



March 1, 2019

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](http://www.regulations.gov)

**Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (CMS-2018-0154)**

Dear Administrator Verma:

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to comment on the 2020 Advance Notice and Call Letter.

ACHP is a national leadership organization bringing together health plans and provider organizations that are among America's best at delivering affordable, high-quality coverage and care. Members are non-profit plans active in 34 states and the District of Columbia, providing both private and public coverage to nearly 22 million Americans, including 2.6 million Medicare beneficiaries. ACHP member plans represent five of the Medicare Advantage program's 14 5-star MA/PD plans, in addition to two 5-star, MA-only plans. Seventy-four percent of beneficiaries in 5-star plans are enrolled in plans offered by ACHP members.

We greatly appreciate CMS' commitment to providing regulatory flexibility and relief from outdated or burdensome requirements in this Advance Notice and Call Letter and in the previously proposed rule for MA and Part D. Proposals in both documents reflect recommendations that ACHP has previously offered and will facilitate the ability of plan sponsors to strengthen benefits that reflect the needs of their enrollees and administer coverage efficiently.

**Summary**

Before presenting detailed comments, we wish to highlight several issues and recommendations in the 2020 Advance Notice and Call Letter:

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- **Restoring Quality Payments:** ACHP urges CMS to pay full quality bonuses created by Congress to ensure seniors receive the highest possible quality of care. Including quality payments in only the post-ACA benchmark calculation has reduced or eliminated quality incentive payments in half of all counties, affecting some 2.5 million seniors. 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. 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. 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.
- **Improving Accuracy of the USPPC and Benchmark Calculation:** While the issue is not directly addressed in the Advance Notice, ACHP urges CMS to revise its calculation of FFS costs. As the Medicare Payment Advisory Commission (MedPAC) has documented, Part A-only FFS beneficiaries have very different utilization and cost patterns from those who enroll in both A and B – and they are a growing segment of the FFS population. The result is that the USPPCs and county MA benchmarks, driven by FFS costs, are lower than they would be if the appropriate comparison group were used – i.e., A/B enrollees. In addition, the proposed, current, and historical MA risk adjustment models will be, are, and have been calibrated with FFS beneficiaries enrolled in both Parts A and B. CMS risk adjustment experts recognize the different utilization and disease burdens of the different populations. We believe that risk adjustment and MA payment rates should be based on the same population. ACHP asks that CMS recalculate the USPPCs, including ESRD USPPCs, and county benchmarks and state ESRD rates using A/B enrollees only. In the 2019 Final Notice released April 2, 2018, in response to our same comment we made a year ago, CMS says: “We will continue to analyze this issue and consider whether any adjustments in the methodology on this point may be warranted in future years”. Please let us know the status of CMS analyzing this issue.
- **Study the Concept of Smaller Geographical Areas for Setting the ESRD Benchmarks. Study the Volatility of the Year-to-Year ESRD Benchmarks:** With the 21<sup>st</sup> Century Cures Act allowing all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, it will become increasingly important for CMS to develop more accurate ESRD rates that better reflect the ESRD FFS costs of a MA plan's local market. We request CMS study the idea of developing ESRD rates on a smaller geographic basis, even as small as a county using credibility factors as described in further detail below. We also encourage CMS to study the ESRD rates' year-to-year rate volatility. We are hoping CMS to perform these additional analyses in time for the 2021 Final Notice.
- **Review the Inclusion of Quality Bonus Payment (QBP) Percentage for the ESRD for 4+ Star MA Plans:** ESRD beneficiaries will be allowed to enroll in MA plans starting in 2021 because MA plans provide better coordinated care to this population than in FFS. Yet MA plans receive no quality bonus currently for coordinating the care for this high cost population. ACA language says that the QBP should be applied at the contract or plan level, which would imply that ESRD membership should be included in the QBP to MA plans. We understand that the QBP is subject to the applicable percentage cap but we seek that the cap be calculated exclusively using ESRD data for ESRD benchmarks. We seek further study on this issue. We urge CMS to study this QBP issue while simultaneously analyzing ESRD benchmarks to be based on smaller geographical areas other than state level. If CMS is able to calculate ESRD benchmarks at a county level basis as we suggest in further detail below, these counties could be “qualifying” counties for the additional quality bonus for ESRD MA membership residing in those counties. We request that

this new work be completed in time for the 2021 Final Notice.

- **Improving Drug Utilization Review Controls for Opioid Overuse/Misuse:** Under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), Medicare Part B must cover opioid use disorder treatment services when furnished by Opioid Treatment Programs. Because those services are mandatory under Part B beginning in CY 2020, Medicare Advantage (MA) Plans will need to provide those services as well. ACHP supports these policies and notes that ACHP plans were strong advocates for passage of the SUPPORT Act. ACHP community health plan members have been at the forefront of the nation's response to the opioid epidemic, often working in regions that have been hit the hardest and developing and implementing innovative approaches to reducing excessive prescribing and use of opioids.
- **Special Supplemental Benefits for Chronically Ill (SSBCI):** ACHP strongly supports the additional flexibility provided under Bipartisan Budget Act of 2018 allowing MA plans to tailor benefits to meet the needs of complex or seriously ill enrollees. CMS proposes to restrict the conditions that may be considered chronic, but ACHP believes plan sponsors are closer to enrollees and can better identify the conditions and social factors that could be most positively impacted by flexible benefits. If CMS does restrict the conditions that may be considered chronic, we strongly support use of a technical advisory panel to periodically review and update the list of acceptable chronic conditions. We advocate that CMS include ACHP or one of its member plans on the technical advisory panel, considering ACHP plans' consistently high quality performance and their experience partnering with community based organizations to deliver value to their members. ACHP will be watching for opportunities to be included on the panel. We urge CMS to share more comprehensive guidance regarding permitted items and items or services that would not be permitted as soon as possible to facilitate innovation in 2020 bids.
- **Star Ratings:** We appreciate CMS' commitment ensuring the star ratings program continues to evolve based on the needs of value-based payment methodologies. Specifically, we support tangible advancement in measures of patient reported outcomes and non-opioid pain management. If CMS proceeds with measure development in support of physician/plan interactions, we encourage doing so based on best practices identified by PCORI-funded work found at [www.transforming-care.org](http://www.transforming-care.org). We urge CMS to discontinue use of the improvement measures which distort the star ratings and are unnecessary given that the entire purpose of the ratings is to incentivize improvement. We support use of the Categorical Adjustment Index as an interim solution to address socioeconomic disparities but identify two problems that could be addressed by stratifying rates.
- **Proposed Part C Risk Adjustment Model:** ACHP supports the proposed phase-in of the proposed Payment Condition Count (PCC) risk adjustment model with the additional HCCS for dementia and pressure ulcers. We recommend that now and going forward CMS spend all its risk adjustment efforts to recalibrate the Part C risk adjustment models every year with the most currently available diagnoses and cost data. It is important that the risk adjustment models reflect the faster than anticipated increase in FFS risk scores. If there is sufficient time available between now and the Final Notice, we recommend the 2017 CMS-HCC model and the proposed 2020 PCC model be updated with 2016 diagnoses and 2017 costs. For 2021 risk adjustment, we recommend both Part C risk adjustment models be updated with 2017 diagnoses and 2018 costs.

