



Michelle Turano

Vice President, Public Policy and Government Affairs

January 16, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244

RE: CMS-4182-P

To Whom It May Concern:

WellCare Health Plans (WellCare) is pleased to submit the enclosed comments in response to the comment opportunity "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program", released by the Public Inspection Desk on November 16, 2017 and published in the Federal Register on November 28, 2017 by the Centers for Medicare & Medicaid Services (CMS). The page numbers referenced in the below comments correspond to the Public Inspection Desk release.

WellCare Health Plans focuses exclusively on providing government-sponsored managed care services, primarily through Medicaid, Medicare Advantage, and Medicare Prescription Drug Plans, to approximately 4.3 million families, children, seniors, and individuals with complex medical needs. WellCare's vision is to be a leader in government-sponsored healthcare programs in partnership with our members, providers, and government partners. We have a long-standing commitment to our federal and state partners to deliver value, access, quality, cost savings, and budget predictability. It is from this vantage point that we offer these comments.

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

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (page 27)

WellCare supports CMS' implementation plan for the CARA Part D drug management program. Lock-in programs have successfully been used by state Medicaid programs and commercial plans for years. We support the implementation of an equivalent program in the Medicare Prescription Drug Program and support a Part D plan's ability to lock a member into a medication regimen, prescriber, pharmacy or any combination of these.

On page 41, CMS requests comment on its proposed approach to frequently abused drugs. WellCare believes CMS' criteria for defining a frequently abused drug is appropriate, and we



support CMS' decision to place opioids on the frequently abused drug list for plan year 2019. However, there are a number of non-opioid drugs that are frequently abused. WellCare encourages CMS to develop a complimentary system allowing a Part D sponsor to request a Point of Sale edit exception and submit a drug for review that could be put on a "restricted access" drug list. For example, a submission could include a Part D sponsor's own data on abuse in its population and justification as to why the specific drug should be included on the list. These submissions could be evaluated by CMS for validity, and CMS could use the data submitted to grant a submitting Part D sponsor permission to continue the current policy for approved non-opioid medications.

Additionally, we think the criterion CMS is proposing to identify potential opioid overutilization is comprehensive, and the proposed lookback timeframe provides a sufficient time period to identify a pattern. However, we think the additional 6 month waiting period before a Part D sponsor can limit a member's access to coverage of frequently abused drugs, noted on page 83, is unnecessary. A 6 month delay in implementation allows additional opportunities for an adverse event, such as an overdose, to occur when a pattern of inappropriate use was known. For patient safety and program effectiveness, we ask CMS to reconsider the length of the currently proposed waiting period.

CMS requests feedback on Part D sponsors' systems capability to account for group practice prescribers and chain pharmacies. We support CMS' proposal to group pharmacies by chain, and to group prescribers by practice, such as by Taxpayer Identification Numbers (TINs) or another mechanism. It should be noted, however, that this proposal may not be feasible for all Part D sponsors due to data availability. For example, a Medicare Advantage Prescription Drug (MA-PD) plan is able to consolidate prescribers by TIN because the plan directly contracts with a prescriber. For a standalone Part D sponsor, the sponsor would not have access to the TIN number because the sponsor does not contract with the prescriber. We ask CMS to consider not making this grouping mandatory. Rather, we encourage CMS to use it as a mechanism to further streamline the identification process to limit beneficiary and prescriber abrasion.

Before selecting a prescriber or pharmacy for lock-in, a Part D sponsor must notify the prescriber and/or pharmacy that the at-risk beneficiary has been identified for inclusion through a notification. CMS further proposes that Part D sponsors obtain confirmation from the prescriber and pharmacy. WellCare fully supports the need for prescriber involvement in consensus of regimen and prescriber or pharmacy lock-in decisions. However, we do not support the need to alert a pharmacy that a member is locked into their pharmacy. The member, prescriber, and plan sponsor are all aware of the details surrounding the edit per the mandated notices. Upon agreement, a plan sponsor has the ability to implement a point of sale edit, so if a member is seeking to fill a prescription at a pharmacy other than that agreed to, the claim would deny at point of sale. This ability negates the need for a pharmacy to confirm receipt of the at-risk beneficiary. Additionally, we are concerned that mandating pharmacy confirmation would limit beneficiary access, as pharmacies may not want to service members who are identified as being at-risk for opioid abuse due to the stigma surrounding opioid abuse.

CMS provides details around data disclosure and sharing of information between Part D sponsors, specifically when a member changes sponsors. WellCare supports the ability for a Part D sponsor to immediately lock-in a new member coming to the plan on a 322 notification based on plan review of information from the previous Part D sponsor. We request that the guidance does not require, but allows, the immediate lock-in based on member circumstance. If the new Part D sponsor reviews the case of a 322 beneficiary and agrees with the decision, a new notification



should not be necessary. In the event the new Part D sponsor does not find sufficient information to justify the previous plan's lock-in, the new Part D sponsor should reserve the right to work the case through their normal processes.

