



Anthony Mader  
Vice President, Public Policy  
Anthem, Inc.  
1121 L Street  
Sacramento, CA 95814  
(916) 403-0522

Submitted via Federal e-Rulemaking Portal: <https://www.regulations.gov>

March 5, 2018

Demetrious Kouzoukas  
Principal Deputy Administrator and Director  
Center for Medicare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model, Medicare Advantage Capitation Rates, Part C and Part D Payment Policies, and 2019 Draft Call Letter**

Dear Mr. Kouzoukas:

Anthem, Inc. ("Anthem") appreciates the opportunity to provide comments in response to the Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model, released on December 27, 2017, and the Advance Notice of Methodological Changes for CY 2019 for MA Capitation Rates, Part C and Part D Payment Policies (Advance Notice) and 2019 Draft Call Letter (Draft Call Letter), released on February 1, 2018.

Anthem is working to transform health care with trusted and caring solutions. Our health plan companies deliver quality products and services that give their members access to the care they need. With over 73 million people served by its affiliated companies, including more than 40 million within its family of health plans, Anthem is one of the nation's leading health benefits companies. For more information about Anthem's family of companies, please visit [www.antheminc.com/companies](http://www.antheminc.com/companies).

**Executive Summary**

Anthem shares CMS' commitment to continuously identifying and implementing innovative approaches for providing Medicare benefits to enrollees, and empowering beneficiaries to make the best health care decisions for their unique needs. As a committed participant in the MA and Part D programs, Anthem asserts that the best way to carry through on this commitment is to emphasize transparency, flexibility, and efficiency, and to find ways to simplify rules to facilitate innovation. We commend CMS for proposing a number of payment and policy updates that support these goals—and, ultimately, continued growth and success of the MA and Part D programs—but also note concerns with how some of CMS' proposals would negatively impact beneficiaries, plans, and the MA and Part D programs themselves.

In addition to our detailed comments and recommendations, which begin on page 2, Anthem highlights the following priorities. Specifically, Anthem urges CMS to:

- **Not modify the methodology for calculating the coding pattern adjustment until CMS provides plans and other stakeholders with significantly more information about and a longer timeline to review and meaningfully comment on contemplated changes.** CMS should maintain

the current statutory minimum 5.90 percent coding pattern adjustment for 2019, and undertake a robust, stakeholder-inclusive process to first determine the ongoing relevance of the coding pattern adjustment, and then, if appropriate, the level of the adjustment.

- **Phase-in implementation of the recalibrated End-Stage Renal Disease (ESRD) risk adjustment model to ensure stability for a highly vulnerable patient population.** MA plans that serve ESRD patients have experienced significant swings in payment rates over the last several years. These frequent and significant fluctuations in payment policy have a direct impact on beneficiaries by making it challenging to design stable benefit packages that limit year-to-year changes for our members. CMS' proposal to recalibrate the ESRD risk adjustment model—while long overdue—is yet another payment update impacting a small, high-need beneficiary population. Anthem urges CMS to phase-in implementation of the recalibrated ESRD risk adjustment model over a three-year period, beginning in 2019, with such changes being fully implemented for 2022 and subsequent years.
- **Begin implementing proposed changes to the Part C CMS-HCC risk model in 2019.** Anthem supports inclusion of additional diagnosis codes related to mental health and substance use disorders and the severity of chronic kidney disease to the 2019 Part C risk adjustment model. We also encourage CMS to move forward to implement its proposed Payment Condition Count model beginning in 2019. Anthem has long been a proponent of risk model updates that promote the early detection of chronic diseases, prevention of complications and disease progression, and management of chronic diseases. CMS' proposals make important strides in achieving these goals.
- **Move forward with its proposal to expand the scope of the primarily health-related supplemental benefit standard to allow plans more flexibility to offer supplemental benefits that can enhance beneficiaries' quality of life and improve health outcomes.** Anthem has long believed that having the flexibility to design benefits that are attractive to members, meet health care needs, and drive utilization of effective services is critical to ensuring the continued growth and success of the MA program. By redefining health-related supplemental benefits, CMS would allow plans to more holistically address the health care needs of their members, leading to improved outcomes, reduced out-of-pocket costs, and decreased system-wide costs.
- **Allow plans the flexibility to offer targeted supplemental benefits to beneficiaries.** Permitting plans to reduce cost sharing for certain benefits, offer specific tailored benefits, and offer lower deductibles for all enrollees that meet specific criteria will remove barriers to innovative benefit design and allow MA plans to further the goals of improving care delivery, promoting wellness and disease management, and achieving cost savings while maintaining quality. This additional flexibility is an important step to ensure that medically vulnerable beneficiaries are receiving the best care for their needs, while also reducing the use of unnecessary, duplicative care.

### **Detailed Comments on Provisions in the Advance Notice**

## **II. Changes in the Part C Payment Methodology for CY 2019**

### *Contract Consolidations and Quality Bonus Payment (QBP)*

CMS notes that it will address its proposal to change how it calculates Star Ratings for contracts that consolidate in the forthcoming final CY 2019 MA and Part D rule. Anthem reiterates its recommendation that CMS finalize its approach as proposed, effective for the 2019 measurement year (and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract

year and used to assign QBP ratings for the 2022 payment year). As with all methodological changes to the Star Ratings program, is important that this change is also applied prospectively in order for it to appropriately and adequately address differences in how data are collected and submitted for certain measures during different periods. We appreciate the steps CMS proposes to take to ensure the Star Ratings provide beneficiaries with accurate, reliable, and timely information for enrollment decisions, and that the system truly rewards higher quality contracts.

#### *Calculation of Fee-for-Service (FFS) Cost*

For several years in a row, CMS has changed how the Average Geographic Adjustment (AGA) is calculated and is proposing to do so again in 2019. CMS should institute a more regular schedule (e.g., every three years) for implementing changes to this calculation, as the tendency to make annual changes creates uncertainty for MA Organizations (MAOs) as we plan and prepare for our annual bid submissions. We encourage CMS to develop a more consistent approach for implementing AGA calculation changes moving forward and to communicate the schedule with plans.

#### *MA Employer Group Waiver Plans*

CMS proposes to continue to waive bidding requirements for all Part C entities that offer Employer/union-only Group Waiver Plans (EGWPs). Payment for these plans in 2019 would be based on 2018 individual market plan bids, rather than a blend of individual market plan bids and EGWP bids from 2018. Anthem continues to agree with CMS' assertion that these bidding and payment changes will further facilitate the offering of Part C plans for employers and unions seeking to establish high quality coverage for their Medicare eligible retirees.

While we appreciate CMS' consideration of a payment adjustment to account for the difference in the proportion of beneficiaries enrolled in Health Maintenance Organization (HMO) versus Preferred Provider Organization (PPO) plan types between EGWPs and individual-market plans, it would be more accurate for CMS to segment the benchmark calculation for HMO and PPO products, given the fundamental differences between these plan types. Anthem also suggests that Dual Eligible Special Needs Plans (D-SNPs) be excluded from the benchmark calculation. D-SNPs are not equivalent to the type of coverage an employer purchases, and are therefore irrelevant to the calculation. We urge CMS to move forward with fully transitioning the EGWP payment-setting process with these modifications.

#### *CMS-HCC Risk Adjustment Model for CY 2019*

The 21<sup>st</sup> Century Cures Act mandated that CMS provide 60-day notice for the following specific changes to the MA risk adjustment model:

- The addition of diagnoses codes related to mental health, substance use disorder, and chronic kidney disease conditions, and
- An adjustment for the number of conditions an individual beneficiary may have.

The law also requires CMS to implement these changes over a three-year period starting in 2019, with all changes phased in by 2022. In Part I of the Advance Notice, released on December 27, CMS outlined its proposed approach for implementing the changes required by legislation, as well as other updates to the CMS-HCC model:

- Calibrating the model with 2014 diagnoses predicting 2015 FFS costs. CMS would select 2014 diagnoses for calibration using the same approach it uses to filter encounter data records; and

- Increasing the percentage of MA enrollee risk scores based on diagnoses submitted through the Encounter Data System (EDS) from 15 percent to 25 percent in 2019. Because EDS inpatient submissions are low compared to corresponding Risk Adjustment Processing System (RAPS) inpatient submissions, sponsors would be permitted to amend inpatient diagnoses from EDS with inpatient diagnoses from RAPS.

Anthem has long been a proponent of risk model updates that promote the early detection of chronic diseases, prevention of complications and disease progression, and management of chronic diseases. Given the significance of risk adjustment within the MA program, we have also advocated for increased transparency and collaboration around contemplated model updates, as well as sufficient time to review, analyze, and provide comments on such updates. Anthem therefore encourages CMS to move forward to implement its proposed Payment Condition Count model—which we agree is more consistent with the 21<sup>st</sup> Century Cures Act’s intent and requirements, as compared to the alternative All Condition Count model—beginning in 2019.

While we are generally supportive of CMS’ proposed 2019 risk model changes, we note that CMS’ proposal to blend the old and new models is overly complex. We also continue to have concerns with the frequency with which CMS implements its MA payment policies and the subsequent significant implications these updates have on MA risk score calculations. Anthem thanks CMS for its commitment over the last few years to increase the transparency necessary to support a viable risk adjustment model. Specifically, the Agency’s efforts to solicit feedback prior to implementation of the 2019 risk adjustment model (which introduced six community segments), and the recent release the Part I of the 2019 Advance Notice were helpful in analyzing complex changes and their impacts on the program outside of the historical 45-day Advance Notice process. However, more can and should be done to ensure that risk model updates are developed collaboratively and transparently, and that implementation is as simple as possible.

To ensure the risk model is clinically accurate, Anthem urges CMS to continue to preview significant risk adjustment model updates at least two years prior to implementation, and to finalize the risk adjustment model coefficients at least one calendar year before implementation. Additionally, in releasing proposed risk adjustment changes as part of the Advanced Notice, CMS should also timely release all supplementary data and models needed to appropriately analyze the proposed changes. For example, the supplementary data needed to support analysis of the 2019 Advance Notice Part I was not released until January 23, 2018, even though the Notice was released on December 27, 2017. We also note that risk model updates cannot be evaluated in isolation; CMS addresses a number of payment updates in the Advance Notice (e.g., FFS normalization factor updates, announcement of the coding pattern intensity adjustment, etc.) that impact risk score calculation. Plans require the ability to evaluate all of these updates holistically to fully understand their impacts on beneficiaries and plan operations. Effective and clinically accurate implementation of any risk adjustment model requires stakeholder input and testing to assess proposed updates; complete information is required to conduct appropriate analysis. We look forward to a continued dialogue with CMS to support a competitive MA marketplace and strong beneficiary access to care.

Anthem also reiterates our concerns with the continued transition to using encounter data to calculate beneficiary risk scores. As we have previously acknowledged, plans and CMS have experienced numerous and complex technical and operational challenges throughout the transition to encounter data. While we appreciate CMS’ efforts to resolve these challenges and increase transparency over the past year, critical issues remain unsolved. As a result of a wide variety of data intake, processing, and other errors, beneficiary risk scores calculated using EDS are substantially lower than risk scores calculated using RAPS. Several

third-party studies, including a review by the Government Accountability Office (GAO)<sup>1,2</sup>, confirm both the widespread nature of the technical challenges and the significant impact on plan payment.

While CMS' proposal to allow sponsor to amend EDS inpatient submissions with RAPS inpatient submissions is a welcome adjustment, it highlights that there are still significant issues with the accuracy of the data. Furthermore, CMS' own impact analysis acknowledges that the transition to encounter data as a source of diagnoses for risk adjustment will result in a payment reduction for MA plans. In fact, the fiscal year (FY) 2019 President's Budget explicitly includes the encounter data transition proposal included in the 2019 Advance Notice as a budget offset. The budget proposal, labeled "Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters," estimates that the proposed transition to encounter data will reduce Medicare Advantage spending by \$11.1 billion over 10 years.