- **Coding Intensity Adjustment:** ACHP is pleased that CMS will not increase the coding intensity adjustment beyond the statutory minimum of -5.91 percent.
- **Normalization Factor:** ACHP encourages CMS to calibrate the Part C risk adjustment models with 2016 diagnoses and 2017 costs so that the FFS normalization factor is 1.000 for the year 2017 rather than 1.000 for 2015, resulting in a more accurate forecast of the normalization factor. There are less years to forecast. Given the increasing magnitude of the normalization factor because of the increasing number of years between the denominator year and the payment year, ACHP encourages CMS to apply an adjustment to the normalization factor for under / over forecast of this factor, just as OACT continues to do when developing the MA growth percentage and FFS growth percentages. Prior years' misestimates are accounted for in the prospective MA payment rates and the same should be true for the normalization factor development. ACHP encourages CMS to better account for ever-increasing Baby Boomer Medicare age-ins into the normalization factor trend, as there seems to be an error of omission in accounting for this demographic change in the factor's development.

### Section-by-Section Comments

Our comments are organized in the order that issues appear in the Advance Notice and Call Letter. We would be happy to answer any questions or provide assistance.

#### **Attachment I. Preliminary Estimate of the National Per Capita Growth Percentage and National Medicare Fee-for-Service Growth Percentage for Calendar Year 2020 (p. 5)**

*ACHP recommends that in addition to the release of the preliminary estimate of the National Per Capita Percentage and National Medicare FFS Growth Percentage, CMS release a preliminary estimate of the county benchmarks for the upcoming contract year at the time of the release of the Advance Notice.* CMS releases the most current year's historical FFS cost data by county. Most MA plans do not have the resources or expertise to use this data to develop a forecast of the Final Notice county benchmarks. In this release of a preliminary estimate of county benchmarks at the time of the Advance Notice, CMS/OACT would list the major assumptions used to develop these preliminary rates, and note that these county rates will change, and could possibly change significantly at the time of the Final Notice as a result of the many data updates that will occur at that time. We discuss this issue in more detail below in Section B. Calculation of Fee For Service Costs.

#### **Sections A and B. MA Growth Percentage and FFS Growth Percentage (p. 5)**

**Develop USPCCs Using the Costs of FFS Beneficiaries Enrolled in Parts A and B:** *ACHP recommends that the USPCCs (aged plus disabled) that determine the MA growth percentage and the FFS growth percentage should use only the costs of the FFS beneficiaries enrolled in both Medicare Parts A and B.* As MedPAC has documented, including the A-only FFS population in the USPCC distorts these estimates because of this population's lower utilization and costs.<sup>1</sup> Because MA enrollees all receive both Part A and B services, we believe that the USPCCs used to determine the MA payment rates should be an apples-to-apples comparison to FFS enrollees. We believe that CMS should be consistent in its calculations of costs for the FFS population: the Part C risk adjustment models are constructed using FFS enrollees in both A and B. ACHP also recommends that the ESRD USPCCs that

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<sup>1</sup> Medicare Payment Advisory Commission, [http://medpac.gov/docs/default-source/reports/mar17\\_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/reports/mar17_entirereport224610adfa9c665e80adff00009edf9c.pdf?sfvrsn=0), ch. 13

determine the ESRD payment rates should use only costs of the FFS beneficiaries enrolled in both Medicare Parts A and B. (We also address this issue under Section B, related to FFS costs.)

## **Attachment II. Changes in the Part C Payment Methodology for CY 2020**

### **Section A3. Quality Bonus Payment Percentage (p 11)**

***ACHP supports CMS review of the inclusion of quality bonus payment (QBP) for the ESRD membership of MA plans beginning in 2021.*** The passage of the 21<sup>st</sup> Century Cures Act to allow ESRD Medicare beneficiaries to enroll in MA plans is based on the strong evidence that MAOs provide both high quality care and well coordinated care to this high risk population. Yet, the quality bonuses for high achieving quality MA plans is not part of the payment rates for MA ESRD membership. Going back to the original language of Affordable Care Act, it states the following:

“(1) IN GENERAL.—Subject to the succeeding paragraphs, in the case of a qualifying plan with respect to a year beginning with 2012, the applicable percentage under subsection (n)(2)(B) shall be increased on a **plan or contract level (bold added for emphasis)**, as determined by the Secretary—

“(A) for 2012, by 1.5 percentage points;

“(B) for 2013, by 3.0 percentage points;

“(C) for 2014 or subsequent year, by 5.0 percentage points.

The ACA language says the quality payment bonus (QBP) amounts should be applied at the “plan or contract level”, meaning ESRD payments are subject to the quality bonus payments.

We understand that CMS / OACT must determine if the add-on quality bonus of 5% for 4+ star plans is subject to the cap based on the applicable percentage for the benchmark. We ask that the calculation of the applicable percentage calculation for ESRD benchmarks be calculated exclusively with ESRD costs and cost trend data. CMS/ OACT has historically treated the ESRD population in this way, e.g., separate risk adjustment model, and should continue to do so when developing future ESRD benchmarks and proposed caps on ESRD benchmarks. In fact, in “Section D. ESRD Rates” below, we are asking CMS to study the use of smaller geographical areas for ESRD benchmarks going forward. If CMS believes that it can calculate ESRD county level benchmarks through the use credibility factors where there are small numbers concerns, we ask that CMS calculate “qualifying” bonus counties for the ESRD population. We are recommending that ESRD rates better account for geographical differences in utilization and costs for other significant medical services other than dialysis provided to this population because of the many other comorbidities that this high risk high cost population experiences.