2. Flexibility in Medicare Advantage Uniformity Requirements (page 106)

The current Medicare Advantage (MA) regulations require plans to offer their plan to all Medicare beneficiaries in a service area with uniform premiums, benefits, and cost sharing for every member. CMS determined it has the authority to allow for flexibility in the uniformity requirement in current Medicare Advantage regulations. We support CMS' determination and the agency's proposal to permit MA organizations to reduce cost sharing for certain covered benefits, offer tailored supplemental benefits, and offer lower deductibles for enrollees meeting specific medical criteria. The ability to build benefit packages designed for certain conditions allows MA plans to innovate their product offerings and provide treatment flexibility to the most vulnerable members. Additionally, permitting flexibility in the uniformity requirement allows members to select a plan tailored to their own unique needs, thereby promoting better health outcomes through the removal of financial barriers to essential care.

On page 108, CMS notes it is "considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits..." In doing so, we ask CMS to consider giving plans more flexibility on the inclusion of supplemental benefits in their plan offerings, particularly for Activities of Daily Living and for other social and necessary support. Medicare Advantage members, especially those who have low incomes, often face struggles beyond their physical health, such as food insecurity. Medicare Advantage plans should be granted greater flexibility in providing benefits and resources to combat these struggles, similar to the benefits offered by Medicaid plans. The option to provide expanded benefits will help address members' social risk factors, which will ultimately lead to improved health outcomes.

3. Segment Benefits Flexibility (page 109)

WellCare supports CMS' proposal to allow MA plan segments to vary by benefits in addition to premium and cost-sharing. A plan's service area may be widespread, and the counties composing that service area often have unique characteristics and geographical differences that may lead to disparate health outcomes. Increasing the flexibility in plan segments allows MA plans to better manage the benefit and design options tailored to specific plan segments.

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (page 109)

On page 112, CMS proposes to amend regulation to establish future maximum out-of-pocket (MOOP) limits based on the most relevant and available data. Additionally, CMS notes that this increased flexibility will allow the agency to annually adjust mandatory and voluntary MOOP limits. While WellCare understands the agency's desire to annually adjust the MOOP limits to ensure the sustainability of the MA program and benefit options, WellCare asks CMS to consider making a change to the MOOP limits only when it is meaningful. The MOOP is a very important figure, especially to members, and its consistency is valuable. To make insignificant changes every year would not be helpful to the members and would make administration of the plans and annual bid



design more challenging. We ask CMS to make changes only when doing so benefits members in a significant and meaningful way.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (page 117)

The current meaningful difference requirement allows CMS to approve a bid only if the benefit package is substantially different from those of other benefit packages offered by the organization in the same service area. This includes differences in premiums, cost sharing, or benefits offered. WellCare supports CMS' proposal to eliminate the existing meaningful difference requirement. Medicare Advantage organizations will now have the ability to design innovative plans and improve plan options without the restriction of meeting the substantially different requirement. As CMS notes on page 123, establishing the necessary difference often requires plans to alter benefits to meet CMS' requirements and not meet members' needs. We agree with CMS' commentary. In designing benefit offerings, there are often complications in effectively calculating meaningful difference. Lifting this limitation would allow plans to put the member at the center of benefit design and offer more innovative products to meet their members' needs. It will also increase competition in the marketplace, leading to a reduction in health care costs.

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (page 126)

WellCare appreciates CMS' proposal to permit default enrollment for Medicaid managed care enrollees who are newly eligible for Medicare. We agree that such a process maintains some level of integration of acute care and coordination of benefits for the beneficiary.

CMS states that under its proposal, an MA organization must obtain approval from CMS before implementing default enrollment. CMS also notes on page 134 that its approval would be granted "only if the applicable state approves the default enrollment through its agreement with the MA organization" and that states can decide if they wish to allow their Medicaid managed care plans to use default enrollment. WellCare asks CMS to encourage transparency in this decision-making process. We encourage the agency to issue additional guidance on suggested criteria states may use in determining whether or not their Medicaid managed care plans and MA plans under the same parent organization can use the default enrollment process. Providing criteria to the states helps ensure a uniform and non-discriminatory process is used in making these determinations.

In its proposal, CMS seeks to include a simplified election for beneficiaries currently enrolled in commercial plans to MA coverage offered by the same organization. WellCare is concerned about a member's transition from a traditional commercial plan into a managed care arrangement. Traditional commercial plans tend to be more open in their provider networks and facility contracting. A commercial member's physicians may not be in the MA plan's network, which could lead to member dissatisfaction. We ask CMS to consider adding additional beneficiary protections for the simplified election process from commercial to MA plan, such as notification on whether or not a beneficiary's primary care physician and specialists are in the MA plan's network.