Anthem continues to emphasize the importance of resolving all technical and operational issues associated with using encounter data to calculate beneficiary risk scores. CMS should retroactively make plans whole for any "lost" risk – and payments – until the encounter data can be certified as complete and accurate. By increasing its reliance on encounter data without resolving the acknowledged issues, CMS is supporting expanded use of inaccurate information, impacting the plan payments that are meant to provide robust beneficiary access to care.

#### *ESRD Risk Adjustment Model for 2019*

While Anthem agrees that recalibration of the ESRD risk adjustment model is long overdue, we are concerned that this update—in combination with the ESRD FFS Normalization Factor—result in yet another substantial reduction in plan payments for a small, high-need beneficiary population. MA plans that serve ESRD patients have experienced significant swings in payment rates over the last several years that have a direct impact on beneficiaries by making it challenging to design stable benefit packages that limit year-to-year changes for our members.

Given these concerns, Anthem requests that CMS take steps to provide year-over-year stability for the ESRD population—specifically, we urge CMS to phase-in implementation of the ESRD Dialysis risk adjustment model over a three-year period, beginning with 2019, with such changes being fully implemented for 2022 and subsequent years (aligned with the timeline for implementation of the CMS-HCC risk model, described above).

More broadly, Anthem requests that future updates to the ESRD risk adjustment model be communicated under a similar timeline as the CMS-HCC model (that is, we urge CMS to allow stakeholders at least 60 days to review and submit comments on all risk adjustment model proposals) in order to give plans enough time to properly analyze any contemplated updated.

#### *Medicare Advantage Coding Pattern Intensity Adjustment (CPIA)*

Anthem urges CMS to not change its methodology for finalizing the MA CPIA factor in the 2019 Rate announcement. CMS should maintain the statutory minimum adjustment of 5.90 percent.

While it is likely that the methodology used to calculate the CPIA should be updated, Anthem recommends CMS not change its methodology until at least 2020, after providing detailed, advance notice of

---

<sup>1</sup> Government Accountability Office. "Medicare Advantage: CMS Should Fully Develop Plans for Encounter Data and Assess Data Quality before Use." July 2014. <https://www.gao.gov/assets/670/665142.pdf>.

<sup>2</sup> Government Accountability Office. "Medicare Advantage: Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments." January 2017. <https://www.gao.gov/assets/690/682145.pdf>.

contemplated methodologies to plans and other stakeholders. The information provided in the 2019 Advance Notice for all three contemplated methodologies is outdated, insufficient, or both. Plans need significantly more details about any potential changes to the CPIA calculation in order to provide meaningful and accurate feedback to CMS.

Anthem notes that the first—and only—time CMS published its methodology for calculating the CPIA was in the 2010 Advance Notice, released February 20, 2009. In the intervening nine years, the Medicare program (both FFS and MA) has changed considerably. Changes in enrollment, demographics, standards of care, treatment patterns, payment policies, and even legislation must be considered in first determining the relevance of the CPIA and then, if appropriate, the level of the adjustment.

As CMS considers updating this methodology, Anthem urges CMS to keep the following questions and concerns in mind, and should provide an opportunity for plans and other stakeholders to weigh in on these issues as part of a comment process:

- What data should the adjustment actually be based on? That is, what cohorts of beneficiaries? What years should be considered?
- To what extent do changing MA enrollee patterns make prior year trends irrelevant?
- How should the disproportionate geographic dispersion of MA versus FFS members be controlled for?
- Should the CPIA be recalibrated along with risk model recalibrations?
- How do the FFS normalization factors interact with the CPIA?
- What is the impact of ICD-10 coding on perceived differences in coding intensity between MA and FFS?
- How should enrollment in different plan types—general MA, SNPs, and Medicare-Medicaid Plans (MMPs)—be factored in to determining a potential adjustment? Do state efforts to promote integrated care have an impact? If so, how should state decisions regarding passive enrollment into D-SNPs be factored into calculating the adjustment?
- What other elements not reflected in the historical FFS or MA data need to be adjusted before performing CPIA studies? For example, to what extent does \$0 cost sharing for Medicare Supplement plans and dual eligibles distort comparisons between MA and FFS members?
- How will CMS review medical records (both MA and FFS) to determine the adjustment?
- Should the adjustment continue to be the same across the industry, or specific to contracts or plans? How will CMS share that information with sponsors?
- Should risk score growth rates be considered a proxy for coding disparity? How will CMS' analyses evaluate whether differences in MA and FFS risk score growth rates are driven by demographics or morbidity or not?

We look forward to CMS providing more information about how it intends to thoroughly review the necessity of and appropriateness of a CPIA before proposing any changes to the calculation methodology.

#### *Normalization Factors*

CMS' proposed 2019 normalization factor for Part C is 1.041 for the CMS-HCC model used for payment in 2017 and 2018, and 1.038 for the proposed "Payment Condition Count" model. Meanwhile, the proposed 2019 normalization factor for the ESRD dialysis model is 1.033. In its Fact Sheet, CMS notes that normalization will result in a 2.26 percent payment reduction to MA plan payments from 2018.

Anthem continues to believe that the growth in FFS risk scores—particularly from 2015-2016 and 2016-2017—is unusual and unexplained. We are concerned that CMS' calculation of the normalization factors

is based on the assumption that average FFS risk scores will continue to grow when, in fact, the large increases in the 2016 and 2017 risk scores are likely due to the introduction of ICD-10 codes that occurred on October 1, 2015. Thus, the normalization factors calculated by CMS are likely a product of coding differences in ICD-10 versus ICD-9, rather than a real indication of higher risk scores in FFS Medicare.

We have long believed that CMS should be more transparent and provide additional insight into the data and methodology used to update the normalization factors. However, while the 2018 Advance Notice did offer a deeper look into CMS' methodology, the 2019 Advance Notice lacks sufficient information such that Anthem continues to have a number of questions about and significant concerns with the data included in CMS' normalization trend analysis, as noted above. Ultimately, we believe that CMS must further review its data, supply additional explanation, and then adjust the normalization factors for the CMS-HCC model and the ESRD dialysis model to ensure they are accurately representative of relevant trends and to ensure plans are reimbursed correctly in 2019.

#### *Quality Payment Program*

Anthem thanks CMS for providing information about how it will determine whether eligible clinicians who participate in Advanced Alternative Payment Models (APMs), but do not meet the thresholds to become Qualifying APM Participants (QPs), can qualify as QPs through the All-Payer Combination Option. We understand that this evaluation will involve both a payer-initiated process and a clinician-initiated process, and that the voluntary payer-initiated process will be carried out in 2018 so that CMS can publicly announce which payment arrangements are Other Payer Advanced APMs prior to the 2019 performance period. We look forward to reviewing the guidance and submission forms that CMS will include in the April 2018 bid submission package for MA plans to submit to determine if their payment arrangements qualify as Other Payer Advanced APMs.

We appreciate CMS' willingness to engage with payers across several different coverage programs and markets. We strongly believe that MA plans and other payers can meaningfully contribute in the shift from volume to value. As CMS finalizes the guidance that will be disseminated to MA plans in April, Anthem urges CMS to afford Other Payer arrangements sufficient flexibility to ensure that they—and their providers—can meaningfully participate in the Advanced APM track.

### **III. Changes in the Payment Methodology for Medicare Part D for CY 2019**

#### *Update of the RxHCC Model*

Anthem generally supports CMS' proposed RxHCC model updates but again requests that future updates to the RxHCC model be communicated under a similar timeline as the 2019 CMS-HCC model (i.e., with 60-days' notice) in order to give plans sufficient time for complete analysis.

#### **Detailed Comments on Draft CY 2019 Call Letter**

#### **I. Parts C and D**

##### *Annual Calendar*

In the CY 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 rule, CMS proposed to revise plan offering disclosure requirements such that MAOs and Part D sponsors would have to make available the necessary information, including the Evidence of Coverage (EOC), by the first day of the Annual Election Period (AEP), October 15, instead of by September 30. Anthem reiterates our

support for this change and urges CMS to finalize it as proposed; however, it is critical that CMS confirm its final decision with plans as soon as possible given the material impact it will have on the MA and Part D calendar. Similarly, we urge CMS to finalize its proposal to revise existing regulatory language to allow for the distribution of the EOC and Summary of Benefits, on a web site or via electronic delivery, so long as notice is provided of the availability of paper copies upon request. The success of these contemplated changes will depend on the ability of plans to implement them in a timely fashion, and thus we urge CMS to update the Annual Calendar accordingly in the Final Call Letter, if not sooner—particularly given some of the existing challenges created by the Calendar, described below.

Despite the establishment of specific timelines in the Annual Calendar, the release of important information has, in past years, been delayed. Any delays in the release of critical guidance makes it much more difficult for sponsors to meet already-compressed filing deadlines—deadlines that sponsors may be penalized for missing. In particular, Anthem requests CMS commit to releasing the Medicare Marketing Guidelines (MMG) by early to mid-May, especially since the Health Plan Management System (HPMS) module for submission of materials is slated to open on June 1 (the 2017 guidance was not released until mid-August, while the 2018 guidance was not released until the end of July). We also ask CMS to issue state-specific guidance for MMPs within two (2) weeks post-MMG release, and preferably no later than mid-June. While we understand the MMP materials require coordination between CMS and the States, the compressed timelines create additional tension and challenges, particularly if there are any delays in the provision of finalized materials. Sponsors rely on these critical guidelines to ensure that all beneficiary-facing materials and engagement are appropriate, timely, and disseminated as required.

CMS indicates it will provide the Annual Notice of Changes (ANOC), EOC, Low-income Subsidy (LIS) Rider, Part D Explanation of Benefits (EOB), formularies, transition notice, provider directory, and pharmacy directory models for CY 2019 in May 2018. However, plans would benefit substantially if CMS could provide these models by early April (or sooner).

In addition, Anthem requests CMS remove the requirement for plans to provide the multi-language insert along with the ANOC/EOC and Summary of Benefits—the insert no longer exists and has been replaced by requirements put forth by Section 1557 of the Affordable Care Act. We also ask that CMS release the model Non-Renewal/Service Area Reduction notices to plans along with the other model documents, with the understanding plans should hold releasing those notices to affected beneficiaries until CMS has provided approval to do so. Finally, we request that, per the MMG, CMS clarify that December 31 is the deadline for both MMPs and D-SNPs that separated the ANOC from the EOC to provide access to the EOC to enrollees (the current calendar only mentions MMPs).

We also note CMS intends to upload the Star Ratings to [www.medicare.gov](http://www.medicare.gov) by October 11, 2018. Anthem requests that upcoming plan year ratings and fliers be made available no later than August 15 to ensure upcoming plan year ratings are ready for use and included with every enrollment form by October 1 – along with the Summary of Benefits as required by Section 30.6 of the 2018 MMG. This will ensure plans have sufficient time to include the coming year’s Star Rating information in prospective member-facing materials for the Annual Election Period, which will reduce beneficiary confusion and appropriately facilitate the enrollment process as CMS intends. Please note that release any later than August 15 will result in the need to pre-print current year fliers for use in Plan Sponsors’ kits and will delay implementation of the upcoming plan year fliers due to industry-standard print/fulfillment timelines.

The Draft Call Letter requires both pharmacy and provider directories be available to beneficiaries by September 30. This places additional pressure on an already compressed materials development timeline. Furthermore, plans are often renegotiating provider contracts in the last quarter of the year (as many contracts expire on December 31). Setting the deadline for directories so early (by September 30) creates unique challenges with respect to contracts that are not finalized until after the deadline. We respectfully



request CMS require availability of directories in hard copy format by October 15—or, in the alternative, allow plans to deliver hard-copy directories by October 15<sup>th</sup>, or within three days of request, whichever is later.

### *Enhancements to the 2019 Star Ratings and Future Measure Concepts*

Anthem is supportive of CMS’ intention to have its current Part C & D Star Ratings contractor, RAND Corporation, establish a Technical Expert Panel (TEP) comprised of representatives across various stakeholder groups to obtain feedback on the Star Ratings framework, topic areas, methodology, and operational measures. Creation of the TEP—along with CMS’ proposal to codify the Star Ratings program, if finalized—would ensure that the Star Ratings system is governed by a process that fosters the transparency and predictability needed to support continued investment in quality improvement activities and, more importantly, ensure beneficiaries are able to rely upon the Star Ratings as a true measure of quality when selecting a plan.