CMS should study this geographic benchmark issue and quality bonus payments at the same time and make a determination of how to proceed forward given the increased ESRD enrollment into MA plans starting in 2021.

### **Section A.5. Cap on Benchmarks (p. 14):**

***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 increases annually.<sup>2</sup> 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. It is our understanding that the benchmark cap has also eliminated quality bonus payments to the ESRD membership of MA plans, a high cost high- risk population that is expected to increase starting in 2021 from the implementation of the 21st Century Cures Act. ESRD quality bonus payments will allow for a better transition of increased enrollment of ESRD into MA plans.

We 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.

## **Section B. Calculation of the Fee for Service Cost (p. 15)**

***County benchmarks should be calculated based on the costs of the FFS beneficiaries enrolled in Medicare Parts A and B.*** ACHP supports excluding the costs of the Part A-only FFS beneficiaries from the county benchmark calculation. MedPAC notes that Part A-only enrollees currently represent 12 percent of the FFS beneficiaries and that this population is increasing. The share of A-only 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. Given continuing growth in MA enrollment, there are increasing numbers of counties in which MA penetration is greater than 50 percent or will soon reach that level. As MA penetration continues to increase, the 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 distorted in representing FFS costs used for payment to MA plans that include enrollees who must be covered for both Parts A and B services.

We believe that the county benchmarks should be based on a population with similar characteristics to that of the MA population. CMS handles risk adjustment in this manner. CMS excludes Part A-only FFS beneficiaries from the calibration of the risk adjustment models because of their different utilization and costs from the A&B population. The county benchmarks used in the MA payment formula are risk adjusted by a RA model incorporating the diagnoses and costs of Parts A and B FFS beneficiaries. We believe these two components of the payment formula should be handled consistently.

ACHP recognizes there are several issues that 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. CMS noted in the 2019 Final Notice that they continue to analyze this issue to consider changing current methodology. We look forward to an update

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<sup>2</sup> Medicare Payment Advisory Commission, <http://medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0>, ch. 12

on where CMS is on reviewing this concern.

***Release of the 2017 FFS cost data by county to be used in the development of the 2020 ratebook.*** ACHP appreciates the release of the 2017 FFS cost data by county at the time of the Advance Notice. This will provide significant assistance to MA plans in forecasting the impact of rebasing.

***ACHP recommends that CMS/OACT take this data release one-step further starting with the 2021 Advance Notice by calculating preliminary county benchmarks noting a number of caveats.*** This new step truly would help everyone better understand the impact of rebasing at the time of the release of the Advance Notice. Understanding the impact of rebasing would help plans finalize benefits and premiums earlier plus develop the Part C bids in a timelier manner. If CMS were to have implemented our proposal in the 2020 Advance Notice, CMS would have calculated 2020 county FFS cost benchmarks using this 2017 county FFS cost data as the latest year of the 5 year AGA and updated the county benchmarks using the preliminary update of the USPCCs. This critical data, although preliminary, are available at the time of the Advance Notice. CMS would make it clear that these are early estimates of the county benchmarks and have not been updated with the latest 2020 price adjustments to the historical FFS costs. Also, the county's AGA would be adjusted by the current 2017 HCC risk adjustment model blended with the proposed PCC risk adjustment model, or if the risk adjustment models are not finalized at the time of the Advance Notice, CMS could use prior contract year's county FFS risk scores. CMS would list all of their assumptions and note items that will be updated in the Final Notice, e.g., repricing of historical claims, USPCC update, county FFS risk scores, etc. We recognize that these numbers could still change significantly from the Advance to the Final Notice, but the preliminary county benchmark estimates would greatly assist plans in forecasting contract year revenues and facilitate development of premiums and benefits for the bid at a much earlier stage than in the past.

#### **Section D. ESRD Rates (p. 22)**

***ACHP encourages the Office of the Actuary (OACT) to perform further actuarial research into studying the concept of smaller geographical areas such as Metropolitan Statistical Areas (MSAs) or potentially by county, as the basis for ESRD dialysis benchmark rates rather than statewide rates.*** Rates for a smaller geographical area may be a more reasonable approach now with growth of this population over time and the cost differences between urban and rural areas. Note, OACT had made this decision to use statewide data many years ago because of "small numbers". ***In addition, ACHP supports additional study of the ESRD rates to better understand the volatility of these rates.*** With the 21<sup>st</sup> Century Cures Act allowing all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021, it will become increasingly important for CMS to develop more accurate ESRD rates that are predictable. We have seen volatility of the ESRD rates in recent years, making these rates difficult to forecast. Therefore, for example, OACT may want to consider using 6 years of historical data for the AGA to reduce the year-to-year rate volatility. The ESRD population is a population that is a high cost population because of not only the disease ESRD but also because of many in this population experience other chronic diseases, particularly diabetes. These Medicare beneficiaries therefore are likely to be high utilizers of high cost medical services beyond dialyses that include hospitalizations and the increased use of physician and many ancillary services. The costs of these high use and high cost medical services that are in addition to dialysis do vary significantly between urban and rural areas of a state. As a result, a significant piece of overall ESRD health care costs in a MA plan's service area are not accurately represented under the current methodology. Statewide rates are not an accurate benchmark for MA plans located in urban markets. ***ACHP encourages CMS to do more research to evaluate if smaller geographical area ESRD rates can be developed even with small FFS enrollment numbers. County rates may be possible with credibility factors. That is, OACT could develop***

**“credibility” adjustments for geographical areas with small ESRD FFS enrollment. The ESRD county benchmark could be, depending upon a credibility formula for the number of ESRD beneficiaries in a county, the actual county data blended with the statewide data, using the statewide data as a manual rate. So, in some instances, the county benchmark could be strictly the manual rate of the statewide data for a county with no ESRD data credibility. Or, the ESRD county benchmark could be the actual county cost and utilization data if the county ESRD data is deemed to be fully credible. This proposed methodology is similar to the methodology CMS prescribes for MA Part C and D bids when the plan enrollment is too small to be credible. We encourage this additional work be done in time for the 2021 Final Payment Announcement released in April 2020.**

#### **Section G. CMS-HCC Risk Adjustment Model for CY 2020 (p. 28 and from Advance Notice Part 1)**

Provisions of the 21<sup>st</sup> Century Cures Act affect the risk adjustment model by directing CMS to incorporate more diagnoses for chronic diseases in the Medicare population. ACHP supports this direction and recommends that CMS consider additional modifications. For example, pancreatic cancer and other cancers involve high costs in the treatment year but much lower costs in subsequent years, so that they are not accounted for in the current model. Treatment for substance use disorders may follow this pathway as well. Another challenge to the model is reflecting the health risks of age-ins; their risk scores are excluded from the HCC model because of its prospective nature. We suggest that both of these challenges should be addressed through a hybrid concurrent and prospective model that better accounts for high-cost, but limited duration treatments and the health risks of the age-in enrollees.