11. Part D Tiering Exceptions (page 148)

WellCare understands that Part D tiering exceptions provide protection to members and allow them to obtain a drug in a higher-cost tier at a lower cost-share. However, we think tiering exceptions undermine the purpose of Part D sponsors methodically creating tiers for their formularies and should be used in very limited circumstances. A Part D sponsor's formulary undergoes a rigorous review process by CMS and is approved only if it is clinically sound and adheres to current clinical guidelines. Allowing tiering exceptions provides no incentive for a member to try a less expensive medication found on a lower tier if the member can get the more expensive higher-tiered medication at a lower cost. The tiering exception policy also makes it difficult to bid accurately and identify an appropriate cost share. Lastly, we have seen branded manufacturers set up call centers to process tiering exception requests for members when the manufacturer's product is not in a preferred tier. The industry should be working to drive to the lowest net cost for both brands and generics. For the same reason CMS is proposing point of sale rebates, to drive members to lower cost alternatives, Part D sponsors should be able to construct a sound formulary that meets the needs of their members.

8. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (page 158)

Current regulations allow eligible beneficiaries to make Part D enrollment changes throughout the year. CMS is proposing that eligible beneficiaries only be able to use the SEP once per year, but may utilize the SEP under other limited circumstances, such as a change in Medicaid or low income subsidy (LIS) status. WellCare asks CMS to clarify the validation process for the SEP election. Specifically, we ask CMS to provide guidance on which entity, the plan or CMS, is responsible for validating the SEP. Operational challenges may exist with a plan or a broker being able to validate SEP at the time of enrollment. For example, upon enrolling a dually eligible member into a plan, a broker would need information on whether or not that individual utilized her/her SEP. We ask CMS how such information would be made available. We also ask CMS to ensure accurate recording of the rationale for the SEP.

On page 167, CMS specifically requests stakeholder feedback on the best ways to educate the affected population and other stakeholders. Television advertisements are the most effective way to reach a mass of people. Direct mail could be beneficial; however, success rates vary with this population due to the amount of individuals who have temporary addresses. WellCare also suggests that CMS educate sales agents, providers and community partners, as they will have more regular interactions with the affected population.

10. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

Background (page 170)

CMS seeks stakeholder feedback on a selection of topics, including the inclusion of survey measures of physician experiences. WellCare is apprehensive of CMS developing a survey tool for collecting information on health and drug plan services for a number of reasons. First, we think the Star Ratings System should focus on the member and his/her experiences and health outcomes and not on the provider. Second, we are not confident that a physician will be able to distinguish one health plan from another in order to accurately complete a survey. If future Star measures will be based on collected survey data, we are concerned that the data may be



incomplete or unreliable. We ask CMS to reconsider surveying physicians and instead focus on new measures, health outcomes, and the member.

Contract Ratings (page 184)

CMS is exploring the feasibility of separately reporting quality data for individual dual special needs plan (D-SNP) plan benefit packages (PBPs), but notes that for a number of measures the data may not be able to be reliably reported. This would lead to Medicare Plan Finder displaying the plan as “too small to be rated.” WellCare appreciates CMS’ consideration of reporting separate Star scores for different PBPs, and we agree that reporting at the individual D-SNP PBP level may pose some challenges. However, it is not uncommon for an MA plan to have many PBP offerings, including various D-SNP PBPs. We ask CMS to consider the feasibility of reporting all of a contract’s D-SNP PBPs collectively for quality purposes. This would separate a plan’s D-SNPs from its non D-SNPs and report quality data for plan types as opposed to individual PBPs. Collectively reporting a contract’s D-SNP PBPs would increase the sample size for those contracts that offer multiple D-SNP PBPs and may alleviate some of the inherent challenges with small scale reporting.

On page 187, CMS specifically requests comments on reporting at different levels for different measures such as the parent organization, contract, plan, or geographic area. We agree with CMS that data reporting at a higher level could ease and simplify existing data collection and reporting. Specifically, WellCare asks CMS to consider measuring the Part C Plan Makes Timely Decisions about Appeals measure, the Part C Reviewing Appeals Decisions measure, and the Part C and Part D Call Center- Foreign Language Interpreter and TTY Availability measures at the parent level. For the appeals measures, collecting data at the parent level would increase the sample size and lead to increased statistical validity. CMS notes, and we agree, that parent organizations “use a consolidated call center to serve all contracts and plans.” We appreciate CMS’ seeking to simplify reporting and ease the administrative burden of collecting data on Star Ratings measures.

Contract Consolidations (page 187)

WellCare asks CMS to clarify the effective date of the contract consolidations proposal. In the *Basis, Purpose, and Applicability of the Quality Star Ratings System* section on page 177, CMS states “data will be collected and performance will be measured using these proposed rules and regulations for the 2019 measurement period.” We ask CMS to provide additional clarification on the timing of when consolidated contracts will begin to be assigned star scores based on the enrollment weighted mean. Specifically, we ask CMS to clarify the earliest plan year during which the enrollment weighted means policy will initiate.