Anthem requests that CMS and RAND take steps to ensure that stakeholder representation on the TEP is broad and diverse, and that plans with unique perspectives in serving the MA and Part D populations have a voice. While we continue to assert that a new MMP quality rating system similar to the MA Star Ratings system is an inappropriate approach, Anthem recommends that MMPs are represented on the TEP. The MMP perspective will be important to include to ensure that CMS and RAND are considering the full spectrum of implications of their decisions on outcomes, processes, and beneficiary experiences across all Medicare plans. Finally, we recommend that the TEP communicate openly and frequently with all stakeholders. More specifically, the TEP must develop a process for disseminating information with stakeholders in a timely fashion so that all parties have a clear line of sight into the panel’s work.

### New Measures

#### *Statin Use in Persons with Diabetes (SUPD)*

CMS proposes to add this measure to the 2019 Star Ratings with a weight of 1, and to increase the weight to 3 (as an intermediate outcome measure) in subsequent years. Anthem agrees with this proposal, along with CMS’ proposal to expand the data sources for identifying all Part D enrollees with ESRD for exclusion from the denominator of the SUPD measure.

#### *Statin Therapy for Patients with Cardiovascular Disease (SPC)*

Anthem disagrees with CMS’ proposal to include this measure in the 2019 Star Ratings. Because this measure focuses on high- or moderate-intensity statin medications—which requires higher levels of provider-patient engagement and discussion, as compared to the SUPD measure, for example—we encourage CMS to retain this measure on the Display Page until at least 2020 and to continue monitoring it, especially as more data becomes available, to assess when incorporation into the Star Ratings would be most appropriate. It is important for CMS and plans alike to better understand measures and associated performance, as well as for plans to develop comprehensive member and provider strategies to support strong performance, before introducing them to the program.

### Changes to Measures for 2019

#### *Improvement Measures*

CMS currently incorporates the improvement measures in determining a contract’s overall Star Rating, and follows a specific methodology for calculating the improvement measures themselves. However, CMS does

not address this methodology specifically in the Draft Call Letter. Anthem reiterates our concerns with CMS' approach, which we most recently provided to CMS in response to the CY 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 proposed rule. Specifically, we recommend that CMS adopt several changes to the improvement measure in order to ensure that the measure rewards plans that improve their quality, while not adversely impacting consistently high-performing plans.

CMS currently calculates the improvement measures in determining a contract's overall Star Rating using a methodology that calls for either inclusion of both Quality Improvement (QI) measures or exclusion of both QI measures. However, the current approach can potentially penalize plans who have consistently high performance in either the Part C or Part D group of measures, year over year.

For example, if Plan A had high performance for Part C measures in Year 1 and maintained that high performance in Year 2, the QI calculated for the Part C QI would be approximately zero change, thus earning Plan A a 3 Star for the QI measure rating. Given that the QI measures (C31 and D07) have a weighting value of 5, this 3 Star negatively effects Plan A's Overall Star Rating. To allow plans the ability to benefit from quality improvement without penalty in the other Part C or D group of measures, CMS should calculate plans' Star Ratings separately for Part C and Part D with and without the improvement measures to first determine if the corresponding QI measure should be included in the overall Star Rating calculation. Currently, the "hold harmless" methodology accounts for both QI measures together. A more appropriate approach would therefore be for CMS to calculate MA plans' Overall Star Ratings separately for Part C and Part D with and without the improvement measures to first determine if the corresponding QI measure should be included in the overall Star Rating calculation. We propose the following revision for MA-PD contracts:

- 1) Calculate the overall rating for MA-PD contracts with just the Part C improvement measure.
- 2) Calculate the overall rating for MA-PD contracts with just the Part D improvement measure.
- 3) Calculate the overall rating for MA-PD contracts *without* including either the Part C or the Part D improvement measures.
- 4) Calculate the overall rating for MA-PD contracts *with both* the Part C and Part D improvement measures.
- 5) If an MA-PD contract in any steps 1 through 4 has four (3.75) or more Stars, CMS should use that overall rating—otherwise, CMS should use the overall rating from step 4.

*Example: Plan A (additional details included in the attached document "Partial QI Harmless Example")*

- Step 1: Overall rating with just Part C improvement measure = 3.783
- Step 2: Overall rating with just Part D improvement measure = 3.628
- Step 3: Overall rating without either improvement measure = 3.681
- Step 4: Overall rating with both improvement measures = 3.727
- Step 5: Use overall rating from Step 1 (include only the Part C improvement measure) = 3.783

CMS' methodology for how the QI measures are calculated (C31 and D07) should also be modified to include measures for which plans achieved and maintained at least 4 Stars in the "hold harmless" category. Though CMS compares year-over-year performance for all QI-eligible measures, the "hold harmless" provision only applies to those measures for which a plan scored 5 Stars for both years in the comparison (and are therefore deemed by CMS to be "not applicable" to the QI calculation). This deviates from the general rule CMS follows for "hold harmless," where plans earning 4 Stars or higher are deemed "high performing." Including measures with 4 Stars in both years would be a more appropriate approach. Anthem recommends that CMS either adjust its methodology and assign "not applicable" when determining "Improvement, Decline, or No Change" (see Column U in the QI template) for measures that increased in

Star Ratings for year two of the comparison, or add these measures to the “hold harmless” provision. Because the “hold harmless” provision is tied to raw rates, and does not take into account the actual Star Rating earned (except in cases when a plan earned a 5 Star Rating in the prior year)—combined with the fact that CMS uses a clustering methodology for the cut points—a plan can improve its “earned” Star Rating while its raw rate declines year-over-year. This can lead to a “significant decline” in the QI calculation. For example: Plan A earned 4 Stars on the Complaints Tracking Module (CTM) with a rate of 0.088 in 2017, and earned 5 Stars with a CTM rate of 0.142 in 2018. Because a lower score on this measure is preferable to a higher score, Plan A actually had a higher complaint rate in 2018, but earned a higher Star Rating. Since the QI calculation is based on raw rate performance, it results in a “significant decline.” We urge CMS to implement our recommended modification to this component of the methodology.

Furthermore, all MA plans that are subject to the improvement measure should be allowed to benefit from it. Anthem does not support any proposal that would limit the application of the improvement measure to only those plans with Star Ratings greater than 2.5 Stars (or any other minimum threshold). Limiting the measure to only plans with more than 2.5 Stars goes against the objective of the improvement measure in encouraging and rewarding improvements in performance, particularly among lower-rated plans. This is important because plans with 2.5 Stars may have a disproportionate share of members who are low income, have low health literacy, or who are otherwise vulnerable and more difficult to reach. As a result, these plans may be struggling to make strides in the Star Ratings and should not be further disadvantaged by being excluded from the improvement measure.<sup>3</sup>

Finally, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) and Health Outcomes Survey (HOS) measures should be removed from the improvement factor calculation because survey data are based on respondents’ perceptions of their health status and thus are not a true reflection of plan performance or members’ outcomes. Plans should not be judged on perceptions, but rather on objective and clinically relevant outcomes. We also note that CMS has had challenges with its CAHPS vendor in recent years, particularly around sample selection, causing us to appeal our results as not statistically valid. If performed inconsistently, the improvement comparison will not be valid—further emphasizing the importance of excluding CAHPS and HOS measures from this calculation.

#### *Medication Adherence for Hypertension (RAS Antagonists), Medication Adherence for Diabetes Medications*

Anthem agrees with CMS’ proposal to expand its data sources for identifying all Part D enrollees with ESRD for exclusion from this measure.

#### *Medicare Plan Finder (MPF) Price Accuracy*

Anthem agrees that it is important to evaluate sponsors’ pricing data as used by beneficiaries, but recommends that CMS take into account the volatility of the market for pharmaceuticals and create allowances for price swings that may occur too rapidly for a plan to update the MPF (or for a beneficiary to become aware of such an update). CMS may want to consider focusing on drugs or plans that are persistent outliers, rather than those with differences that can be attributed to normal market fluctuations. We note that some plan contracts require pharmacies to offer their members their absolute lowest price on the day of the sale, leaving plans at the mercy of the pharmacy even though the intent and end result is a significant benefit to our members.

---

<sup>3</sup> ASPE. “Report to Congress: Social Risk Factors and Performance Under Medicare’s Value-Based Payment Programs.” December 21, 2016. Available at: <https://aspe.hhs.gov/pdf-report/reportcongress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs>. Accessed on February 20, 2017.

## Removal of Measures from Star Ratings

### *Beneficiary Access and Performance Problems (BAPP)*

CMS' proposal to retire the current BAPP measure and to replace it with a BAPP measure that only includes Compliance Activity Module (CAM) data would appropriately ensure that the Star Ratings program and the audit program accurately reflect the issues each are independently intended to measure. It would also ensure that plans are not assessed duplicative penalties. Anthem agrees with CMS' plan to include the revised BAPP measure on the 2019 Display Page, and asks CMS to confirm that the measure will remain on until 2020, per CMS' policy of retaining measures on the Display Page for a minimum of two years before introducing them as Star Ratings measures.

## Data Integrity and Proposed Scaled Reductions for Appeals Independent Review Entity (IRE) Data Completeness Issues

Anthem supports CMS' proposal to scale reductions for the appeals measures when there are data integrity issues. Distinguishing between plans that may have an occasional data error versus plans that have significant, material errors due to major systemic issues is critical when assessing and rating plans based on the integrity of their data. Further, existing CMS policy results in inequities because audited plans' Star Ratings are evaluated against the Star Ratings of plans that are not audited. The approach CMS outlines for scaling reductions for appeals IRE data completeness issues appropriately addresses these issues and should be finalized as proposed. However, to ensure a truly level playing field across the Star Ratings system, Anthem urges CMS to apply scaled reductions for all measure ratings that can be reduced based on incomplete or biased data, including the Part C and D Reporting Requirements measures (SNP Care Management and Medication Therapy Management [MTM] Program Completion Rate for Comprehensive Medication Reviews [CMR]).

## 2019 Star Ratings Program and the Categorical Adjustment Index (CAI)

Anthem agrees that beneficiary-level characteristics have a meaningful impact on Star Ratings and that it is critical to allow plans that care for the program's most vulnerable beneficiaries to compete on an equal playing field. However, in our experience, the CAI is insufficient to address this important problem. CMS has also acknowledged that the CAI has a very small impact on plan ratings. Thus, Anthem urges CMS to continue working with plans to identify a long-term solution to the impact of dual status and SES on Star Ratings. Anthem appreciates CMS' ongoing attention to and focus on the impact of beneficiary-level characteristics—specifically, dual status and socio-economic factors—on plan performance. We understand that the CAI is a temporary solution, but we urge CMS to work quickly to evaluate the options recently proposed by the Assistant Secretary for Planning and Evaluation (ASPE) and develop a longer-term, meaningful fix.

We are also interested in learning more about the Pharmacy Quality Alliance's (PQA's) work on potential risk adjustment of the three medication adherence measures (Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, and Medication Adherence for Cholesterol), as well as the National Committee for Quality Assurance's (NCQA's) ideas for stratified reporting of four Star Ratings measures (Breast Cancer Screening, Colorectal Cancer Screening, Comprehensive Diabetes Care – Eye Exam Performed, and Plan All-Cause Readmissions). While these changes represent potential improvements to accounting for the impact of SES on the Star Ratings, stakeholders require more insight into how CMS might incorporate them in order to provide more meaningfully feedback. We urge CMS, in collaboration with the measure developers, to include plans and other relevant stakeholders in any discussions on these issues.

## Disaster Implications

Anthem appreciates CMS' acknowledgement that Hurricanes Harvey, Irma, and Maria, along with the wildfires in California, created extreme and uncontrollable circumstances that negatively impacted the underlying operation and clinical systems that plans (and CMS) rely on for accurate performance measurement in the Star Ratings program. We support CMS' proposal to adjust the 2019 and 2020 Star Ratings to take into account the effects of the disasters that occurred during the performance periods. With respect to CMS' proposed policy for identifying which contracts were impacted—and therefore eligible for CMS' proposed adjustments—Anthem urges CMS to ensure timely alignment to and accurate updating of the Federal Emergency Management Agency (FEMA) web site – if it will be used as the source of truth to determine eligibility.