#### **Payment Condition Count CMS-HCC Model**

***ACHP appreciates development of the Payment Condition Count CMS-HCC model.*** ACHP supports the inclusion of dementia and pressure ulcers, and the addition of new variables that take into account the number of conditions a beneficiary has. ACHP supports the proposed phase-in approach to the PCC model and the phase-in approach to the use of EDS-reported data to be used as part of the PCC model phase-in.

#### **Use of More Current Data for Calibrating Part C Risk Adjustment Models**

***ACHP supports updating both the 2017 HCC model and the 2020 PCC model with more recent historical data.*** In fact, if time permits, we suggest that CMS use the most current data for the recalibration of all the models – 2016 diagnoses and 2017 costs. It is important that the model be calibrated using a full year of ICD-10 data; the more precise of ICD-10 diagnoses will allow greater differentiation of conditions in the model, improved coding, and more accurate predictive costs.

Going forward, ACHP supports updating the Part C risk adjustment models every year with the most current available diagnoses and cost data. Just like CMS / OACT has concluded that rebasing every year is very important to take into account the changes in county FFS costs, it is now become increasingly important to update the risk adjustment models with more current FFS data, particularly given the faster than expected increases in FFS risk scores in the past few years.

This issue is discussed further in Section I. Normalization Factors.

**Section H. ESRD Risk Adjustment Model for CY 2020 (p. 29):**

***ACHP recommends the recalibration of the ESRD risk adjustment model in light of provisions in the 21<sup>st</sup> Century Cures Act allowing all Medicare beneficiaries with ESRD to enroll in MA plans beginning in 2021.*** An important component of the ESRD RA model that is missing from the proposed calibration is an update to the methodology that accounts for the costs of first-year ESRD MA members. We suggest that CMS develop a concurrent RA model rather than a simple demographic model for risk adjusting new ESRD MA members. These high-cost ESRD members often have multiple conditions in their first year of eligibility for ESRD or when newly enrolling in a MA plan. A demographic model poorly predicts the high costs of these first-year members, and it can take only a few incorrect payments for this very high-cost population to affect the overall financial results of a MA plan.

In addition, for Dialysis New Enrollee and Functioning Graft New Enrollee, it is likely that a concurrent risk adjustment model would be a much better predictor of these members costs given the nature of these members being “new” to ESRD.

This is another reason why we urge CMS to develop a hybrid concurrent/prospective model rather than rely only on the prospective model, especially for the ESRD risk adjustment model.

**Section K. Medicare Advantage Coding Pattern Adjustment (p. 36):**

***ACHP supports updating the coding intensity adjustment by no more than the statutory minimum.***

**Section L. Normalization Factors (p. 36):**

***ACHP recommends that CMS consider adjusting the normalization factor for past errors in prediction.*** It is possible that the large increase in the FFS risk scores for the two latest years is, in part, due to the conversion of ICD-9 to ICD-10, a one-time event. It is also possible that the introduction of MIPS-related payment under MACRA has an effect on FFS coding. These one-time events would not suggest a long-term trend in increased FFS coding. We hope that CMS will re-analyze the data and provide information on factors that are driving the risk scores, and whether they are indicative only of short-term anomalies. If, in fact, the increase in the rate of FFS risk scores do not turn out to be a long-term trend, it will be very easy to over-forecast the slope of the trend line, and therefore over-estimate the normalization factor. We would therefore suggest CMS develop an adjustment for a historical over/under forecast of the previous year’s normalization factor to be applied in the contract year’s normalization factor. This same type of historical mis-forecast adjustment has always been part of the MA and FFS growth rate calculation.

***ACHP encourages CMS to recalibrate the Part C risk adjustment models with the most current data available, 2016 diagnoses and 2017 costs.*** CMS had suggested in last year’s Advance Notice that the transition from ICD-9 to ICD-10 in 2015 has made data from that year unreliable. Our member plans believe the transition to ICD-10 generally went smoothly. Now 2016 diagnoses and 2017 cost data are available but neither the 2017 HCC model or the proposed PCC model were updated with this more current data. The denominator year would be 2017 at 1.000 rather than 2015 as proposed in the Advance Notice. With a 1.000 normalization factor in 2017, two less years are needed to trend off the 1.000 factor, resulting in a smaller normalization factor for 2020, and therefore less likely for there to be a significant error in forecasting the factor. It is especially important that the forecast of the contract year’s normalization factors be as up to date as possible because CMS currently does not correct for past years’ forecasting errors.

If the timing is too late to recalibrate the 2020 Part C models with 2016 diagnosis/2017 cost data, ACHP encourages CMS to recalibrate the 2021 models so that the denominator year would be the year 2017 or 2018. We prefer CMS update the Part C models every year going forward with the most current data to reduce the impact of the normalization factor, and reduce the probability of mis-forecasting the ever-increasing normalization factor given the longer and longer timeframe between the denominator year and the payment year.

***ACHP recommends CMS adjust the normalization factor for the growth of Medicare age-ins between the diagnoses year (2014) and payment year (2020).*** CMS explains that one reason for the increasing FFS risk scores at a faster rate is the result of “changes in demographics.” One would have expected that with the Baby Boomers aging into Medicare, the overall FFS risk score increases would begin to slow down with this significant demographic shift. However, there is a two year lag on when large influx of age-ins will be included in the calibration of the risk adjustment models. The RA models require at least a 12 month calendar year diagnoses period for a FFS beneficiary to be included in the model. As a result, all 65 and 66 year old FFS Medicare beneficiaries (unless previously disabled) are excluded from the model’s calibration, and therefore are seemingly excluded from any normalization factor trend calculation. Only age 67 and older FFS population are included in the original RA model’s calibration in the diagnoses year, 2014. Note, the 65 and 66 year old population is likely the fastest growing segment of the Medicare population.

