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

RE: CY2019 Proposed Policy and Technical Changes to the Medicare Advantage Program CMS-4182-P

Dear Administrator Verma:

Centene Corporation appreciates the opportunity to provide feedback on CMS' Proposed Rule: *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*, published November 16, 2017.

Founded in 1984, Centene Corporation (hereinafter "Centene") has established itself as a national leader in the healthcare services field with over 12.2 million members across the country. Centene provides health plans through Medicaid, Medicare, and the Health Insurance Marketplace and other Health Solutions through our specialty services companies. Centene covers 243,000 Medicare Advantage (including Special Needs Plan) beneficiaries across 13 states, and 48,000 Medicare-Medicaid Plan (MMP) beneficiaries. For 2018, we have expanded our footprint into six additional states.

INTRODUCTORY COMMENTS

Before presenting detailed comments, Centene would like to highlight some specific important areas, some of which are directly related to the proposed rule while others are broader, but would benefit the Medicare Advantage and Part D program as well:

- In the Medicare program, as well as in other areas, Centene has prided itself at providing health care access to the most vulnerable populations of our country, with focus on meeting the needs of our members with high-quality and affordable coverage. Our experience with these populations helps us to see the diversity of these individuals and the importance of tailored interventions that optimize both medical care as well as social determinates of health. We have highlighted areas where we see positive regulatory changes or possible refinements related to serving vulnerable individuals—including where additional regulatory flexibility could directly benefit care to our members.

- As it specifically concerns the dual-eligible population, this population particularly benefits the most from the enhanced care management and coordination associated with managed care. While CMS continues to make advancements in aligning Medicaid and Medicare through Special Needs Plans (SNPs) and the Financial Alignment Demonstrations, more can still be done to improve alignment and ensure that the incentive structure is

such that plans are not penalized for serving a disproportionate share of high-needs, high-cost populations. In addition, the program must provide the necessary flexibility, so plans can meet beneficiaries' needs in a way that leads to better outcomes long-term. Centene has included several comments to the proposed rules that would address some of the existing issues and we look forward to working with CMS in the coming years to further improve the way in which public programs serve vulnerable populations.

- We are supportive of CMS' efforts to continue to refine the Star Ratings and encourage CMS to advance its efforts to reflect population differences among MCOs, in particular as it relates to accounting for low-income and dual eligible beneficiaries (although we suggest continued work in this area); enhance the overall reliability of measures included in the Star Ratings and on the display page; and look, where possible, to reduce the overall quality reporting burden on plans by reconciling duplicative and overlapping measures. Additionally, consistent with CMS' past comments in the MA and Part D Call Letter and Payment Notice, Centene believes strongly that Star Ratings should be based on the most up to date information possible and operate under guidelines grounded in the ultimate goal of providing accurate and helpful information to beneficiaries relevant to their plan selection. To this end we encourage CMS to take immediate steps to remove the impact of audit findings on star measures particularly as it relates to the quality bonus calculation, including the QBP calculation for 2019 payment year and going forward. CMS has already recognized that the audit findings may not be appropriate to include in the quality measures and that any adjustments related to enforcement actions should reflect the magnitude of the audit issue. Consistent with these policies, and CMS' existing policy related to sanctioned plans, we recommend CMS remove CMP deductions from the BAPP calculation so plans are not penalized in the current/future year for a policy that is now in question.

- We are appreciative of CMS' willingness to provide additional flexibility as it relates to tailoring benefit design under the uniformity requirements in the Part C program. This will allow us to design benefit packages that better meet the needs of individuals with chronic conditions, rather than continuing to use a "one size fits all" approach. With that said, we have several recommendations as to how this proposed policy could be further amended to benefit even more Medicare Advantage beneficiaries, including allowing plans to tailor benefits based on LIS-status and extending the flexibility to the Part D program.

- Additionally, as CMS works to refine its compliance activities with plans, we encourage CMS to do this in consideration of the President's orders around reducing regulatory burden. We look forward to being a productive stakeholder with CMS as it continually assesses how to maintain effective and efficient oversight functions to protect Medicare Advantage beneficiaries.