We note that the FEMA website (<https://www.fema.gov/disaster/3396>) has yet to be updated for the December California Wildfire Disaster Declaration (declared December 8, 2017 and referenced here: <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/cawildfires-11Dec17.aspx>). Anthem at one point had to refer to the Presidential Declaration to determine impacted counties, but note that as of February 13, 2018, that Declaration was no longer available. Based on the current information available, Anthem would not be eligible in the counties impacted by the wildfires because CMS' criteria "a"<sup>4</sup> does not align with CMS' criteria "c,"<sup>5</sup> but based upon previously provided information by the White House, certain Anthem contracts should qualify.

We recognize that CMS itself does not have control over when or how these criteria are disseminated. However, because of their meaningful impact on Star Ratings, we urge CMS to work with its Federal Agency partners to ensure the necessary information is updated as quickly as possible. CMS should also notify sponsors of contracts that meet CMS' eligibility criteria.

## New 2019 Display Measure

### *Plan Makes Timely Decisions about Appeals*

CMS is proposing to display a new appeals measure, based on 2017 data, that includes cases dismissed by the IRE because the plan has subsequently approved coverage and/or payment. All cases dismissed or withdrawn by the IRE would be included in this measure. Anthem recommends that CMS not include dismissed or withdrawn appeals in this measure because there is no easy way to determine whether these appeals were appropriate or not. Given the variation that could exist across plans, we are also concerned that this proposal would lead to indirect comparisons that do not ultimately help beneficiaries select a plan. Ultimately, Anthem questions how valuable such a measure would be to beneficiaries.

## Changes to Existing Display Measures

### *High Risk Medication*

Anthem agrees that this measure should remain on the Display Page for 2019, using PQA's updated High Risk Medication (HRM) drug list and measure specification for the numerator.

---

<sup>4</sup> The service area is within an "emergency area" during an "emergency period" as defined in Section 1135(g) of the Act.

<sup>5</sup> At least one enrollee under the contract resides in a FEMA-designated Individual Assistance area either at the time of the survey (for CAHPS and HOS adjustments to survey responses) or at the time of the disaster (for all other adjustments). For some adjustments, a certain percentage (25% or 60%) of the enrollees under the contract must reside in a FEMA-designated Individual Assistance area.

### *Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer*

While all three of PQA's opioid measures will continue to be reported to plans via the Patient Safety reports, CMS is proposing to include only Measure 3, Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP) to the 2019 Part D Display Page. Anthem supports this proposal, as this would better align with CMS' Drug Utilization Review (DUR) requirements and the quarterly Overutilization Monitoring System (OMS) report. However, in an effort to keep all opioid programs aligned, Anthem urges CMS to update the threshold and criteria to match that of the recent updates made to the OMS. Additionally, we caution CMS to conduct careful evaluation of the upcoming Part D Drug Management Program to understand how it will impact the OHDMP measure (or other opioid-related measures) before determining to add it to the Star Ratings program.

### Forecasting to 2020 and Beyond

Anthem has long asserted that an annual and formal notice and comment rulemaking process should be used to propose and finalize changes to the Star Ratings system. We thank CMS for responding to this feedback and support the proposed policy to codify Star Ratings measurements and methodology beginning with the 2019 measurement periods. Anthem agrees that having codified regulations to govern the Star Ratings will foster the transparency and predictability needed to support continued investment in quality improvement activities and, more importantly, ensure beneficiaries are able to rely upon the Star Ratings as a true measure of quality when selecting a plan. We look forward to continuing to engage CMS on the Star Ratings through this regulatory process.

### Potential Changes to Existing Measures

#### *Controlling High Blood Pressure*

NCQA's work to evaluate updates to the Controlling High Blood Pressure measure for the Healthcare Effectiveness Data and Information Set (HEDIS) 2019 as a result of new hypertension treatment guidelines from the American College of Cardiology and the American Heart Association is an important step in hypertension prevention. As CMS considers modifications to this measure, Anthem encourages CMS to include out-of-office remote monitoring encounters towards the measure rate calculation. This would make significant strides in identifying individuals with masked hypertension and ensuring that their blood pressure is adequately controlled.

#### *Telehealth and Remote Access Technologies*

CMS asks for feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare covered telehealth services and/or as provided by the MAO as an MA supplemental benefit, as eligible encounters in various Part C quality measures. In general, Anthem is supportive of such initiatives; we believe that including these types of encounters will help ensure robust access to care, improve efficiencies, expand disease management programs, assist in transitional care activities/coordination of care amongst the Medicare population, and generally drive improvements in patient experience.

#### *Cross-Cutting Exclusions for Advanced Illness*

As CMS considers the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected Part C measures, Anthem recommends that patients receiving palliative care be excluded from measures with a preventive care focus.

### *Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR)*

PQA's 2018 update to this measure includes a new denominator exception for patients eligible for CMR with fewer than 61 days of continuous enrollment in the MTM program, such that beneficiaries would be excluded from the denominator if they did not receive a CMR within the 61 day timeframe (but would be included in both the numerator and denominator if they received a CMR within this timeframe). Anthem agrees with CMS' decision to apply this denominator exception to the 2020 Star Ratings, based on 2018 data.

### Potential New Measures for 2020 and Beyond

#### *Transitions of Care*

Measuring the quality of transitions of care is a complex and challenging process due to the multiple providers and multiple health care settings that are often involved. Therefore, Anthem encourages CMS to ensure that the measure indicators include all providers who can appropriately support a beneficiary during a care transition, and not to limit the measure to "Primary Care Practitioners (PCPs)," since patients with chronic care needs can be primarily managed by a specialist rather than a traditional PCP or general practitioner.

Furthermore, it seems that all four component indicators CMS lists (Notification of Inpatient Admission; Receipt of Discharge Information; Patient Engagement after Inpatient Discharge; and Medication Reconciliation) in the Draft Call Letter must be satisfied to close a gap for this contemplated measure. Anthem cautions that such a requirement could be counter-productive to the ultimate goal of the measure, similar to the concern noted above. MA plans often have programs in place to support the transition home that do not necessarily require that a member have a PCP visit (e.g., visiting nurses, or registered pharmacists who complete the medication reconciliation). These programs provide valuable services to improve the quality of care transitions from an inpatient setting to home and should not be discounted or inadvertently discouraged as a result of this potential measure.

#### *Care Coordination Measures*

Anthem agrees with CMS that care coordination is central to the MA program's success, and that many highly rated MA contracts perform well on the Star Ratings measures because they effectively coordinate care for their members. We are eager to learn more about the care coordination measures CMS is testing; however, we remind CMS about our serious concerns with the use of survey-based measures in the Star Ratings, and particularly for measures assessing care coordination, which require beneficiary recall and rely on perception rather than data-driven evidence. Any care coordination measures contemplated by CMS for inclusion in the Star Ratings system must be based on objective clinical relevance. Ultimately, it will be important for CMS to adopt a gradual approach for how it measures care coordination with respect to Stars, which will require collaboration with plans and other stakeholders to develop the best measure and the most appropriate implementation process.

#### *Assessment of Care for People with Multiple High-Risk Chronic Conditions*

Approximately 30 percent of Medicare beneficiaries have at least one chronic condition, while over two-thirds have two or more chronic conditions, according to CMS' latest data. Beneficiaries with multiple chronic conditions account for a disproportionate share of Medicare spending. As the Medicare population continues to grow, and the prevalence of multiple chronic conditions increases, Anthem supports efforts that focus on ensuring proper assessments of this high-risk, high-need population.

### *Depression Screening and Follow-up for Adolescents and Adults*

As CMS and NCQA continue to evaluate a measure assessing the percentage of patients age 12 and older who were screened for depression using a standardized assessment tool and, if positive, received appropriate follow-up care within 30 days of the positive screen, Anthem notes that the Patient Health Questionnaire (PHQ-9) is a common tool used in physician settings and there are appropriate codes for submission/monitoring. Should this provider-level measure be implemented into the Star Ratings program, we recommend that the survey based measure in HOS (improving or maintaining mental health) be phased out of the Star Ratings.

### *Polypharmacy Measures*

The PQA developed and endorsed three measures that identify potentially harmful concurrent drug use or polypharmacy, which CMS is proposing for potential inclusion in Patient Safety reporting, on the Display Page, or as Star Ratings in the future. Before taking steps to incorporate these polypharmacy measures in the Star Ratings program in any capacity, we urge CMS to re-evaluate the utility of reporting the HRM Patient Safety reports and display measure since many of the same drugs are included in both the Use of Multiple Anticholinergic Medications in Older Adults and Use of Multiple Central Nervous System-Active Medications in Older Adults measures. CMS could consider retiring the HRM measure, or clearly differentiating drugs that would fall under each measure's program. We request that CMS further evaluate this overlap and provide plans with the results of that evaluation before moving forward.

### Measurement and Methodological Enhancements

CMS intends to continue to analyze existing ratings measures to determine if measure scores are “topped out” or showing high performance across all contracts, noting that it does not have a strict formula for deciding which measures to transition to the Display Page. Anthem strongly believes that measures showing high performance across all contracts should remain in the Star Ratings program. Plans work hard to improve their performance on the array of measures that are important to patient quality—removing such measures unjustly penalizes plans for their efforts. Furthermore, the importance of these measures does not lessen due to plans' effective management of the measures. Therefore, CMS should not transition so-called “topped out” measures to the Display Page.

CMS also seeks feedback on development of new or enhanced measures of beneficiary access. In addition to the current measures of sponsoring organizations' timeliness and reliable decision-making, CMS is interested in evaluating sponsoring organizations' compliance with effectuating appeals and provider outreach requirements, as well as appropriate clinical-decision making and notification to beneficiaries. Anthem is concerned by the direction of this work—the areas CMS is considering including address issues that are not easily reportable and are subject to significant variation among plans. Because these kinds of beneficiary access measures would not facilitate true apples-to-apples comparison, we question how valuable such measures would be to beneficiaries. Anthem urges CMS to not move forward with these measures for the 2020 Star Ratings, but to provide plans with greater insight into what standards it might measure, how performance would be measured, and what (if any) new reporting requirements may be imposed so that plans can provide meaningful feedback.

### *Plan Corrections*

In the Draft Call Letter, CMS indicates that the plan correction window will be open from early September to late September 2018. According to CMS, organizations and sponsors submitting plan corrections will receive a compliance notice and will be suppressed in the MPF until the first MPF update in November. CMS states that an organization or sponsor that has demonstrated a consistent pattern of bid submission



errors over multiple contract years and/or that previously received a compliance notice for CY 2018 may receive a more severe type of compliance action in CY 2019.

CMS' corrections processes and standards are unnecessarily harsh and fail to recognize that errors happen despite plans' best efforts to avoid them. CMS' process allows for no degree of error, which Anthem believes is unrealistic and unduly punitive for plans. Timelines are tight and there is a large amount of information which continues to change even after plans submit their bids. The intention of the plan corrections window should be to ensure that beneficiaries receive accurate and complete information, but CMS' proposal allows no room for inconsequential changes. The bid process moves quickly and information is constantly changing, which increases the likelihood for errors considerably and necessitates opportunities for corrections.

To facilitate information accuracy and transparency, Anthem asks CMS to provide MAOs and Part D sponsors more flexibility throughout the corrections process. For example, we ask CMS to consider establishing an exception process for minor adjustments that would not be subject to CMS corrective action. Specifically, we recommend that CMS allow plans the opportunity to demonstrate that the revisions are minor (e.g., correction of a keying error) or that there are extenuating circumstances that legitimately warrant a later submission (e.g., CMS system slowness or errors that can be documented). As an example, we point to the changed approach CMS implemented in 2017 for ANOC and EOC errors. CMS further defined the type of errors for which plans needed to submit an errata, versus the type of errors that did not (i.e., those that were more minimal in nature). This was exceptionally helpful as the ANOC/EOC documents both contain a significant amount of detailed plan information with quick turnaround times.