Adding, Updating, and Removing Measures (page 196)

CMS is proposing new processes for adding, updating, and removing measures. CMS also proposes that it may develop its own measures to evaluate and reflect performance in the Medicare program. If CMS does decide to develop its own measures for use in the Star Ratings program, WellCare asks that all CMS developed measures undergo the same rigorous processes as those measures developed by other measure stewards such as the Pharmacy Quality Alliance



(PQA) or the National Committee for Quality Assurance (NCQA). Aligning the review processes, including reliability and validity testing ensures that the measure is statistically sound. We also recommend CMS- developed measures undergo the measure endorsement process conducted by the National Quality Forum (NQF).

On page 201, CMS notes that new performance measures would “initially be incorporated into the display page for at least 2 years...” WellCare appreciates CMS’ proposal to add consistency to the amount of time a new measure remains on display. However, we ask CMS to consider increasing the amount of time new measures remain on display to at least 3 years. Given the performance cycle, by the time a plan receives the results of the first year of display, the measure is ready to be incorporated into the Star Ratings. Keeping new measures on display for at least 3 years allows plans to establish a baseline for the measure and understand how they compare to their peers. Additionally, the 3 year timeframe allows for plans to develop internal processes for quality measurement and improvement, which will lead to improved health outcomes for beneficiaries.

Improvement Measures (page 217)

CMS seeks comment on the methodology for the improvement measures, including the hold harmless provision for individual measures. WellCare supports CMS’ special rule proposal “to hold harmless sponsoring organizations that have a 5-star rating for both years on a measure used for the improvement measure calculation.” Once a plan reaches a 5-star rating on an individual measure, improving is difficult. A plan’s measure score may decrease, but the plan may still receive a 5 star on the particular measure. We agree with CMS’ rationale that a hold harmless provision should be in place to prevent a measure rating of 5 stars from lowering a contract’s improvement measure when the contract still demonstrates high performance.

WellCare supports CMS’ proposal for using two separate clustering algorithms for determining the improvement measure score cut points. On page 218, CMS proposes that “improvement measure scores of zero and above would use the clustering algorithm to determine the cut points for the Star Rating levels of 3 and above.” WellCare agrees with CMS’ methodology. If a plan does not improve or does not decline, the plan should not be penalized. This aligns with CMS’ guiding principles for the Star Ratings and ensures that the methodology minimizes the risk of misclassification.

Measure-Level Star Ratings (page 229)

In the “Announcement of Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter” released on April 6, 2015, CMS eliminated the pre-determined 4-star thresholds. In its rationale, CMS stated that removing the thresholds will “improve the accuracy of the assignment of overall Part C and D summary star ratings and to make certain the system creates incentives for quality improvement.” CMS again seeks comments on the publication of pre-determined 4-star thresholds.

Since the removal of the pre-determined 4-star thresholds, there has been volatility in the cut points for Star Ratings measures due to plan outliers and use of the clustering methodology. The variations in cut points are difficult for MA plans to manage, as quality improvement efforts are more easily designed and more effectively implemented with defined goals, such as a predetermined cut point. WellCare encourages CMS to revisit the pre-determination of the 4-star thresholds. Specifically, CMS should establish a minimum threshold which, if a plan meets,



guarantees that it will get at least 4 stars but could possibly receive a higher score based on how all plans cluster. This methodology gives plans a defined target upon which to focus quality improvement efforts, allows for natural variability in performance, and gives CMS the discretion to positively adjust the star score based on outliers and clustering.

However, if CMS does not reinstate the pre-determined 4-star thresholds, we ask CMS to remove the plan outliers from the calculation of cut points. Outliers have the ability to dramatically impact the data and contribute to skewed thresholds. Removing outliers eliminates their impact and would serve to minimize year-to-year volatility in cut points.

Additionally, WellCare asks CMS to examine the necessity of an individual measure when the overwhelming majority of plans are successfully reaching percentages in the high 90s. For a number of measures, such as the Adult BMI Assessment, the threshold differences between star scores are getting closer and closer. Because of the minimal difference in cut points, the star scores are not accurate measures of performance because the vast majority of plans are doing well. Plans with an insignificant difference in performance are being penalized, and the measure is not reflecting true performance. We ask CMS to consider removing these measures from the calculation of Star Ratings and moving them to the display page for informational purposes only.

