissatisfaction and imposing undue costs, we recommend that notice communications be modeled on how the HIPAA Privacy Notices are provided to members. That is, the Nondiscrimination Notice should be sent out annually along with information on how to obtain a copy of the notice at other times. Each new member to the plans or health care facility would obtain a notice in their new enrollee mailing or on their first encounter. The notice would be included in all major documents such as Evidence of Coverage and Annual Notice of Change packages. The notices would also continue to be provided on plan websites. We also recommend that the tagline be placed in the Appeal and Grievance packages that are sent to members as an alternative to including them in every member communication.

ACHP appreciates CMS' response to recommendations that we and others have made for regulatory relief and administrative flexibility. Thank you for considering our views on the proposed rule. If there are questions or a need for additional information, please contact Howard Shapiro, Director of Public Policy, at hshapiro@achp.org.

Sincerely,

Ceci Connolly

President and CEO
Alliance of Community Health Plans