In general, uniform implementation of compliance actions based on minor issues as compared to a complete disregard for program rules is inequitable. We also note that the Federally-facilitated Marketplaces distinguish between plan corrections that are significant (e.g., changes to proposed service areas) and those that are more routine, and encourage CMS to adopt a similar approach here.

### *Validation Audits*

The proposals CMS puts forth to modify the program audit validation program would result in important process improvements, promote consistency, and reduce burden on sponsors. Anthem encourages CMS to move forward with these enhancements, which will allow sponsors to target resources efficiently during program audit validation.

Anthem supports CMS' proposal to exclude Compliance Program Effectiveness (CPE) conditions from the threshold calculation used in determining whether a sponsoring organization would be required to hire an independent auditing firm. However, we encourage CMS to consider the severity of the non-CPE conditions, in addition to setting a specific numerical threshold, to determine when sponsors with non-CPE conditions cited in their final audit report would be required to hire an independent auditing firm. CMS' audit scoring already considers both the number and severity of non-compliant conditions detected in a sponsor's operations. Establishment of a threshold calculation based on a combination of the number and severity of a condition would ensure that the focus of the audit validation program remains on conditions that have the potential to impact beneficiary access, rather than those conditions that likely require a lower level of effort from auditors to determine if the non-compliance has been corrected.

In addition, Anthem looks forward to reviewing and providing comments on CMS' draft validation work plan template that sponsoring organizations undergoing independent validation audits in 2019 would be required to submit. Because the format and design of validation audit work plans and reports are currently left to the discretion of the independent auditing firm, implementation of a standardized audit work plan template will promote consistency and efficiency. We urge CMS to be as detailed and specific as possible

when defining each field in the template so that plans can conduct sufficient reviews and provide feedback that eliminates any speculation once the template is being used in practice.

We also support CMS' proposal to provide plans with 180 days, as opposed to 150 days, from the date that CMS accepts their program audit Corrective Action Plans (CAPs) to undergo a validation audit and submit the independent audit report to CMS for review. This extended timeframe will allow for more sufficient time to first remediate issues, then accumulate a sufficient "clean period" to use as the basis for validation testing, as well as to complete meaningful validation testing. To promote efficiency throughout the process, Anthem requests that CMS' evaluation of the validation audit report to determine if conditions are corrected be completed within 30 days of receipt of the report.

Finally, we appreciate CMS' confirmation that sponsors can submit additional documentation addressing any concerns with, or rebuttals to, the auditor's report. This will be an important opportunity for sponsors in completing the validation audit process.

#### *Plan Finder Civil Money Penalty (CMP) Icon or Other Type of Notice*

Anthem urges CMS to reconsider its proposal to display an icon or other type of notice on Plan Finder for sponsoring organizations that have received a CMP. There are many potential reasons a plan could receive a CMP—including reasons that have nothing to do with access to care or benefit coverage—and if these reasons are not clearly explained to beneficiaries, the icon could cause significant confusion and lead to unfounded conclusions that hinder enrollment decisions. We recommend that CMS not display a CMP icon on MPF, but instead continue to post CMP information for the public on its Part C and Part D Enforcement Actions webpage.

#### *Enforcement Actions for Provider Directories*

While Anthem supports CMS' ongoing focus on ensuring provider directories are accurate for Medicare beneficiaries and their caregivers, we continue to have significant concerns with the corresponding expectations and requirements put forth by CMS, including the burden they place on providers. We agree that timely dissemination of comprehensive and correct consumer information is important and thus continually work to ensure a high-quality consumer experience. However, CMS' current rules around the information required in MA plan directories, the timeframe for directory updates, and quarterly outreach to providers for validation are overly burdensome and duplicative, detrimentally impacting plans, providers, and beneficiaries. The outbound outreach in particular has caused significant process and operational work impacting our ability to focus on more proactive provider education and communication campaigns. In addition, since providers receive these inquiries not just from Anthem, but from other MAOs as well, this creates a significant administrative burden that leads to provider abrasion. Anthem's goal is to limit duplicative transactions and streamline processes impacting providers. Anthem asserts that a more efficient process would be for CMS to require providers to submit updates directly to CMS and to make this data available to MAOs. Providers have a higher level of responsiveness to CMS and this centralized process would eliminate the need for duplication of administrative queries to providers from multiple plans versus queries from a singular point of contact.

#### *Audit of the Sponsoring Organization's Compliance Program Effectiveness*

Allowing sponsoring organizations that have undergone a program audit to treat the program audit as meeting the annual compliance program audit requirement for one year from the date of the CMS program audit will reduce burden and eliminate the duplication of effort. Anthem urges CMS to finalize this change as proposed.

## II. Part C

### *Meaningful Difference (Substantially Duplicative Plan Offerings)*

As indicated in our comments in response to the CY 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 proposed rule, Anthem agrees with CMS' assertion that elimination of the meaningful difference requirement will improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation. We look forward to CMS' finalization of this policy for CY 2019 in the final rule, the Final Call Letter, or an HPMS memo, and remind CMS that we stand ready to work with the Agency as it 1) aims to improve MPF and 1-800-MEDICARE to help beneficiaries easily compare multiple plans and 2) updates guidance and model materials for MAOs to use to provide valuable information to enrollees to evaluate and select the best plan for their needs.

### *Total Beneficiary Cost (TBC)*

Anthem continues to oppose CMS' methodology for calculating the TBC threshold for ESRD Chronic Condition SNPs (C-SNPs). ESRD payment rates have fluctuated substantially from year-to-year, forcing plans to make benefit additions in certain years despite the fact that payment rates have remained fairly flat. In recent years, CMS has used the "rebasement" value for ESRD payment rates as the TBC threshold for ESRD. Anthem does not agree with this methodology as it is not consistent with total changes in payment each year.

Anthem also remains concerned that the standard model used to value benefit changes is calibrated to a population that excludes ESRD members (the typical population for which plans submit MA bids), yet are applied to ESRD plans. If TBC rules are to be applied to ESRD plans, then the rules must reflect plans' experience with the ESRD population.

With this in mind, Anthem supports CMS' consideration of eliminating of the current TBC evaluation in future years. In the CY 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 proposed rule, CMS indicated that it was proposing to eliminate the meaningful difference requirement because doing so would "improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation." Anthem asserts that attainment of these goals would be supported through elimination of the TBC evaluation.

Although the TBC test only compares a plan to itself year-over-year, there are benefit elements that are not captured by CMS' current Out-of-Pocket Cost (OOPC) model. For example, a number of supplemental benefits that are important to beneficiaries, such as over-the-counter benefits, transportation, meals, etc., are not valued in the OOPC model but can significantly impact the benefit richness of the plan. In addition, tiering of benefits and provider network changes impact beneficiaries' enrollment decisions—but these factors are not reflected in the current OOPC model. We also note that Part D OOPC changes are valued on an old set of drug utilization, and new drugs are not taken into account when conducting the TBC test.

For these reasons, Anthem urges CMS to discontinue its TBC evaluations based on the OOPC model. While we are supportive of evaluations that control for drastic annual benefit changes, we do not support an arbitrary limit that does not effectively account for the innovative benefits MA plans provide to their members. As CMS' work on eliminating the TBC test continues, Anthem encourages CMS to collaborate

closely with the plan community to ensure that any alternate approach for determining whether plan bids propose too significant an increase in cost sharing or decrease in benefits from one plan year to the next is sound and enables truly meaningful assessments by beneficiaries. Anthem stands ready to partner with CMS on this work.

### *Part C Cost-Sharing Standards*

Anthem supports CMS' proposal to increase both the voluntary and mandatory thresholds for the Emergency Care/Post Stabilization Care limit for plans for CY 2019. We agree that this will better align cost sharing with actual costs and create an incentive to use primary and specialty care services for routine care and avoid using the emergency room for non-emergent routine services.

For CY 2020, CMS is considering changes to its policies related to service category cost-sharing limits, an initiative Anthem strongly supports because CMS' current interpretation of the cost-sharing limits may impact plans' ability to offer more flexible benefit designs that would provide beneficiaries with valuable plan options. For example, we note that CMS is not permitting cost sharing for the first 20 days of the Skilled Nursing Facility (SNF) benefit for CY 2019, but may apply cost sharing for days 21 through 100. Moving forward, CMS should allow plans flexibility in applying cost sharing to support the quality of care provided to their members, while meeting actuarial equivalence standards necessary to align with FFS.

### *Tiered Cost Sharing of Medical Benefits*

For CY 2019, CMS will not expect MAOs to submit a proposal summarizing their intent to tier cost sharing of medical benefits prior to bid submission. Anthem supports elimination of the proposal summary, but asks CMS to clarify whether plans' intentions to tier cost sharing would come up as part of the desk review process.

### *Outpatient Observation Services*

We commend CMS for proposing to distinguish the cost sharing for observation services from other outpatient hospital services in the modifying the Plan Benefit Package (PBP). The ability to make this differentiation will ensure that cost sharing for observation services is more transparent.

### *Health-Related Supplemental Benefits*

Anthem has long-recommended that CMS consider options that would allow MA plans to offer a wider array of supplemental benefits than they can today. These additional supplemental benefits could be medical services or other non-medical, social services that improve the overall health of individuals with chronic disease (for example, homemaker services, home-delivered meals, personal care services to assist with bathing and dressing, transportation services, inpatient custodial level care, in-home caregiver relief, adult day care services, and medical and safety equipment). Therefore, we strongly support CMS' intention to expand the scope of the primarily health related supplemental benefit standard so that MA plans may offer additional benefits as "supplemental benefits" if they diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and health care utilization.

This kind of flexibility is only extended to Fully-Integrated Dual Eligible SNPs (FIDE SNPs) today; however, providing this additional flexibility to more than just FIDE-SNPs would allow significantly more beneficiaries to reap the benefits—and these beneficiaries could perhaps benefit even more because many of them may not be dual eligibles who would otherwise obtain some of these benefits through Medicaid.

We also note that families and caregivers are an integral part of the support team for individuals with chronic illness. For optimal care management, CMS cannot ignore home-based care. Historically, Medicare has better supported family- and home-based models of care by including services such as family respite, certain home-aide assistance, and home-care benefits, as part of the Medicare benefit package. We interpret CMS' proposal to mean that these types of benefits would be permitted under the expanded definition of supplemental benefits, but ask that CMS confirm this interpretation.

#### *MA Uniformity Flexibility*

Beginning with CY 2019, CMS proposes to allow MA plans the flexibility to offer targeted supplemental Part C benefits to medically vulnerable enrollees. These benefit packages could offer differential access to enhanced services, or reduced cost-sharing or different deductibles for certain services, and MA plans must use objective and measurable criteria to identify enrollees eligible for such tailored supplemental benefits.

As noted in our comments to the proposed rule, Anthem appreciates the additional flexibility that CMS is proposing for MA plans to tailor benefits to their members, which should include sufficient latitude for plans to identify eligible enrollees. As CMS moves to enact this flexibility, we urge CMS to clarify that plans will have the ability to appropriately market these benefits to eligible members—and that the Agency will undertake beneficiary education efforts—to mitigate confusion and ensure that beneficiaries are able to make informed coverage decisions that best meet their health care needs.

#### *SNP-Specific Networks Research and Development*

Although CMS states the current network adequacy criteria and exception request process account for the unique health care needs and delivery patterns for MA beneficiaries enrolled in SNPs, Anthem continues to assert that beneficiaries with chronic conditions, dual eligible status, or institutional-level health care needs must have access to provider networks that reflects their unique needs. Anthem is committed to treating each beneficiary's health conditions comprehensively and appropriately, irrespective of the plan or product in which the member is enrolled. To that end, as CMS continues to examine the need for SNP-specific network adequacy evaluations, we request that CMS identify key questions, describe potential alternatives, and generally provide additional clarity so that plans can respond with concrete and actionable feedback before any proposal is finalized.

As potential changes to SNP network requirements are contemplated, Anthem notes that CMS' current emphasis on time-and-distance standards can often be overly prescriptive and ultimately limit sponsors' ability to serve certain geographic areas and harder-to-reach members. Accordingly, any new standards related to SNP network evaluation should not unduly emphasize inflexible time-and-distance metrics, and must not have the unintended effect of making it harder for plans to serve Medicare's most vulnerable beneficiaries.