So, a risk adjustment model calibrated with 2014 diagnoses data (the 2017 HCC model and the proposed PCC model), would have excluded Medicare eligibles who turned 65 and 66 years old in the year 2014. The proposed RA models will have a payment year of 2020, the end year for forecasting the normalization factor. A large increase in the Medicare age-in population is forecasted by CMS to occur between the years 2013 and 2020 because of the Baby Boomers aging into Medicare. This important demographic shift is NOT reflected in the forecasted trend of the normalization factor. In other words, the forecasted 1.000 factor in the year 2020 for both Part C RA models does not incorporate the increased size of 2020 Medicare age-in population.

So, one question is that when CMS calculates a 1.000 FFS risk score for a RA model in the denominator year (2015), we assume that CMS folds back into the recalibration calculation the simple “demographic” risk scores for FFS Medicare age-in population for the diagnoses year of 2014. If so, there should be some sort of “actuarial” or “demographic” adjustment to account for the large growth of Medicare age-ins between the model’s diagnoses year and the payment year. That is, for the year 2020 the demographic risk scores for the Medicare age-ins, a larger percentage of the Medicare population than in 2014, should be folded back into the new 1.000 calculation. This demographic adjustment is important and is likely to be significant when forecasting the normalization factor for the payment year of 2020.

***We look forward to further discussion of this important issue. We seek a discussion of how CMS handles the recalibrating the RA models to account for Medicare age-ins in the original recalibration of the models (2014 diagnoses year), and an additional discussion of how CMS handles the recalibration of the RA models in the payment year of 2020 to 1.000, with the growth of the age-ins in those intervening years.***

**Attachment VI. Draft CY 2019 Call Letter**

**Section I – Parts C and D**

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

ACHP appreciates CMS' commitment to quality improvement and the star ratings. ACHP submitted extensive comments on star ratings issues included in the proposed rule for MA and Part D (CMS-4182-P). We offer the following additional comments on specific proposals in the call letter:

### **Measure Updates**

ACHP agrees with CMS's proposed measure updates and the general approach outlined for advancing performance measurement through the Stars Program. ACHP and its member plans have long believed that the current measurement enterprise is not adequate for a value-based environment. While we caution CMS against changes that hold health plans accountable for measures that require sharing of information that is prevented by systemic barriers to data exchange, we strongly encourage a comprehensive, step-wise approach using a variety of incentives across stakeholder groups to overcome these systemic challenges.

#### *Improvement Measures (Parts C and D)*

ACHP addressed this issue in our comments on the proposed MA/Part D rule. ***We urge CMS to reconsider use of the improvement measures which are unnecessary and distort the star ratings for both health plans and consumers.*** The entire thrust of the star ratings system and the quality payments is to incentivize improvement. A separate measure of improvement blurs the distinction between high-performing plans and others. Consistency and stability in performance over time should be rewarded more than improvement in any given year. ACHP believes that star ratings are more appropriately based on performance across the entire range of clinical, patient experience and administrative/compliance measures.

## **2019 Star Ratings Program and the Categorical Adjustment Index (p. 122)**

CMS's proposal to incorporate differences in SES and demographic factors into performance measurement for health plans is a good one. Many ACHP plans provide coverage for dual-eligible and Medicaid populations, and many also serve rural and frontier communities. Our members' history of providing reliable health coverage to a variety of populations using a non-profit, community based model has made them especially attentive to health disparities and inequities experienced by their members. We fully support CMS's leadership in making sure that its quality and value-based payment programs not only improve care at the population level, but also for the sub-populations experiencing the greatest health inequities.

ACHP applauds CMS for focusing the first step in this process on stratification. While risk adjustment may well prove vital to a fair and equitable strategy for incorporating social factors into quality measurement, ACHP believes using it as the only way to incorporate these critical factors will not adequately address the problem of health inequities and outcome disparities – two vital components of meeting the Quadruple Aim. Improving the health of the whole population is not possible without measuring and reporting performance across different segments of that population. ACHP and its member plans enthusiastically offer our support to CMS in better understanding how improved care and experiences can be achieved for ALL populations.

### **New Measure Concepts**

ACHP plans applaud advancements by CMS and NCQA on measures that address the opioid crisis our nation faces. Our plans feel the impact of the opioid crisis keenly, given their community focus, and

policies that promote expanded access to non-opioid alternatives for pain management remain an area of focus for our work.

As mentioned above, ACHP and its members feel strongly that current quality measurement and reporting efforts are insufficient for the value-based payment environment toward which we are all working. We are therefore encouraged by the new measure concepts proposed. We understand that measure development is a long process, and also recognize that measurement gaps have been topics of conversation for many years. We therefore recommend prioritizing among the new measure concept areas to advance concepts that are both feasible and support tangible advancement in value-based payment for the most covered lives.

In our view, the area most in need of tangible progress is patient reported outcome measures. ACHP plans have focused significant resources toward improving current patient reported outcome measures, but have found that variations in performance are difficult or impossible to correlate with specific improvement efforts. Given the explosion of new technologies enabling patient and member access to their health data, we believe a fresh approach to the methodologies used to measure and report patient outcomes is imperative.

Harnessing patient-driven data approaches could also prompt more rapid advancement of interoperability. ACHP cautions CMS against developing new measures that hold MA plans accountable for obtaining information that is actively withheld by provider systems, or that require data intermediaries that do not exist in their coverage areas.

Additionally, we caution CMS against taking a measurement approach to physician/plan interactions that primarily results in documentation and reporting burden. Rather, we would encourage efforts that build upon the best practices our member plans identified in a recently completed PCORI-funded project. The case studies available at [www.transforming-care.org](http://www.transforming-care.org) show that community-based, non-profit health plans have successfully delivered on better value through relationship-oriented practices focused on alignment of goals, improving quality and reducing harm to patients, and supporting changes through appropriate financial incentives.