- Finally, as CMS undertakes efforts to reduce regulatory burden, we also encourage the issue of developing a common regulatory framework across federal health programs and within the same program (e.g., common framework amongst PACE, SNPs, etc.) to ensure they receive equal attention and are on a level playing field. Often Medicare beneficiaries are covered not just by Medicare, but Medicaid and/or a state LTSS program. In many instances, these programs have inconsistent or conflicting requirements, such that reducing regulatory burden in one program may not have the desired outcome as compliance is still required with the overlapping provision in another program. Where possible, we encourage CMS to build off many of the proposed changes in this rule and create needed alignment with other federal health programs.

Our specific comments are organized in the order that issues appear in the proposed rule:

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

Implementation of the Comprehensive Addiction and Recovery Act (CARA)

A.1.c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS

CMS proposes to codify current policies, with some modifications, for retrospective Drug Utilization Reviews (DUR) and the Opioid Monitoring System (OMS). CMS also proposes detailed rules that implement the option under CARA for Part D plans to limit coverage of frequently abused drugs for those determined to be at risk of misuse or abuse to selected prescribers, pharmacies, or both.

Centene supports CMSs approach; however, we have several recommendations to ensure that the finalized policy protects Medicare beneficiaries from misuse or abuse of opioids while retaining access to pain medications, reduces the burden placed on sponsors in administering such programs, and ensures the integrity of the Part D program.

A.1.c.(2). Proposed Requirements for Part D Drug Management Programs (§§ 423.100 and 423.153)

As part of its implementation of the CARA legislation, CMS proposes definitions for "Potential At-Risk Beneficiary", "At-Risk Beneficiary", "Frequently Abused Drug", "Clinical Guidelines", "Program Size," and "Exempted Beneficiary". Additionally, CMS also proposes to define elements and requirements of Drug Management Programs for purposes of implementation including policies and procedures, case management and clinical contact requirements, allowed coverage limitations, requirements for limiting access, and beneficiary notice.

Frequently Abused Drug

The Proposed Rule limits the 2019 designation of frequently abused drugs to opioids, except for buprenorphine when used as a medication-assisted treatment for opioid addition.

Centene recommends that CMS continue to review evidence around the use of high-risk medications (e.g. hypnotic-sedative and muscle relaxants) in conjunction with opioids and update the drugs designated as frequently abused drugs when appropriate.

Exempted Beneficiaries

The Proposed Rule exempts certain beneficiaries—those electing to receive hospice care, residents of certain facilities, and patients with a cancer diagnosis—from being designated at-risk beneficiaries.

Centene does not recommend that CMS exempt people in Assisted Living Facilities (ALFs), group homes, and adult day care (ADC) from an "at-risk" designation. Even though medication is supervised in these settings (and in LTC facilities), there have been documented cases of abuse where people in these settings have been given high doses to make them more docile or "easier to care for." If a beneficiary is going to ADC for only a few days a week, furthermore, their medications may not be supervised. For these reasons, Centene recommends the "at-risk" designation and exemptions to this designation be based on prescribing patterns and particular diagnoses (e.g. cancer or end-of-life) rather than on an individual's specific location or setting.

Case Management, Clinical Contact, & Prescriber Verification

The Proposed Rule requires clinical staff to contact prescribers to verify that a potentially at-risk beneficiary is in fact at-risk.

Centene believes that the expectation of three prescriber outreach attempts by phone after a written attempt is burdensome and unnecessary. We ask that CMS consider a potentially less burdensome approach (e.g., two prescriber outreaches).

Limitations on Access to Coverage for Frequently Abused Drugs

CMS proposes providing Part D plan sponsors with the option to use point of sale edits and prescriber and/or pharmacy lock-in programs as part of the broader national strategy to stem the misuse and abuse of opioids.

Centene supports this approach, but has concerns with the proposal to prohibit the use of prescriber lock-ins until at least six months after the beneficiary was first identified as a potential at-risk beneficiary in an OMS report. We recognize CMS expects prescriber lock-in to be implemented as a last resort after other options are exhausted. However, each situation is unique, and facts and circumstances may clearly indicate that other options are clearly not sufficient. We recommend that a shorter waiting period be used instead (i.e., one to three months). This would provide sponsors with more flexibility in structuring beneficiary protections against misuse or abuse of opioids.