#### *Rewards and Incentives for Completion of a Health Risk Assessment (HRA)*

Anthem supports CMS' proposal to allow MA plans to include the completion of an HRA as a permitted health-related activity in a Rewards and Incentives (RI) program. HRAs, as noted by CMS, are important tools that facilitate the assessment of a patient's holistic (medical, functional, cognitive, psychosocial, and mental) health needs. Including HRAs in RI programs creates an important opportunity for patients, providers, and plans to continue focusing on patient-centered care that promotes proper care management, improved health, and efficient use of resources.

### *Improving Beneficiary Communications and Reducing Burden for Integrated D-SNPs*

Anthem commends CMS for its efforts to maximize the potential to align benefits and improve coordination for dual eligible beneficiaries. As CMS works with states, it should also incorporate feedback and lessons-learned from plans, which also have a vested interest in promoting integration. Below, Anthem provides comments on the priority areas CMS identified for its work:

- Integrated Model Materials: The Center for Medicare & Medicaid Innovation (CMMI), in coordination with the Medicare-Medicaid Coordination Office (MMCO), should explore models that allow states and participating FIDE-SNPs, D-SNPs, and Medicaid plans to test the delivery of services to dual eligibles under certain regulatory flexibilities. Similar to the structure and goals of the MMP model, these Medicaid plans, D-SNPs and FIDE-SNPs serving dual eligibles could have the ability to test the positive impact that a single set of Medicare and Medicaid standards (i.e., unified appeals and grievances processes, unified beneficiaries materials, a single coverage identification card, benefit flexibility, and other integrated elements) could have on effective, efficient operation of programs covering dual eligibles. This may be an especially valuable model to test among those issuers serving the same dual eligible individuals in both of their Medicaid and Medicare products and are equipped to deploy tools and processes that offer an integrated experience. This type of model could promote a better experience for enrolled dual eligibles and network providers in these programs. It also promises higher levels of integration that could produce better outcomes and cost efficiencies. CMMI should enlist the input of stakeholders to identify those areas of needed integration and alignment as well as additional model elements in order to develop a demonstration inclusive of this concept.
- Non-renewals: As more states move towards integration, a streamlined process regarding pending non-renewals, service area reduction, and terminations will become increasingly critical. Alternatively, CMS could consider developing a truly integrated termination notice in which plans would be able to include optional, customizable language outlining the steps members should take if they receive Medicaid services from the non-renewing or terminating plan as well. Ultimately, while Anthem supports a streamlined process, we continue to believe it would be most helpful for CMS to be less prescriptive and allow for plan flexibility when it comes to member materials and communication.
- Model of Care (MOC): CMS had previously noted its desire to explore allowing states to review MOCs against their requirements concurrent with NCQA's review of MOCs in HPMS to avoid duplicative reviews by each program. Anthem notes that this is the process that occurs under the MMP demonstration—however, one challenge that Anthem has experienced in this process is receiving consistent, timely feedback and approval from both the state and CMS. Anthem supports CMS and states conducting a joint review and providing one set of comments instead of two. We note that this joint MOC review would need to allow for nuances such that MOC standards for Long-Term Services and Supports (LTSS) at the state-level are appropriately factored into the requirements for D-SNP beneficiaries (keeping in mind that not all D-SNP beneficiaries need or receive LTSS). Because of this, applying a one-size-fits-all approach to the D-SNP MOC review process (which could mean LTSS standards being applied to non-LTSS membership) could add unnecessary costs, and portions of it may not be meaningful to all models. Plans could be more exposed to these challenges as they move providers into risk-based contracts.

### *Parts A and B Cost Sharing for Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program*

CMS continues to remind plans of their obligations to educate network providers about QMB billing rules and to maintain procedures that ensure network providers do not discriminate against enrollees based on

their payment status. Anthem appreciates these reminders that are aimed at ensuring beneficiaries enrolled in the QMB program are protected from the collection of Medicare Part A and Medicare Part B deductibles, coinsurance and copayments. However, in Anthem’s experience, there remains significant confusion among the various entities involved in assuring compliance with this protection. Anthem supports the increased educational activities that CMS is leading to help educate providers regarding the QMB billing prohibition, including those carried out under the Medicare Learning Network. Similarly, Anthem takes appropriate measures to inform network providers regarding proper billing procedures and resources in our contracts.

However, despite these efforts, we believe there are additional opportunities for CMS leadership to identify and help address the ongoing challenges experienced by health plans, state Medicaid agencies, and providers (including pharmacists) in assuring accurate cost-sharing protections for the QMB population. One challenge we recognize must be addressed is guaranteeing proper identification of QMBs by providers. Currently, CMS instructs providers to contact state agencies and health plans to learn how to identify QMBs and to become familiar with identification cards used in their state. We suggest that CMS work with providers, health plans, and states to develop clear processes and protocols for QMB identification among all entities involved to help minimize provider confusion. For example, CMS could require the establishment of clear points of contact at state Medicaid agencies for inquiries regarding QMB balance billing and explore the use of simpler, standardized approaches for QMB identification (e.g., particular identifiers that may be assigned). Lastly, Anthem encourages CMS to continue to hold all entities, including health plans, states, and all provider types, accountable for compliance with the balance billing protection of QMB enrollees.

#### *Encounter Data Listening Forums, Monitoring and Compliance Activities*

Though the current EDS faces numerous challenges, Anthem continues to support an eventual transition to a risk adjustment system based fully on encounter data. However, we stress the importance of established milestones—including the need for all testing of the filtering logic to be completed prior to bid submission—in order for the transition to be successfully implemented. These milestones require plan engagement and CMS transparency—two elements that are key to a properly functioning, valid, and accurate system. Below we highlight those milestones:

| <b>Milestone</b>                           | <b>Measure</b>   |
|--|--|
| Accurate data capture and intake by CMS    | <ul style="list-style-type: none"> <li>• Plan MAO-002 submissions match data input by CMS (this phase is largely complete).</li> <li>• CMS and plans address all issues with the new version of the MAO-004.</li> </ul>  |
| Accurate data processing in payment system | <ul style="list-style-type: none"> <li>• Every submitted encounter that is eligible for payment must be accepted by CMS. Conversely, encounters that are not eligible for payment must be denied. Specifically, this standard has two vital parts: <ul style="list-style-type: none"> <li>○ Data Accuracy (6 to 12-month validation period): <ul style="list-style-type: none"> <li>– Data must be retained throughout processing. All accepted encounter data needs to match submitted data to ensure integrity of the data and process.</li> <li>– For example: Eliminate mismatched Beneficiary Health Insurance Claim Numbers (HICNs).</li> </ul> </li> <li>○ Filtering logic programmed to accurately reflect payment policy: <ul style="list-style-type: none"> <li>– All information that impacts MA payment needs to be accurately configured in the filtering logic.</li> </ul> </li> </ul> </li> <li>• CMS should share comparisons they have with each plan and/or mask a couple contracts and show results at a high level.</li> </ul> |

| Milestone  | Measure  |
|--|--|
|  | <ul style="list-style-type: none"> <li>Plans should be involved in testing of the EDS payments. Testing should use DOS 2015 or a model of focus on a particular contract.</li> </ul>   |
| Rigorous testing of filtering logic                                      | <ul style="list-style-type: none"> <li>CMS should partner with plans and provide raps to EDS compare reports by Payment Year. We have questions internally about DOS 2016 and have a level of doubt as there is delay in MAO-004 (~45 days)</li> <li>All testing must be completed prospectively before the bid submission deadline (i.e., for the 2019 bid cycle, CMS should complete all testing of the filtering logic by June 2018).</li> <li>Plans rely on this information to form assumptions, which are then built into the bid submitted to CMS. Inaccurate information leads to real beneficiary impacts, including the loss of value-added benefits.</li> </ul> |
| Payment Validation   | <ul style="list-style-type: none"> <li>Ensure a clear and complete outline of reconciliation process, including: <ul style="list-style-type: none"> <li>Method of payment validation, including models and examples</li> <li>Data to be used in payment validation</li> <li>Output from a test sample or contract</li> <li>Timeline for payment and reconciliation</li> <li>Appeals structure</li> <li>Testing methodology</li> </ul> </li> </ul>  |
| Increased Transparency; Transactional Reports Must be Available to Plans | <ul style="list-style-type: none"> <li>All RAPS based reports should be made available for EDS data, with a 3 to 6-month testing period.</li> <li>CMS should increase the rate at which MAO-004 will be issued.</li> </ul>   |

While work towards achieving the above milestones is ongoing, Anthem continues to assert that integrating performance metrics related to EDS submissions into potential compliance actions, negatively impacting plans, is premature. Anthem understands the need for CMS to ensure that plan sponsors are actively engaged in making the transition to encounter data, and we support any efforts to improve both plans' and CMS' understanding of this data. While Anthem agrees that CMS should be monitoring this data, plan sponsors should not be penalized—whether through warning letters or CAPs—with respect to the timeliness or quality of encounter data submissions until CMS' systems are consistently able to intake, process, and reconcile encounter data submissions with all sponsors.

Anthem urges CMS to continue collaborating with stakeholders to develop sound, realistic standards that are representative of the issues important to CMS, sponsors, and providers before implementing any oversight and enforcement activities. This is a critical step that must be taken to ensure the ultimate success of an encounter data-based system.

#### *Transparency and Timeliness with Prior Authorization (PA) Processes*

The stakeholder concerns about the burdens imposed by coverage restriction like PA that CMS mentions in the Draft Call Letter are a twofold issue, which we describe in detail below. In light of the challenges described, Anthem urges CMS to take steps to:

- Hold all Medicare participating providers accountable to the same standards, which will eliminate confusion, prevent abuse, eliminate the disparity between FFS and MA processing, and stop rewarding bad behavior with inappropriate billing;
- Identify all CMS sub-regulatory guidance that applies to the referenced processes and provide clarification, but most importantly; and



- Protect the Medicare beneficiary and ultimately the Medicare program

First, Anthem notes that while an MAO's contracted provider network must follow the rules as established by the plan, even contracted MAO provider staff have difficulty managing all the PA requirements, not due to a lack of information provided by the MAO, but due to the number of MAOs they are contracted with and the different services that require PA by plan. This can be challenging for many offices to navigate while also taking into consideration the type of plan a beneficiary may have and the benefits associated with those plans (PPO, HMO, HMO-POS, MMP, SNP, etc.). These challenges are further complicated by those beneficiaries who have a Special Election Period (SEP) and can enroll in, change, or disenroll from coverage as frequently as monthly. Anthem appreciates the burden facing contracted providers; however, current CMS guidance hinders our ability to fully review for appropriateness of services being requested and ensure services are covered and reimbursable under the Medicare program, essentially necessitating the application of a PA requirement. Updates to MAO guidance in other areas would lead to better reception of PA requirements.

Second, while CMS focuses on concerns associated with PA, Anthem urges CMS to consider why MAOs have found the need to require PA on certain services:

- Lack of Requirements or Guidance for Non-Contracted Providers: Some plans have out-of-network benefits (PPO and HMO-POS) and while PA is not required, a PA can be requested (unless urgent or emergent). However, MAOs with these plans receive very limited PA requests as there are no requirements or guidelines for non-contracted providers (with the MAO) to provide any information to the MAO. The burden is on the member to ensure a PA or claims review is completed.
- Disparity between MA and FFS: Under the FFS program, providers are held accountable for notifying members with an Advance Beneficiary Notice of Non-coverage (ABN) in situations where Medicare payment is expected to be denied. The ABN is not an MAO document. The burden of obtaining plan PA documents—particularly in light of Plan-Directed Care updates to Chapter 4: Benefits and Beneficiary Protections of the Medicare Managed Care Manual—is significant, as providers cannot use standard CMS documents and must use individual MAO notification materials. Under FFS, if the provider failed to either bill with the modifier showing the ABN was issued or produce the plan-specific document, the provider is held accountable. Under MA rules, the plan is responsible. Furthermore, when beneficiaries are referred outside of the plan network, the MAO is liable for all services.