What our plans found is that improved physician/plan interactions related to coverage and payment decisions are a result of extended collaboration around shared goals, not arbitrary methods of accountability. ACHP and its member plans would be delighted to work with CMS to develop measure concepts that flow naturally from these best practices for health plan and provider collaboration to deliver greater value.

## **Section II – Part C**

### **Total Beneficiary Cost (p. 149):**

***ACHP supports the proposed different TBCs for plans with increases / decreases of in payment rates dues to quality bonus payment and/or rebate percentage.*** However, CMS has set up a “cliff” situation where the consequences for just a minor difference in payment rates will have large consequences to the TBC amount. Therefore, we support a smoother transition to the increase / decrease in the TBC amount in the following two situations noted below and we support the other proposed TBC thresholds:

- CMS proposes that if a plan has an increase of quality bonus payment and/or rebate percentage, and an overall payment adjustment amount of greater than \$36.00 pmpm, the plan will have a TBC of \$0.00. So, a plan that experiences a \$36.00 increase because of quality bonus and/or

rebate percentage can change its benefit design / premiums by \$36.00 pmpm while a plan with a payment increase of \$36.01 cannot change any of its benefits or premiums. Our recommendation would to have one additional TBC level such that if a plan's payment increased between \$36.01 to \$54.00 pmpm, the TBC would be -0.5 times the TBC, or \$18 pmpm, and if the plan payment increased by \$54.01 or more, the TBC would be -1 time the TBC or \$0.00 pmpm.

- CMS proposes that if a plan has a decrease of quality bonus payment and/or rebate percentage, and an overall payment adjustment amount of less than -\$36.00 pmpm, the plan will have a TBC change threshold of \$72.00 pmpm. So, a plan that experiences a -\$36.01 pmpm decrease in payment rates can change its benefit design / premiums by \$72.00 while a plan that experiences a payment decrease of -\$36.00 pmpm can change any of its benefits or premiums by a total of \$36.00. Our recommendation would to have one additional TBC level such that if a plan's payment decreased by between -\$36.01 and -\$54.00, the TBC would be 1.5 times the TBC, or \$54 pmpm, and if the payment decreased by less than -\$54.00, the TBC would be 2 times the TBC or \$72.00 pmpm
- ACHP supports CMS' proposed TBC change threshold of \$72.00 for plans with a star rating of 3.0 and an overall payment adjustment amount less than -\$36.00 pmpm.
- ACHP supports keeping the TBC at \$36 pmpm limit for all plans not accounted for in the three above situations.

### **SUPPORT Act Required Coverage of Opioid Use Disorder Treatment Services (p. 158)**

CMS describes the requirement, established under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), that Medicare Part B cover opioid use disorder treatment services when furnished by Opioid Treatment Programs.<sup>3</sup> Because those services are mandatory under Part B beginning in CY 2020, Medicare Advantage (MA) Plans will need to provide those services as well. CMS further encourages MA plans to provide non-opioid pain management services as supplemental benefits, to cover opioid reversal agents, and to place naloxone on low cost-sharing tiers.

ACHP supports these policies and notes that ACHP plans were strong advocates for passage of the SUPPORT Act. ACHP community health plan members have been at the forefront of the nation's response to the opioid epidemic, often working in regions that have been hit the hardest and developing and implementing innovative approaches to reducing excessive prescribing and use of opioids.

Our plans are leaders in working collaboratively with physicians and delivery systems to ensure appropriate and judicious use of these highly addictive substances, to guide prescribing practices, to identify outliers, to educate patients and to reduce harm. The strategies our plans have adopted are congruent with those policies that CMS is encouraging in the proposed Advance Notice and Call Letter.

ACHP plans have also focused on ensuring that treatment and recovery services are accessible for individuals and families impacted by opioid use disorder, especially and including access to Medication-Assisted Treatment ("MAT"), a critical tool to manage opioid addiction. Our member plans are working

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<sup>3</sup> P.L. 115-271.

to increase the number of MAT providers available in the communities they serve and the quality of services provided. Many are offering non-pharmacologic approaches to pain management including acupuncture, massage, and mindfulness, for example.

ACHP commends CMS for continuing to ensure that Medicare plans are addressing and making the nation's opioid epidemic a top priority. Our plans also continue to work in partnership with clinicians and community leaders, to implement multifaceted strategies to address opioid use disorders and to test new solutions. We know that much more work must be done to reduce opioid use disorder and bring this epidemic to an end, and we remain committed partners in this effort.

**Potential Changes in Maximum Out-of-Pocket (MOOP) and Cost Sharing Standards for CY 2021**  
(p. 159):

ACHP recognizes that a lower voluntary MOOP benefit helps the frailest and highest cost members. ***We encourage CMS to continue to incentivize MA plans to offer the lower voluntary MOOP.*** Rather than proposing a third MOOP, known as an “intermediate” MOOP between the current voluntary MOOP and mandatory MOOP, we recommend the following changes that are allowed under current CMS rules to the current two MOOPs. In addition, ACHP would like to suggest some other proposals that would require CMS to use its demo authority or would require Congressional action. Here are the changes proposed under current rules:

- Change the voluntary MOOP to \$4,000 which through interpolation represents something on the order of 87<sup>th</sup> percentile of projected Original Medicare out-of-pocket costs. There is nothing sacrosanct about maintaining the voluntary MOOP at \$3,400 and at the 85<sup>th</sup> percentile. It is more important to move the voluntary MOOP and mandatory MOOP amounts to be closer together to incentivize plans to move to the voluntary MOOP. MA plan cost sharing has increased significantly over the last 10 to 15 years, yet the voluntary MOOP has remained at \$3,400 over that same time period. As MA plans increase their cost sharing over time, the voluntary MOOP limit should increase concomitantly. For CY 2022, CMS should consider increasing voluntary MOOP to reflect the 88<sup>th</sup> percentile, for example.
- We recommend that CMS differentiate the MOOP cost sharing values between the voluntary MOOP and mandatory MOOP that will strengthen the actuarial incentives for MAOs to offer the voluntary MOOP. CMS should change and differentiate the maximum copays between those service categories that have higher utilization by Medicare beneficiaries. The two service categories with the highest Medicare utilization are: Primary Care Physician (7a) and Physician Specialist (7d). Currently, the maximum copays for these are the same under voluntary and mandatory MOOPs. In considering which MOOP to offer as part of their overall benefit package, MA plans will take under consideration which MOOP offers service categories that will allow the plan to charge a higher copay that will result in a larger actuarial value of copayments (utilization multiplied by copays). The more service categories that CMS differentiates between the MOOPs, especially for those services with higher Medicare utilization, the more likely an MA plan will choose to offer the voluntary MOOP.
- We do support CMS adding one or two more additional inpatient length of stay scenarios for both acute and psychiatric care. Next to physician visits, inpatient services have the highest Medicare utilization, and therefore the largest actuarial value. A larger actuarial value offers greater incentive for plan to choose the voluntary MOOP.