Beneficiary Preferences

The Proposed Rule provides that a sponsor must select a network prescriber and pharmacy in accordance with an at-risk beneficiary's preference.

Centene supports reasonable rules that honor beneficiary preferences. However, we find the beneficiary's unlimited opportunity to change preferences for prescribers and pharmacies to be problematic and burdensome. Centene recommends that CMS place a limit – such as once per year – on the number of times a preference change can be made. We also suggest that CMS consider requiring an at-risk beneficiary provide a reasonable rationale for a prescriber change.

Chain Pharmacies and Group Practices

For purposes of determining whether an individual is an at-risk beneficiary due to use of multiple pharmacies or prescribers, the Proposed Rule treats pharmacies with multiple locations as a single pharmacy if they share real-time electronic data. In addition, prescribers in a group practice using a shared tax identification number (TIN) are considered a single prescriber.

Centene supports the concept of treating chain pharmacies and group practices as single entities where appropriate. However, we understand that sponsors and their contracted pharmacy benefit managers (PBMs) often do not have

access to prescriber TINs as they are absent from pharmacy submitted claims. We recommend that CMS re-evaluate the proposed policy of using TINs and offer another more feasible option for those with difficulties in obtaining and working with TINs. We also recommend that CMS re-evaluate their policy for determining chain pharmacies, as identification of which pharmacies share real-time data may be difficult in many situations; additionally, even with the presence of real-time electronic data, different locations may be staffed with different pharmacists who do not take the same approach to evaluating prescription appropriateness.

Termination of a Beneficiary's Potential At-Risk or At-Risk Status

The Proposed Rule provides that a beneficiary's at-risk identification terminates after 12 months (or if earlier, the date the beneficiary demonstrates the beneficiary is no longer at-risk).

Centene urges CMS to allow the sponsor, prior to the expiration of the 12-month period, to determine if a continuation is warranted, and if so, to allow for extension of the designation for another 12-month period. We believe this flexibility to continue limits without interruption is necessary to best protect against misuse and abuse of opioids. Beneficiaries could then be allowed to seek a redetermination of the extension.

A.1.c.(2).(vii).(B). Limitation on the Special Enrollment Period for LIS Beneficiaries with an At-Risk Status (§423.38)

CMS proposes a limitation on the use of Special Enrollment Periods (SEPs) for beneficiaries determined to be at-risk through a Part D Drug Management Program.

Centene supports this this proposed limitation and believes it provides the greatest opportunity for at-risk beneficiaries to receive the most appropriate monitoring and care. Given that CMS receives information regarding a beneficiary's status, CMS is likely in the best position to facilitate this process and would need to build an edit that would result in an enrollment transaction being rejected upon submission.

BENEFITS

A.2. Flexibility in the Medicare Advantage Uniformity Requirements

CMS proposes to allow greater flexibility under the Medicare Advantage uniformity requirements that would allow plans to tailor benefits to vulnerable beneficiaries in a manner that provides them access to lower cost sharing or enhanced benefits, while still complying with non-discrimination requirements.

Centene appreciates and strongly supports the flexibility that CMS is proposing to provide plans an option to tailor benefits to best meet the needs of the beneficiaries we serve. CMS references "medical criteria" when discussing tailoring benefits, but certain kinds of benefits, such as those that address social determinants of health, are likely to be most impactful on lower income individuals, in particular for those that are dually eligible for Medicaid and Medicare. Benefits that address social determinants of health may include food and housing insecurity along with those benefits that are considered "in lieu of services." For example, a low-income individual that is frequently visiting the emergency department in warmer months may benefit from the provision of an air conditioner that may prevent avoidable emergency

department visits. These benefits may be best suited for individuals that are diagnosed with a chronic condition and are low-income rather than one or the other. While Centene is supportive of allowing for more flexibility in the uniformity requirements, we advocate that income be an allowable criterion for the purpose of tailoring benefits. We recommend this be operationalized by using the low-income subsidy (LIS) identifier that's a part of Part D to serve as an indicator for allowing plans to tailor benefits based on income.