Measure Weights (page 240)

On page 242, CMS states it is considering increasing the weight of the patient experience/complaints and access measures. If CMS were to increase the weight, it notes that it is considering “increasing it from a weight of 1.0 to between 1.5 and 3.” WellCare asks CMS to clarify its proposal and specifically the proposed change in weight. On the 2018 Part C & D Star Ratings Measures list available at cms.gov, the weight listed for patient experience/complaints and access measures is 1.5. WellCare feels this weighting is appropriate. The measure weighting of 3 should be reserved for clinical outcome measures only.

Categorical Adjustment Index (page 249)

In 2016, CMS implemented the Categorical Adjustment Index (CAI) as an interim analytical adjustment to address the low income subsidy/dual eligible (LIS/DE) and disability effect. The research which drove the adjustment, entitled “Examining the Potential Effects of Socioeconomic Factors on Star Ratings,” released on September 8, 2015, stated that the analysis included “a total of 16 clinical measures.” In the initial CAI proposal, CMS moved forward with adjustments on six MA-only and MA-PD plans, and one additional measure for MA-PDs and PDPs. CMS stated that “the measures selected for adjustment were determined by our research and include the measures that had the greatest differences in outcomes between LIS/DE and/or disability beneficiaries and non-LIS/DE and/or non-Disabled beneficiaries within the same contracts.” WellCare asks CMS to provide additional detail around their selection of measures; specifically what metrics were used to decide what measures had “the greatest differences.” Providing this detail aligns with CMS’ guiding principle of developing methodology that is transparent. Releasing the details of the methodology and measure selection criteria will invite multi-stakeholder input on how to adjust for low SES and other social risk factors, as desired by the agency. Further, we ask CMS to annually reexamine which measures are included in the CAI and release the results of their findings,

Additionally, WellCare encourages CMS to re-examine the impact of adjustment on all measures, process, intermediate outcome, outcome, and administrative to determine where any differences in



performance based on low income and disability status exist, as we believe there may be additional measures that are affected by population differences that may not have been included in the September 8, 2015 analysis and subsequently, not included in the CAI adjustment. Additionally, WellCare asks CMS to provide additional detail regarding selection of the Medication Adherence for Hypertension for adjustment in the MA-PD and PDP contracts while not providing an adjustment on the other two medication adherence measures. In our experience, members do not selectively choose which medications to which they will adhere. We are interested in the data differentials between the three Medication Adherence measures, and the rationale for selecting only one of the three measures for adjustment.

Despite the interim adjustment, more meaningful adjustments are needed to appropriately account for the challenges plans undertake when serving the dual eligible, LIS, and disabled populations. WellCare continues to believe that population differences among beneficiaries contribute to differences in performance on quality measures, and the Assistance Secretary for Planning and Evaluation (ASPE) study, released on December 21, 2016, only confirmed this belief. In its report, ASPE researchers found that beneficiaries with social risk factors had worse outcomes on many quality measures, regardless of the providers they saw, and dual enrollment status was the most powerful predictor of poor outcomes. ASPE also found that beneficiaries with social risk factors had poorer outcomes on all forms of quality measures, including process measures, clinical outcome measures, safety, and patient experience measures. These differences are not currently accounted for in an adequate way under the CAI, and we think there is more research that could be done to help identify possibilities for a longer term solution.

For example, CMS could conduct a study examining differences in clustering between similarly situated plans, based on similar percentages of dual and/or disability, in cut point determination. If this study indicated that higher percentage plans performed better on certain measures as evidenced by higher cut points than lower percentage plans, those lower percentage plans could benefit from a positive adjustment. Conducting an initial study examining performance differences between plans serving various populations would provide a preliminary analysis upon which plans and other stakeholders could provide feedback. Determining a long term solution to the inequities in the Star Ratings methodology must be a collaborative effort among all types of plans.

13. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (page 262)

Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy (page 266)

There is great variance in the delivery and practice of specialty pharmacies. Collaborations between specialty pharmacies, retail settings, hospitals, and manufacturers are becoming increasingly commonplace. The scope of a specialty pharmacy is very broad, and while we acknowledge CMS' reluctance to propose a definition of specialty pharmacy at this time, we encourage CMS to consider defining specialty pharmacy in future rulemaking. The Academy of Managed Care Pharmacy and the Specialty Pharmacy Association of America both recently published definitions of specialty pharmacy. Similarities seen within these definitions include the distribution of specialty pharmaceuticals and high-touch, patient-centered management that maximally benefits the patient's medication experience. WellCare urges CMS to consider reviewing these definitions, examining the scope of the specialty pharmacy practice, and drafting a definition for comment in future rulemaking.

Timing of Contracting Requirements (page 276)

On page 277, CMS proposes to require that “Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request.” WellCare asks CMS to reconsider the two day deadline, as this is often a coordinated effort with a pharmacy benefit manager (PBM) partner. We suggest a time frame of at least 5 days, which provides ample time for the coordinated efforts.

14. Changes to the Days’ Supply Required by the Part D Transition Process

WellCare supports CMS’ proposal to shorten the required transition days’ supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. Aligning the requirements provides uniformity across settings.

15. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (page 282)

We support this update and agree that the proposed provisions would provide for more formulary flexibility. Generic drugs are clinically equivalent to brand name drugs; they contain the same active ingredient(s), are of the same dosage form, have the same route of administration, are identical in strength or concentration, and are expected to have the same effect and safety profile when administered to patients according to the labeling. The proposal aligns Medicare Part D with current Medicaid and commercial insurance guidance and provides consistency in various programs.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (page 296)

WellCare supports the treatment of follow-on biological products as generics and supports CMS’ revised definition of generic drug to include follow-on biological products for purposes of cost-sharing. We recognize that follow-on biologic products are similar to, but not the same as, the innovator drug, and we are encouraged by CMS’ inclusion of these products into the definition of generics for this limited purpose. Follow-on biologics, like generics, should be encouraged as a substitute for brand drugs, and we support CMS’ proposed policy changes.

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Difference (page 300)

Current regulations allow for a Medicare Advantage sponsor to offer an enhanced alternative plan that is meaningfully different from the basic plan by providing additional value to beneficiaries in the form of reduced deductibles or reduced copays. In an effort to increase beneficiary choice, CMS is proposing to eliminate the requirement that one enhanced alternative plan be meaningfully different from another enhanced alternative plan offered by the same sponsor. CMS specifically notes that it will be “maintaining the requirement that enhanced plans be meaningfully different from the basic plan.” We ask CMS to reconsider the meaningful difference requirement between the basic plan and the enhanced plan. Relaxing the requirements allows plan sponsors to create different plan types with different benefit offerings, thus increasing choice for members.



B. Improving the CMS Customer Experience

2. Reducing the Burden of the Compliance Program Training Requirements (page 343)

WellCare supports CMS' proposal to reduce the burden of compliance program training requirements and deletion of regulatory provisions that require use of CMS-developed training. We appreciate the recognition of the industry's proactive approach to compliance training and agree that this proposal gives plans flexibility in their compliance program design and administration. We ask CMS to ensure timely notification of any changes in compliance training requirements so plans have ample time to build and deliver updated training.

4. Revisions to Timing and Method of Disclosure Requirement (page 350)

We support CMS' proposal to require MA plans and Part D sponsors to provide the Evidence of Coverage (EOC), provider directory, pharmacy directory, and formulary by the first day of the annual enrollment period, rather than 15 days before. Postponing the delivery of these materials by 15 days gives plans extra time to provide the most accurate information to members. The Annual Notice of Coverage (ANOC) and EOC are massive documents in size and scope. Members often find their receipt overwhelming and confusing, and therefore may not even review them. Providing two separate mailings to members will likely increase utilization of the documents. We also ask CMS to consider including supplemental mailings alongside the Annual Notice of Coverage (ANOC). Including a summarized version of the ANOC, written at the CMS standard 6th grade reading level, would likely increase a member's comprehension and utilization of the document. This summarized version would include high-level topics such as coverage and premiums as well as any changes to the plan's benefits or network. This would serve as an easy reference guide for the member to navigate his/her plan's benefits.

CMS also proposes to give plans more flexibility to provide the materials electronically. WellCare supports CMS' proposal to provide plans greater flexibility to provide documents in electronic format and make them available in hard copy upon request. We agree with CMS that electronic documents include many advantages over hard copy, including the ability to word search or magnify text. Providing documents in an electronic format not only reduces burden on plans, but it provides members with the ability to choose a format that best suits their needs.

5. Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities (page 357)

WellCare supports CMS' proposal to distinguish communication materials from marketing materials. We agree that these materials serve different purposes and therefore should be subject to different requirements. With the proposed definitions and differing regulatory requirements, we ask CMS to maintain current requirements of the File & Use and standard template process for marketing materials. We also seek clarification on how the refinement and reclassification of marketing materials will impact the calculation of the File & Use percentage, as various model materials are proposed to be removed from the File & Use category.



6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (page 372)

WellCare supports CMS' proposal to lengthen the adjudication timeframe from 7 calendar days to 14 calendar days. We ask CMS to clarify if the issuing of payment is included in the 14 days or if Part D sponsors would still have 30 days to process.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (page 374)

The proposed rule states that the IRE would be responsible for notifying a member that the IRE has received and will be reviewing a member's case. WellCare supports this change, and we agree that a plan issuing a notice is "duplicative and nonessential." WellCare asks CMS to consider setting a timeframe by which the IRE must acknowledge receipt of a member's case. In the EOC, members are given a timeframe in which they should expect a response from their plan. If the IRE takes too long to acknowledge receipt of a member's case, it will likely generate a call to the plan and possibly a complaint against the plan, resulting in a higher CTM rate. We ask CMS to ensure the IRE acknowledges receipt of a member's case promptly, within 5 days of receipt.