- We do support CMS varying the cost sharing limits for emergency care/post stabilization, home health services, and physician specialist services. We would add the service category - primary care physician (7a). Increasing the differential for emergency care / post stabilization is an important service category for increased copays. Increased copays on emergency room care incentivizes members to use the appropriate level of care, e.g., physician visits or urgent care, and not over utilize the higher cost ER services. Also, although we support home health service copay differentiation, it should be noted that home health services copay differentiation does not equate to much actuarial value given its low utilization. In addition, many plans do not impose home health copays primarily because it is difficult to collect copays. Many home health agencies are not set up to collect cost sharing under Original Medicare.
- We do support adding new cost sharing limits for observation services and ambulance services but, it is even more important that CMS differentiate the maximum copays for these services in the voluntary and mandatory MOOP copays.
- We do not support any more differentiation in the nominal cost sharing limits for the first 20 days of a SNF stay. The current differentiation between the copays is currently reasonable, and the utilization for this service is very low so there is not much of an actuarial value for a nominal copay of \$10 or \$20 per day on this service category, meaning it will not be much of an incentive for a plan to choose the voluntary MOOP.

Here are the proposed changes that would require CMS to use its demonstration authority or would require Congressional action. If CMS is serious about moving more plans to the voluntary MOOP these proposed actions would likely succeed in moving many more plans to the voluntary MOOP:

- Allowing plans with low voluntary MOOP to recognize certain mandatory supplemental benefits as “original Medicare” as part of the bidding process. This could be done in either of two ways. CMS could suggest a list of mandatory supplemental benefits that would fall into this category or, secondly, CMS could require MA plans to suggest a supplemental benefit that does not exceed a certain actuarial value. In the end, plans would not be required to use any rebate amount in order to offer these proposed mandatory supplemental benefits.
- Increasing the rebate percentage by a small amount, say 5%, e.g., 70% to 75%.

We also propose two additional actions, not actuarial in nature, that CMS could take now. These actions would be allowed under current rules that would incentivize MA plans to move to voluntary MOOP:

- Giving some additional star credit rating value for a plan imposing the lower voluntary MOOP.
- Giving priority CMS advertising of MA plans with a low voluntary MOOP. For example, in the Medicare Personal Plan Finder, plans with lower MOOP could be highlighted with a “star” next to the plan with the appropriate footnote. Another example in the Medicare Personal Plan Finder is for CMS to list MA plans with lower MOOP further up in the list of MA plans, noting that these plans are listed in this new order of member out-of-pocket costs because these plans offer a lower MOOP. Or, in Medicare Personal Plan Finder, for a local market, there could be a special section listing all the local MA plans with the lower voluntary MOOP.

We believe offering three MOOPs is not the best solution to fixing the incentives for MAOs to offer lower MOOPs. Offering three MOOPs will be more confusing for MAOs to figure out which MOOP offers best “value” and, more importantly, will be more confusing to current and prospective MA members as they decide which MA plan to choose to enroll in.

We believe the above-noted steps would provide a strong actuarial incentive for MA plans to move to the voluntary MOOP, a benefit that best serves the frail and high cost/high utilizing member.

### **Special Supplemental Benefits for Chronically Ill (SSBCI) (p. 161)**

ACHP strongly supports the additional flexibility provided under Bipartisan Budget Act of 2018 (BBA 2018)<sup>[1]</sup> allowing MA plans to tailor benefits to meet the needs of complex or seriously ill enrollees. Allowing MA plans to incorporate the most innovative benefits allowable by law is critical for meeting the goals of the Quadruple Aim. While ACHP recognizes the need for some limitation, restricting MA plans' ability to address the vast majority of factors that impact health undermines our shared goals of better health, better experiences and lower cost. As community-based, non-profit health plans, our members have always provided significant value to their members and communities. Supplemental benefit flexibilities provide opportunity to extend that value to specific beneficiaries, based on their individual health-related needs.

Our members are actively exploring ways to use these flexibilities to target the social factors acting as barriers to improved health for members. CMS proposes to restrict the conditions that may be considered chronic conditions under this new authority to those identified in Chapter 16b of the Medicare Managed Care Manual; List of Chronic Conditions for Special Needs Plans.<sup>[2]</sup> We believe plan sponsors are closer to enrollees and can better identify the conditions and social factors that could be most positively impacted by flexible benefits. Greater flexibility to determine the conditions and benefits offering the greatest value to members will support innovation that better meets individual needs.

We appreciate that CMS has begun, in the proposed call letter, to provide more information about the benefits that may be permitted under the BBA 2018. We urge CMS to share more comprehensive guidance regarding permitted items (such as transportation for non-medical needs, home-delivered meals, food and produce) and items or services that would not be permitted under this authority (such as capital or structural improvements to the home of the enrollee that could potentially increase property value) as soon as possible. Lack of clarity on these points has resulted in plan hesitation in building innovations having the most impact into their benefit packages.

### **Section III – Part D**

#### **RFI on Risk-Based Arrangements (p. 171)**

ACHP supports CMS continuing to explore arrangements that encourage the goals of improving the experience of health care, improving health and reducing cost. Our community health plans are innovators. As nonprofit, community-based, provider-aligned health plans, we have a unique ability to influence provider and prescriber behavior to deliver better value. We would like to work with CMS to develop an understanding of the policy goals and the agency's ideas for achieving them. We are interested to learn more about what CMS considers "risk-based arrangements with non-pharmacy providers" and to share the experiences of our members that work best in achieving lower cost while providing high quality health care.

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<sup>[1]</sup> P.L. 115-123.

<sup>[2]</sup> Section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual.