In addition, this proposal has been limited to the Part C program and we would advocate that CMS extend this flexibility to the Part D program as well. There are significant advantages to tailoring drug benefits for individuals so that the drugs that help manage their chronic condition are more accessible and affordable. Additionally, there is precedent for allowing such flexibility—value-based insurance design in the Part D program is permitted as part of the Medicare Advantage Value-Based Insurance Design (VBID) model demonstration.

A.3. Segment Benefits Flexibility

CMS has determined that the statute and existing regulations may be interpreted to allow Medicare Advantage plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of a plan's service area. Plan segments are county-level portions of a plan's overall service area—under existing policy, plans are able to have different cost sharing and premiums by segments so long as they are consistent for the entire segment.

Centene supports this interpretation and believes this new benefit design option will help improve care and outcomes for its members.

A.4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101)

CMS proposes to change its existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending in the future. CMS expects to establish future limits by striking the appropriate balance between limiting MOOP costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages. Additionally, CMS clarifies its authority to increase the voluntary MOOP limit to another percentile level of Medicare FFS, increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount, and implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits.

Centene is supportive of this proposal and believes that it will help encourage additional plan offerings with lower MOOP limits.

A.5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

CMS determines annually the level at which certain cost sharing becomes discriminatory. The review parameters are currently based on Medicare FFS data and reflect a combination of patient utilization scenarios and length of stays or services used by average to sicker patients. CMS proposes to clarify that it may use Medicare FFS data to establish

appropriate cost sharing limits. In addition, CMS intends to use MA utilization encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory.

Centene supports this change which will allow CMS to use the most relevant and appropriate information in determining cost sharing standards and thresholds to ensure cost sharing is not discriminatory.

A.6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§422.254 and 422.256)

CMS proposes to eliminate this meaningful difference requirement beginning with the Medicare Advantage bid submissions for contract year 2019.

Centene is supportive of this change. There are times when conformity with these requirements have previously resulted in benefits being decreased or cost sharing increased. This change will help plans focus on beneficiary needs and affordability in benefit design rather than satisfying meaningful difference rules.

ENROLLMENT

A.7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

CMS proposes to set new limits on the seamless enrollment process. Default enrollments by the MA organization would only be permitted into dual-eligible special needs plans (D-SNPs) and be subject to five substantive conditions: (1) the individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the Medicare Advantage organization; (3) the individual does not opt out of the default enrollment; (4) the Medicare Advantage organization provides a notice that meets CMS requirements to the individual; *and* (5) CMS has approved the Medicare Advantage organization to use the default enrollment process before any enrollments are processed. Given that the seamless enrollment option would only be available for dual eligibles, CMS is also proposing through separate sub-regulatory guidance, a new and simplified positive (that is, "opt in") election process that would be available to *all* Medicare Advantage organizations when a beneficiary from one of their commercial, Medicaid or other non-Medicare plans become eligible for Medicare Advantage.

Centene supports these changes, with additional refinements (below), to both the seamless enrollment process and the new "opt-in" process for non-dual eligibles and looks forward to reviewing and commenting on the sub-regulatory guidance regarding the "opt in."

While it is not limited to Medicaid beneficiaries, seamless conversion as practiced today is primarily used when Medicaid beneficiaries attain Medicare eligibility based on age. It is also beneficial, however, for individuals who become dually eligible for Medicaid and Medicare and either have a disability (aged, blind, or disabled) or have a disability that requires long-term services and supports (LTSS). It can help ensure that the organization coordinating that member's Medicare-funded acute services (primary care, for example) is also responsible for coordinating that member's Medicaid-funded LTSS (in-home personal attendant, for example). As numerous studies have shown, effective acute and LTSS

coordination results in better health outcomes, decreased ER utilization, and other improvements in important quality measures.

To this end, we respectfully request that CMS add language to the final rule clarifying that in States with an existing Medicare-Medicaid Plan (MMP) that choose to implement the more limited default enrollment process, those State have the right to use passive enrollment as a priority over seamless conversion at the State's discretion.