9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (page 384)

WellCare supports CMS' proposal to reduce the past performance review period from 14 months to 12 months. We agree with those commenters suggesting that "some non-compliance is 'double counted' based solely on the timing." Additionally, we suggest that CMS move to the 12 month review cycle beginning with the spring 2018 rating release, which is used to evaluate plan applications during the 2019 application cycle. This would allow the intended changes to be in effect for the 2019 application cycle rather than postponing the benefit of the change to the 2020 application.

10. Preclusion List- Part D Provisions (page 386)

WellCare supports CMS' targeted approach to Part D prescribers. We are specifically supportive of CMS' revision to focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers rather than requiring enrollment of Part D prescribers into Medicare. This targeted approach achieves an appropriate balance between burden reduction and beneficiary protection.

CMS details a process by which a prescriber may be added to a CMS preclusion list. Currently, the Office of the Inspector General (OIG) has the authority to exclude individuals and entities from federally funded health care programs and maintains a list of all currently excluded individuals and entities called the List of Excluded Individuals/Entities (LEIE). The OIG LEIE list has its own application process for reinstatement, and the OIG has authority to waive an individual's inclusion on this list. WellCare asks CMS to provide guidance on how the OIG exclusion list will work with the CMS preclusion list. Specifically, we ask CMS to clarify whether the CMS preclusion list will be independent of the LEIE, or if the LEIE will be incorporated by reference. We also ask CMS to clarify whether the process for reinstatement and waiver applications will be identical for the two lists.



On page 400, CMS seeks comment on a reasonable time period for Part D sponsors and PBMs to incorporate the preclusion list into claims adjudication systems. WellCare suggests an initial implementation date of at least 180 days. This would give Part D sponsors and PBM sufficient time to prepare their systems and operationalize the changes. After the initial incorporation, we encourage CMS to post the preclusion list by the 15th of every month and require Part D sponsors to utilize the list beginning on the first day of the following month.

Under the provisional coverage section, CMS seeks comment on limits and guardrails it should set with respect to doses for opioid prescriptions. WellCare agrees that members need access to their medications, including opioids; however, we think CMS should manage the opioid epidemic outside these proposed provisions. Creating separate policies for opioid and non-opioid medications is extremely burdensome. It introduces additional and unnecessary complexities into a new process when there are already better clinical programs in place to manage this crisis. We encourage CMS to issue uniform regulations regarding provisional fills and utilize Part D sponsors' clinical programs to combat the opioid epidemic.

WellCare agrees with CMS that individuals who are on the preclusion list should be permitted to appeal their inclusion on the list, and we support CMS' proposed approach. However, WellCare asks CMS to issue additional operational guidance on the appeals process. Specifically, we ask CMS to provide additional detail on the communication that a prescriber's appeal was successful and timeline for removal from the preclusion list.

11. Preclusion List- Part C/Medicare Advantage Cost Plan and PACE Provisions (page 411)

WellCare supports CMS' decision to utilize the same preclusion list concept in Medicare Advantage. We reiterate our above comments, specifically the request for additional guidance on the OIG LEIE list's functionality with the CMS preclusion list and the communications around appeals outcomes.

12. Removal of Quality Improvement Project for Medicare Advantage Organizations (page 438)

We support CMS' proposal to remove the Quality Improvement Project (QIP) from regulation. CMS notes, and we agree, that many QIPs are duplicative of individual MA organization's efforts to meet their own plan needs, including an internal focus on the Medicare Advantage Star Ratings System. As an NCQA accredited organization, WellCare maintains robust internal quality improvement programs and pilots targeted quality initiatives. We appreciate CMS' recognition of the various redundancies in programs and reporting, and remain committed to ensuring our members receive the highest quality of care.

13. Reducing Provider Burden- Comment Solicitation (page 442)

In this section, CMS is exploring ways to reduce the burden on providers arising from requests for medical record documentation by MA plans. WellCare appreciates CMS' interest in this topic, and we respectfully submit our feedback on the below issues of interest identified by CMS.

The nature and extent of medical record requests, including the following:

- Reasoning behind the request sent by the MA organization to the provider.