### **CY 2019 Formulary Reference File (p. 172 in 2020 letter)**

CMS is analyzing the Part D utilization of current Formulary Reference File (FRF) drugs and indicates it will remove drugs from the FRF based on these results. CMS intends to update the 2019 FRF in mid-to-late May, prior to the June 4 formulary submission deadline. While having an updated and accurate FRF is important, we note that the FRF is already missing several medications covered by Part D plans. Plans are accountable for paying for all Part D medications covered by definitions in Chapter 6 of the Medicare Prescription Drug Manual. Given that there are already several missing medications in the FRF and coding and maintenance are difficult challenges for plan sponsors, ***ACHP recommends against removal of medications from the FRF at this time.***

### **Benefit Review -- Meaningful Difference Standards (p. 177)**

CMS has made a series of changes to requirements that plan sponsors offer options that are meaningfully different from other plan options. In 2017, the meaningful difference standard was eliminated for MA plans. Eliminating that requirement was intended to increase innovative and competitive plan offerings, and improve plan flexibility. For prescription drug plans, the requirement that an enhanced alternative plan option must be meaningfully different from another enhanced alternative plan was also eliminated. CMS, however, retained the requirement that there must be a meaningful difference between an enhanced alternative benefit Part D plan and a basic benefit plan.

In the proposed 2020 Call Letter, CMS would retain the remaining meaningful difference standards as applicable in Part D in 2019, but notes that it is considering future changes based on stakeholder feedback to the 2017 proposed regulatory changes.

ACHP believes that meaningful difference standards should be eliminated altogether. CMS' existing requirements for marketing materials and nondiscriminatory benefit designs are sufficient consumer safeguards. Further, CMS plan finders and other support tools help beneficiaries discriminate between plan choices and identify those plans that best meet their needs.

### **Specialty Tiers and Composition (p. 179)**

CMS proposes to maintain the same specialty tier threshold as last year's amount. For 2020, the sponsor negotiated price of a drug included on the specialty tier must exceed \$670 per month. In years past, the specialty tier threshold was set based on an amount such that 99% of all monthly fills fell below that amount. In 2020, however, just under 99% of monthly fills are below the \$670 threshold. CMS seeks comment on how it might evaluate setting or making changes to this threshold in the future.

### **Improving Access to Part D Vaccines (p. 179)**

CMS encourages Part D sponsors to offer a \$0 vaccine tier or to place vaccines on a formulary tier with low cost-sharing. We agree with the goal of achieving greater vaccination rates but want to share our concern about the potential impact on the rest of the formulary. Plans are allowed only six tiers for their formularies. Using an entire tier for zero cost-sharing vaccines makes management of the rest of the tiered structure significantly more difficult. It would require a formulary management action plan to offset the costs to the plan of absorbing the vaccines' cost sharing amounts. Particularly for newer vaccines, costs can be substantial, and Part D sponsors will have to analyze carefully the benefits and potential downside effects of CMS' recommended action.

## **Improving Access to Generic and Biosimilar Medicines (p. 180)**

CMS is considering discouraging or prohibiting plan sponsors from placing generics on brand formulary tiers and brand drugs on generic formulary tier, and eliminating the non-preferred drug tier. Under such a policy, drug tiers would no longer include a mix of generic and brand products. Generics would be part of generic formulary tiers and brands would be part of brand formulary tiers. CMS would expect that FDA-approved, therapeutically equivalent generics would be automatically included on a generic formulary tier immediately after launch.

ACHP has long supported the ability of plans to implement policies that drive value especially when generics and biosimilars are available. Our members carefully develop formularies to provide the best lowest cost alternative taking into account all available products, as well as their prices and effectiveness.

We do not, however, support CMS adding additional restrictions and limitations on a plan's ability to identify the tiering structure that can best achieve those principles. While many times a generic may provide the best value, this is not always the case. As such, we oppose a policy that would not permit a plan sponsor to establish formularies based on the best value products and reduce a plan's ability to promote the use of the best and lowest-cost alternatives.

We strongly support policies that encourage the use of lower cost biosimilars when determined to be interchangeable with a reference biologic product. Under the Biologics Price Competition and Innovation Act, an interchangeable biosimilar is a biosimilar that is expected to produce the same clinical result as the reference product in any given patient and the risk in terms of safety or efficacy of switching or alternating between biological products is no higher than using the reference product alone.<sup>4</sup>

We believe that CMS could make a greater impact on encouraging the use of lower cost biosimilars by identifying, reviewing, and revising National Coverage Determinations (NCDs) that impose barriers on the ability of plans to apply utilization management policies that encourage their use. Likewise, CMS should ensure that Local Coverage Determinations (LCDs) undergo the same review and revision. LCDs and NCDs should ensure that plans may impose a requirement of prerequisite treatment with another pharmaceutical product or biosimilar before prescribing other products for any relevant indications consistent recent guidance and regulations permitting greater use of utilization management.

### **Conclusion**

In addition to the comments above on the proposed Advance Notice and Call Letter, we encourage CMS to consider providing additional flexibilities to health plans in future rulemaking and/or demonstration projects. Specifically, ACHP is supportive of the following changes that we believe would further enhance our members' ability to lower drug expenditures and costs:

- Limit routine physician exception requests to formulary requirements. These exceptions undermine formulary tiering and other criteria, which are developed by pharmacy and therapeutics committees comprised of pharmacists, primary care physicians and specialists to allow Part D plans to provide clinically sound, cost-effective and affordable pharmacy benefits. For a limited number of exceptions, physicians should be required to provide a clinically-driven rationale specific to an individual patient's needs.

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<sup>4</sup> P.L. 111-148.

- Eliminate the “any willing provider” rule for pharmacies so that Part D plans have the ability to use tiered or closed networks. Narrow networks can be beneficial for consumers by facilitating better care coordination and cost management for selected specialty medications.
- Eliminate cost-sharing for generics, including biosimilars, to the greatest extent possible under the statute for the millions of beneficiaries receiving the Low-Income Subsidy.

Thank you for consideration of ACHP’s recommendations. If you have questions or require additional information, please contact Anthony Montoya, at [amontoya@achp.org](mailto:amontoya@achp.org).

Sincerely,

A handwritten signature in cursive script that reads "Ceci Connolly".

Ceci Connolly  
President and CEO