While the MAO can educate its contracted providers, the lack of guidance for non-contracted providers, combined with the disparity between MA and FFS rules, complicates plans' and non-contracted providers' ability to effectively coordinate care for a beneficiary. More importantly, these challenges often burden beneficiaries with administrative and financial liabilities and do not hold non-contracted providers accountable. Because there are no requirements or guidelines for non-contracted providers to provide information to the MAO, the burden is left to the member. Additionally, even if the beneficiary is referred only for a consultation or specific service, the MAO is liable for any service the non-contracted provider renders. Since the ABN cannot be used and the non-contracted provider has no consequences for failure to follow Medicare rules, the provider is able to bill the beneficiary if the MAO does not pay.

We note that MAO contracted providers do not always know what services a non-contracted provider is rendering, or that they are not communicating with the beneficiary's MAO as contracted providers would. If the MAO determines that the service provided would not have been reimbursed under FFS—even in the case of care rendered outside of National Coverage Determination and Local Coverage Determination (NCD/LCD) guidelines—the only option is to deny the request and issue an Integrated Denial Notice (IDN),

which places beneficiary liability on the service. While this decision can be appealed per the beneficiary appeals process under Chapter 13 of the Medicare Managed Care Manual, the non-contracted provider is not required to appeal and can bill the member directly due to the denial being issued to the member.

If the MAO wants to shield the beneficiary from financial and administrative burdens, the only option is to pay the Medicare rate of reimbursement for the actual codes submitted by the non-contracted provider, even if FFS would not allow the member to have the burden of the appeals process. Even if upheld by the IRE, the member is still liable—a result that Anthem disagrees with. The beneficiary is following the advice and direction of a clinician. However, the current Non-Contracted Provider Dispute process does not allow for these types of decisions to be disputed and only looks at if the rate of payment is correct; we note that this does not cover site-of-service decisions like non-contracted providers billing for inpatient Diagnosis-Related Group (DRG) admissions when observation level of care was appropriate. There are guidelines that protect the beneficiary from liability but do not hold the non-contracted provider accountable for following the FFS rules of rendering only Medicare covered services or providing advanced notification. Thus, the MAO pays for services that would not otherwise be covered by the Medicare program.

MAOs are ultimately responsible for adhering to and otherwise fully complying with all terms and conditions of their contract with CMS and have the obligation to comply with Federal laws and regulations—but the guidance can be contradictory. While the burdensome process of PA is certainly a legitimate concern, the issues described above play a significant role in why MAOs attempt to even have PA. Anthem urges CMS to hold all Medicare participating providers to the same standards to eliminate confusion, prevent abuse, and—most importantly—protect the beneficiary. These goals can be achieved by updating CMS guidance regarding Provider Payment Dispute Resolution for Non-Contracted Providers. Anthem stands ready to work closely with CMS to resolve these issues.

### **III: Part D**

#### *Formulary Submissions*

##### CY 2019 Formulary Reference File (FRF)

CMS indicates that it will update the 2019 FRF in mid- to late-May. Anthem requests that CMS release the final FRF at least two weeks before the formulary submission deadline of June 4. At this late date, plans should be focused on formulary quality checks rather than more significant changes, but CMS' historically late release of the FRF update hinders our ability to direct resources in that manner.

While we appreciate CMS' intention to move the summer formulary update window later into the summer to allow for inclusion of newly approved brand and generics that occur in July and August, Anthem urges CMS to retain the current timeline and open the window no later than late July. Any later compresses plans' abilities to meet subsequent milestones as outlined in the Annual Calendar.

With respect to the enhancement-only window that CMS intends to add in late fall, Anthem requests that this window open prior to open enrollment in order for it to be truly beneficiary-friendly; if it occurs after open enrollment, beneficiaries will not have full and complete information when making enrollment decisions.

##### Changes for CY 2019 Formulary Submissions

Anthem agrees with CMS' proposals to 1) make the Additional Demonstration Drug (ADD) file available in advance of the ADD File submission deadline, 2) eliminate the Non-Extended Day Supply (NDS) file,

and 3) modify the Over-the-Counter (OTC) Validation File to reduce burden on sponsors and streamline CMS review.

### *Tier Composition*

Anthem appreciates CMS defining the maximum threshold of generic composition that provides for use of the non-preferred brand tier label.

### *Improving Drug Utilization Review Controls in Medicare Part D: Retrospective DUR*

### Comprehensive Addiction and Recovery Act of 2016 (CARA)

Substance use disorders are chronic conditions which require an integrated and holistic plan to support each individual and that individual's family. In recognizing the priority that should be placed on addressing the escalating opioid epidemic, and the important role of the health plan in the collective effort, Anthem has instituted a comprehensive suite of services designed to meet the growing need. Such services range from Medication Assisted Treatment (MAT), to peer recovery supports, community treatment options, and chronic pain management. At the core of our strategy are the fundamental objectives of prevention, treatment, recovery, and deterrence. As part of our strategy, Anthem reached the company's collective goal of reducing prescribed opioids filled at pharmacies by 30 percent since 2012—two years earlier than the initial goal. Anthem has now updated its goal to achieve a 35 percent reduction by 2019. We commend CMS for its ongoing dedication to address the opioid epidemic, and thank the Agency for the efforts it has undertaken to propose a framework for the Part D drug management program established under CARA. Anthem provided extensive comments on CMS' November 2017 proposal to implement this framework. We now urge CMS to provide the template letters that sponsors should use to inform at-risk beneficiaries of their eligibility for the drug management program. With implementation less than a year away, sponsors need guidelines on these templates as soon as possible.

### Overutilization Monitoring System (OMS) Metrics

Anthem supports CMS' proposal to change the Opioid Daily Dose measurement period from 12 months to 6 months to align with the revised OMS criteria measurement period. We also agree that the OMS report should include a second Opioid Daily Dose rate with a 90 Morphine Milligram Equivalent (MME) threshold to further align with the revised 2018 OMS criteria.

### Opioid Potentiator Drugs

Given the widespread impact of the opioid epidemic, Anthem supports CMS' efforts to monitor use of drugs that are used to increase the effects of a substance (potentiator drugs), increasing both the substance and the potentiator's abuse potential. While adding a concurrent opioid-gabapentin/pregabalin flag to OMS is an important step, we ask CMS to consider including a flag for carisoprodol, as combining opioids with benzodiazepines and skeletal muscle relaxants like carisoprodol has a known potentiating effect. In addition, we ask CMS to clarify whether it will allow sponsors to apply a restriction at the Point-of-Sale (POS) for potentiator drugs, including benzodiazepines. Regarding benzodiazepines, Anthem recommends that CMS refine its definition of this class to include zolpidem, zaleplon, and eszopiclone and to, in turn, apply OMS flags for these potentiator drugs. While not technically benzodiazepines, zolpidem, zaleplon, and eszopiclone are also known to potentiate the effects of substances like opioids and thus should be flagged in OMS.

## *Improving Drug Utilization Review (DUR) Controls in Medicare Part D: Concurrent DUR*

### Cumulative Morphine Milligram Equivalent Daily Dose (MME) Safety Edits for High, Chronic Prescription Opioid User

More can and should be done to address chronic, high prescription opioid overuse. Therefore, Anthem supports CMS' proposal for all sponsors to implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME). We agree that allowing beneficiaries to receive a 7-day supply of the prescription that triggered the hard edit as written would appropriately balance beneficiary access to medically necessary drug regimens and reduce the potential for any unintended consequences. However, we ask that CMS clarify a number of items, including if the one-time 7-day supply would be per drug. If so, Anthem notes that this would be difficult to administer, particularly when factoring in overrides, emergency situations, etc. We also request that CMS make clear whether this edit would replace or be in addition to the current 200 MME edit. In addition, we would appreciate insight into whether this edit would apply for new starts only, or for all fills. Finally, as CMS has just reduced the MME threshold for IDURC case management program to 90 MME, we ask CMS to define how this new program will integrate with retrospective DUR. We urge CMS to consider how providers may be impacted by a POS edit, as well as case management outreach.

We appreciate CMS' request for comment on when and how to best communicate to beneficiaries that the one-time 7 day supply would not be available for future prescriptions should the MME level remain at 90 mg or higher. Anthem suggests that this information could be included in the ANOC, and that network pharmacists could be trained to counsel patients on this specific reject code. In addition, outreach to members following receipt of the edit would ensure they understand both the limitations and the reasons for the limitations.

### *Days Supply Limits for Opioid Naïve Patients*

In 2019, CMS will expect all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed 7 days for the treatment of acute pain. Anthem is in strong support of this proposal given the magnitude of the opioid use crisis, its alignment with current Centers for Disease Control and Prevention (CDC) Guidelines for Prescribing Opioids for Chronic Pain, and the impact to prescription claim volume that Anthem has demonstrated post-implementation of a similar policy in our Commercial and Medicaid lines of business.

In implementing this change, Anthem notes that current submission quantity limits are based on 30 days. HPMS submission must be updated to allow for 7- or 10-day limits on opioids. The HPMS factor needs to be updated to allow treatment similar to antibiotics, which normally allows a 7- to 14-day supply per fill and may get more than 1 course of therapy. We also request CMS to allow overrides for the following circumstances:

- Chronic pain (for situations where the member is using short-acting opioids as-needed for pain but, the pain is deemed chronic and the look-back set up in the system does not recognize consistent as-needed use);
- Cancer-related pain;
- Pain related to palliative care or terminal illness; and
- Pain related to sickle cell disease

### *Opioid Duplicative Therapy Safety Edits*

Following an analysis investigating duplicate opioid use in Part D, CMS will expect all Part D plan sponsors to implement a soft POS edit for duplicative long-acting opioid therapy beginning in 2019, with or without a multiple prescriber criterion. When such an edit is triggered for concurrent use of opioids and buprenorphine, CMS notes that the soft edit should only reject the opioid prescription following the buprenorphine claim and should not impede access to buprenorphine for MAT. While Anthem appreciates CMS' efforts to help reduce excess opioid supplies and reduce adverse events, soft edits only notify the dispensing pharmacist of duplicate or concurrent use and can be passed easily, dampening the effect CMS is aiming to achieve. We are concerned that an opioid duplicative safety edit like the one proposed here will lead to the continued overestimation of the benefits of opioids relative to the risks of opioid use disorder and diversion. As noted elsewhere in this letter, Anthem is supportive of the more effective (in our experience) hard edit.

### *Concurrent Use of Opioids and Benzodiazepines*

CMS proposes that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit. As noted above, Anthem struggles to see the value in soft edits. We are concerned that some pharmacies may get into the habit of overriding the edit instead of focusing on the true intention of the edit which, in this case, is the reduction of inappropriate concurrent use of prescription opioid analgesics, opioid-containing cough products, and benzodiazepines. Rather than implement a soft edit requirement, Anthem recommends that CMS expand retrospective DUR programs for potentiator drugs (as noted above). In addition, we note that provider education about the serious risks of concurrent use of opioids and benzodiazepines is an important tool in limiting inappropriate concurrent use of these prescriptions.

### *Using the Best Available Information when making B vs D Coverage Determinations for Immunosuppressants and Inhalation Durable Medical Equipment (DME) Supply Drugs*

CMS proposes clarifications on how to determine the appropriate coverage benefit for immunosuppressant drugs and for certain inhalation drugs. Specifically, CMS is proposing new guidance on how Part D sponsors should determine whether immunosuppressant drugs are covered under Part D or Part B that are used to prevent transplant rejections. Going forward, Part D sponsors are to rely solely on information from CMS (the Medicare Advantage and Prescription Drug [MARx] system) which will indicate whether—in the cases of renal transplant—the transplant was or was not covered by Medicare. No changes need to be made to prior Part D claims.

Anthem recommends that all immunosuppressants be covered under Medicare Part D. This will ensure that beneficiaries do not have access-to-care issues in obtaining needed medications. Such a policy would also minimize administrative burdens around determining which Part of the Medicare program paid for a transplant, which would be substantial under CMS' proposal, as we describe below.