- The reasoning behind the request varies greatly. WellCare requests medical records to determine medical necessity for an appeal, for prior authorization purposes, to determine the medical necessity of an Emergency Department visit, among others.
- WellCare's quality improvement department requests medical records for three initiatives annually: Healthcare Effectiveness Data and Information Set (HEDIS) to fulfill the mandatory reporting requirement by CMS and NCQA; Ambulatory Medical Record Review (AMRR), an internal compliance requirement that reviews files for general medical record keeping practices, adherence to selected preventive care guidelines, and coordination and continuity of care between primary care providers (PCPs) and specialists; and Potential Quality of Care (PQOC) to determine if there is a confirmed quality of care issue.
- Risk Adjustment Payment System (RAPS) requests records to ensure complete and accurate reporting of diagnosis codes to CMS. Typically, providers only submit four diagnoses and/or do not report all diagnosis that impacted medical decision making during a visit.
- Amount of time afforded to providers to respond to such requests.
 - For the quality improvement initiatives, providers have 10 business days to respond to HEDIS requests, 7 business days to respond to AMRR requests, and 7 business days to respond to PQOC requests.
 - RAPS requests are made in June with a final due date in December.
- Frequency of requests for providers to submit medical records.
 - For the quality improvement initiatives, WellCare requests records for HEDIS annually, from February through May. This timeline is dictated by NCQA. For AMRR, our internal timeline for requests is annual, from August through December. The PQOC requests are ad hoc and vary in frequency.
 - RAPS requests are made annually.
- Volume of medical records in a given request.
 - Appeals documents average 41 pages per submission.
 - PLP documents average 26 pages per submission.
 - The volume of requests for our quality improvement initiatives vary. For HEDIS, the volume varies by members that fall into the particular requested measures and the provider's panel size. We could request as few as one member or as many as 100. The AMRR maintains a rule of 10 charts, and we request one file for PQOC.
 - RAPS requests are significantly large.
- Method of collection and submission of medical records.
 - The primary method of collection for quality initiative requests is in paper form via a PO Box delivery. However, we also collect medical records via fax, on-site retrieval, or plan access to electronic medical records for an electronic pull.
 - RAPS data is collected on-site, by fax, mail, secure portal, or remote access.

- How narrowly or broadly the requests are framed (for example, whether the request is for a single visit, a specific condition, and for what timeframe).
 - HEDIS data is requested for a single measurement year. For example, HEDIS 2017 data requests were for care rendered in 2016. HEDIS conducts a retrospective review process. The AMRR requests are similar to that of HEDIS. It is also a retrospective review. PQOC requests are targeted and seek records for the episode of care in question.
 - RAPS record requests span an entire year, which is the date of service collection period.
- Extent to which requests are made pursuant to a CMS-conducted RADV audit, other CMS activities, or for other purposes (please specify what the other purposes are).
 - HEDIS requests are a CMS requirement.
 - RAPS data is for CMS.
- Considerations that may be unique to solo providers.
 - Solo providers often have limited office staff to pull requested records. In such instances, we would offer to travel to the offices to retrieve the requested files.
 - Every health plan is collecting HEDIS records during the same time period. The continual request for records places an administrative burden on smaller practices, particularly solo practitioners.
- Impact on burden due to increased adoption of electronic health record systems.
 - The increased adoption of electronic health record systems improves the readability of files. It also allows providers to conduct a search in order to pull files.
- Specific examples of medical record requests (for example, anecdotes and/or the requests themselves, appropriately redacted of confidential information and PII/PHI).
 - Please see examples following the conclusion of our comments.

The nature and extent of requests related to medical record attestations, including the following:

- Reasoning behind the attestation request.
 - Attestations are required for RADV audits.
- Amount of time afforded to providers to respond to such requests.
 - The time afforded for RADV audits is limited to one week.
- Frequency of requests for providers to sign attestations.
 - The frequency varies based on whether or not we are undergoing a RADV audit.
- Volume of requests.
 - The volume for a RADV audit is roughly 15% of medical record requests.
- Level and duration for which attestations are requested (for example, for each medical record, for all medical records for a beneficiary for a particular date of service or for a particular year).

- Attestations are requested for the date of a specific service.
- Whether there is reduced burden associated with electronic signatures.
 - Electronic signatures increase the burden, as typically electronic signatures do not include the date of the signature, which is needed in RADV attestations.
- Specific examples of medical record attestations and attestation requests.
 - Please see examples following the conclusion of our comments.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (page 446)

WellCare supports CMS' proposals to change the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. Medicare Advantage organizations should be incentivized to implement programs and increase efforts to combat fraud. These efforts ultimately achieve savings in the Medicare program. We agree with CMS' rationale for the proposal, and support the agency's decision.

In an effort to reduce reporting burden, CMS is proposing regulatory changes to the reporting requirements. Current reporting requirements include a 3 page template with multiple sections and subsections. WellCare asks CMS to confirm that the only data that will need to be reported are the three data fields included in the chart on page 456. If so, WellCare is concerned that such a drastic reduction in reporting will increase the burden on audits on both CMS and Medicare Advantage plans regarding data quality. We ask CMS to issue guidance on how the agency will facilitate the current desk review in light of the proposed changes.

Conclusion

WellCare appreciates the opportunity to provide comments on these important policy issues and to partner with CMS. If your staff would like further detail on any of our recommendations, please feel free to contact me at (813) 206-5606. Thank you for your consideration.

Sincerely,



Michelle Turano