First, MARx does not currently state if Medicare paid for a transplant. MARx only provides the Medicare Part A eligibility and the transplant date—and this information is only provided when the transplant is for a kidney. There is no indicator as to whether Medicare Part A paid for the transplant or not. Thus, if CMS moves forward with its contemplated change, Anthem asks CMS to clarify if it will start providing who covered the transplant for all types of transplants. We urge CMS to enhance the MARx system to flag if a transplant was covered by Medicare.

Second, when relying solely on Medicare Part A eligibility versus just the transplant date, Anthem has received conflicting information from beneficiaries who state Medicare Part A did not pay for their transplant and/or that the facility was not eligible for coverage under Part A. We ask CMS to provide more

information about how it would intend to handle situations in which, based on the information and proposed new guidance, the immunosuppressant should be covered under Part B, but information from the member indicates the product should be covered under Part D.

We also note that there is currently no reporting mechanism that would allow a plan sponsor to know whether Medicare Part A paid for the transplant. The only way a plan sponsor would know is if the plan sponsor paid for the transplant. We ask CMS to consider reporting to all types of sponsors (e.g., MA, PDP, etc.) on all types of transplants (e.g., heart, lung, etc.) and if they were covered under Medicare Part A or not.

Finally, CMS should clarify if, under its proposed clarifications, plans would be required to delete prescription drug event (PDE) records and/or be penalized if it was determined that Part D should not have covered the transplant retrospectively. CMS has previously conducted select audits and required PDEs to be deleted and/or penalized the plan when claims were mistakenly paid under Part D based on the default of Part D. We request clarity around whether CMS will penalize plan sponsors that default to coverage under Part D if it is later determined that the transplant should not have been covered under Part D.

*Part D Mail-Order Refill Consents Policy—Solicitation for Comments*

While Anthem agrees that taking steps to decrease waste and unnecessary costs associated with unneeded or unwanted prescriptions is important, requiring patient consent to deliver a new or refill prescription prior to each delivery hinders medication adherence and can negatively impact our enrollees' health. Plans, in conjunction with their pharmacy benefit managers, should have the flexibility to implement systems that best meet the needs of their members. Anthem supports the development of beneficiary protections that would apply to all mail-order refill programs, but that still allow plans to vary their approach to mail order in an effort to respond to beneficiary need and meet goals around cost effectiveness.

\*\*\*

Anthem appreciates this opportunity to provide input on the CY 2019 Advance Notice and Draft Call Letter. We are eager to work with CMS to ensure the delivery of robust benefits and quality care via the MA and Part D programs. Should you have any questions or wish to discuss our comments further, please contact Danielle Horne at 818.298.7830 or [Danielle.Horne@Anthem.com](mailto:Danielle.Horne@Anthem.com) or Leah Hirsch at 202.508.7881 or [Leah.Hirsch@Anthem.com](mailto:Leah.Hirsch@Anthem.com).

Sincerely,



Anthony Mader  
Vice President, Public Policy

Enclosure: Partial QI Harmless Example

Star Rating Final

|   |              |  |             | Plan A  |         |           |         |
|---|--------------|--|-------------|---------|---------|-----------|---------|
| Category                                    | Source       | Star Measure   | 2016 Weight |         |         | Rate      | Star    |
| Part C:                                     |              |  |             |         |         |           |         |
| HEDIS                                       | HEDIS        | C01: Breast Cancer Screening   | 1.0         |         |         | 65.00%    | 3       |
|   | HEDIS        | C02: Colorectal Cancer Screening                                     | 1.0         |         |         | 66.00%    | 3       |
|   | HEDIS        | C07: Adult BMI Assessment  | 1.0         |         |         | 92.00%    | 4       |
|   | HEDIS        | C09: Care for Older Adults - Medication Review                       | 1.0         |         |         | N/A       | N/A     |
|   | HEDIS        | C10: Care for Older Adults - Functional Status Assessment            | 1.0         |         |         | N/A       | N/A     |
|   | HEDIS        | C11: Care for Older Adults - Pain Assessment                         | 1.0         |         |         | N/A       | N/A     |
|   | HEDIS        | C12: Osteoporosis Management in Women who had a Fracture             | 1.0         |         |         | 30.00%    | 2       |
|   | HEDIS        | C13: Diabetes Care - Eye Exam  | 1.0         |         |         | 60.00%    | 2       |
|   | HEDIS        | C14: Diabetes Care - Kidney Disease Monitoring                       | 1.0         |         |         | 89.00%    | 3       |
|   | HEDIS        | C15: Diabetes Care - Blood Sugar Controlled                          | 3.0         |         |         | 78.00%    | 4       |
|   | HEDIS        | C16: Controlling Blood Pressure                                      | 3.0         |         |         | 72.00%    | 3       |
|   | HEDIS        | C17: Rheumatoid Arthritis Management                                 | 1.0         |         |         | 77.00%    | 3       |
|   | HEDIS        | C21: Plan All-Cause Readmissions                                     | 3.0         |         |         | 10.00%    | 3       |
|   | HEDIS        | C20: Medication Reconciliation Post Discharge                        | 0.0         |         |         | N/A       | N/A     |
| SNP HRA                                     | HEDIS        | TBD: Hospitalizations for Potentially Preventable Complications      | 0.0         |         |         | N/A       | N/A     |
|   | Part C Rptg  | C08: Special Needs Plan (SNP) Care Management                        | 1.0         |         |         | N/A       | N/A     |
| HOS   | HOS          | C04: Improving or Maintaining Physical Health                        | 3.0         |         |         | 71.00%    | 4       |
|   | HOS          | C05: Improving or Maintaining Mental Health                          | 3.0         |         |         | 89.00%    | 5       |
|   | HEDIS / HOS  | C19: Improving Bladder Control                                       | 0.0         |         |         | N/A       | N/A     |
|   | HEDIS / HOS  | C06: Monitoring Physical Activity                                    | 1.0         |         |         | 49.00%    | 3       |
| CAHPS                                       | HEDIS / HOS  | C18: Reducing the Risk of Falling                                    | 1.0         |         |         | 47.00%    | 1       |
|   | CAHPS        | C03: Annual Flu Vaccine  | 1.0         |         |         | 75.00%    | 4       |
|   | CAHPS        | C22: Getting Needed Care   | 1.5         |         |         | 85.00%    | 4       |
|   | CAHPS        | C23: Getting Appointments and Care Quickly                           | 1.5         |         |         | 78.00%    | 4       |
|   | CAHPS        | C24: Customer Service  | 1.5         |         |         | 80.00%    | 1       |
|   | CAHPS        | C25: Rating of Health Care Quality                                   | 1.5         |         |         | 86.00%    | 4       |
|   | CAHPS        | C26: Rating of Health Plan   | 1.5         |         |         | 80.00%    | 2       |
| Complaints                                  | CTM          | C27: Care Coordination   | 1.5         |         |         | 89.00%    | 5       |
|   | CTM          | C28: Complaints about the Health Plan                                | 1.5         |         |         | 0.29      | 3       |
| Appeals                                     | IRE          | C32: Plan Makes Timely Decisions about Appeals                       | 1.5         |         |         | N/A       | N/A     |
|   | IRE          | C33: Reviewing Appeals Decisions                                     | 1.5         |         |         | N/A       | N/A     |
| Disenrollment                               | CMS Admin    | C29: Members Choosing to Leave the Plan                              | 1.5         |         |         | 13.00%    | 4       |
| Compliance                                  | CMS Admin    | C30: Beneficiary Access and Performance Problems                     | 1.0         |         |         | 100       | 5       |
| Call Center                                 | CMS Admin    | C34: Call Center - Foreign Language Interpreter and TTY Availability | 1.5         |         |         | 99.0%     | 5       |
| Improvement                                 | Star Ratings | C31: Health Plan Quality Improvement                                 | 5.0         |         |         | 0.660     | 5       |
| Part C Weighted Star Points:                |              |  |             |         |         |           | 163.00  |
| Part C Weight:                              |              |  |             |         |         |           | 44.50   |
| Part C Summary Rating (Unrounded):          |              |  |             |         |         |           | 3.663   |
| Reward Factor (i-Factor):                   |              |  |             |         |         |           | 0.0     |
| Part C CAI Value:                           |              |  |             |         |         |           |         |
| Adjusted Part C Summary Rating (Unrounded): |              |  |             |         |         |           | 3.663   |
| Adjusted Part C Summary Rating (Rounded):   |              |  |             |         |         |           | 3.50    |
| Part D:                                     |              |  |             |         |         |           |         |
| Clinical Rx                                 | PDE          | TBD: High Risk Medication  | 3.0         |         |         | 8.00%     | 4       |
|   | PDE          | D11: Medication Adherence for Diabetes Medications                   | 3.0         |         |         | 79.00%    | 4       |
|   | PDE          | D12: Medication Adherence for Hypertension (RAS antagonists)         | 3.0         |         |         | 81.00%    | 5       |
|   | PDE          | D13: Medication Adherence for Cholesterol (Statins)                  | 3.0         |         |         | 79.00%    | 5       |
| MTM CMR                                     | Part D Rptg  | D14: MTM Program Completion Rate for CMR                             | 1.0         |         |         | 25.1%     | 2       |
| CAHPS                                       | CAHPS        | D08: Rating of Drug Plan   | 1.5         |         |         | 78.00%    | 1       |
|   | CAHPS        | D09: Getting Needed Prescription Drugs                               | 1.5         |         |         | 89.00%    | 3       |
| Complaints                                  | CTM          | D04: Complaints about the Drug Plan                                  | 1.5         |         |         | 0.29      | 3       |
| Appeals                                     | IRE          | D02: Appeals Auto-Forward  | 1.5         |         |         | 2.50      | 5       |
|   | IRE          | D03: Appeals Upheld  | 1.5         |         |         | N/A       | N/A     |
| Disenrollment                               | CMS Admin    | D05: Members Choosing to Leave the Plan                              | 1.5         |         |         | 13.00%    | 4       |
| Compliance                                  | CMS Admin    | D06: Beneficiary Access and Performance Problems                     | 1.0         |         |         | 100       | 5       |
| Call Center                                 | CMS Admin    | D01: Call Center - Foreign Language Interpreter and TTY Availability | 1.5         |         |         | 98.0%     | 5       |
| MPF   | CMS Admin    | D10: MPF Price Accuracy  | 1.0         |         |         | 99.0      | 4       |
| Improvement                                 | Star Ratings | D07: Drug Plan Quality Improvement                                   | 5.0         |         |         | 0.008     | 3       |
| Part D Weighted Star Points:                |              |  |             |         |         |           | 111.50  |
| Part D Weight:                              |              |  |             |         |         |           | 29.00   |
| Part D Summary Rating (Unrounded):          |              |  |             |         |         |           | 3.845   |
| Reward Factor (i-Factor):                   |              |  |             |         |         |           | 0.0     |
| Part D MA-PD CAI Value:                     |              |  |             |         |         |           |         |
| Adjusted Part D Summary Rating (Unrounded): |              |  |             |         |         |           | 3.845   |
| Adjusted Part D Summary Rating (Rounded):   |              |  |             |         |         |           | 4.00    |
| Overall:                                    |              |  |             | w. C QI | w. D QI | w.o. 2 QI | w. 2 QI |
| Overall Weighted Star Points:               |              |  |             | 244.00  | 234.00  | 219.00    | 259.00  |
| Overall Weight:                             |              |  |             | 64.50   | 64.50   | 59.50     | 69.50   |
| Baseline Overall Rating (Unrounded):        |              |  |             | 3.783   | 3.628   | 3.681     | 3.727   |
| Reward Factor:                              |              |  |             | 0.0     | 0.0     | 0.0       | 0.0     |
| Overall Rating (Unrounded):                 |              |  |             | 3.783   | 3.628   | 3.681     | 3.727   |
| Overall Rating (Held Harmless):             |              |  |             |         |         |           | 3.783   |
| Overall CAI Value:                          |              |  |             |         |         |           |         |
| Final Overall Rating (Unrounded):           |              |  |             |         |         |           | 3.783   |
| Adjusted Overall Rating (Rounded):          |              |  |             |         |         |           | 4.00    |