Furthermore, Centene does not support the proposed alternative approach of limiting seamless conversion to seniors only as there are beneficiaries under 65 with concurrent benefits who are eligible for Medicaid and Medicare as a result of receiving both SSI and SSDI. Take, for example, a family with Medicaid whose child (under 18) sustains a disability and is now eligible for SSDI and Medicare based on the parent's earned work credits under Social Security. While identifying that particular member for seamless conversion (based on disability) is certainly more complex than it is for age, most people with disabilities under 65 (with the exception of those with amyotrophic lateral sclerosis - ALS) qualify for Medicare when they have received SSDI benefits for 24 months, so there is ample lead time for MA organizations to identify these individuals and confirm their Part A eligibility. Instead of using the MMA file from CMS, however, to try and identify these individuals, Centene recommends CMS partner with the Social Security Administration (SSA) to make SSDI data available to MA organizations.

As previously noted, while integrated and aligned care coordination is valuable for seniors without disabilities, it is even more critical for dually-eligible individuals with disabilities of all ages that require LTSS. By limiting seamless conversion with "opt-out" to dual-eligibles currently enrolled in an affiliated Medicaid health plan that will remain in the Medicaid health plan after age 65, and requiring that MA organizations proactively secure the consent of other members for seamless conversion ("opt-in"), Centene believes CMS strikes a good balance between the need for effective care coordination and protection of beneficiary choice.

A.8. Passive Enrollment Flexibilities to Protect Continuity of Integrated Care for Dually Eligible Beneficiaries. (§ 422.60(g))

CMS proposes limited regulatory changes to allow the use of passive enrollment for certain dually eligible beneficiaries in instances where integrated care coverage would otherwise be disrupted. Plans would have the ability to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP only in instances when all of the following conditions are met:

- When necessary to promote integrated care and continuity of care;
- Where such action is taken in consultation with the state Medicaid agency;
- Where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and
- Where certain other conditions are met to promote continuity and quality of care.

Centene supports this limited ability to passively enroll individuals in an effort to maintain integrated coverage options for full-benefit dual eligibles. Specifically, Centene supports an expansion of CMS' regulatory authority to passively enroll full-benefit duals who are already enrolled in a DSNP into another integrated DSNP under specified conditions as this could help minimize disruptions in continuity of care for dually-eligible beneficiaries with disabilities that require

LTSS, particularly during Medicaid re-procurement or in other situations when States discontinue programs serving this population, such as the Financial Alignment Initiative (FAI).

We believe that ultimately passive enrollment should be permitted more broadly into Medicare Advantage plans. Plans offer more robust monitoring for care gaps and prioritizes facilitating care coordination over what is provided in FFS. While we understand that default passive enrollment into managed care would likely require a legislative change, we believe this ultimately will lead to better outcomes for those that are Medicare eligible, including dual eligibles. Short of legislation, one possibility would be for CMS to consider whether its Centers for Medicare and Medicaid Innovation (CMMI) might have authority to allow broader passive enrollment under certain conditions.

A.9. Part D Tiering Exceptions. (§§ 423.560, 423.578(a) and (c))

Part D requires that a beneficiary be permitted to request an exception, under certain circumstances, from a plan's cost sharing tiering rules. When a tiering exception is granted, it allows the beneficiary to pay the cost sharing that applies to an "alternative" drug on a lower cost sharing tier. The current Part D regulation specifies circumstances under which a sponsor is permitted to limit the application of tiering exceptions. CMS is proposing several revisions to these permissible limits. CMS also proposes to clarify that an alternative drug for tiering exception purposes is a drug on a lower cost sharing tier that is appropriate for treating a beneficiary, taking into consideration the facts and circumstances of the individual's specific clinical condition, including comorbidities and characteristics of the enrollee and/or drug regimen.

Centene supports CMS' clarification on "alternative" drugs for purposes of these tiering exception rules. We believe as a matter of statutory interpretation that these rules are intended to apply to actual clinical alternatives rather than to any drug that shares an indication. An inappropriately broad interpretation of the tiering exception policy would be inconsistent with the legislative intent and would also substantially inhibit the proven ability of Part D plans to use formulary tiering as a means of ensuring cost effective Part D coverage for beneficiaries.

However, Centene recommends that CMS offer further clarity of what constitutes an "alternative" drug by producing sufficient examples of "alternatives" to non-preferred drugs in the final regulation and through sub-regulatory processes (i.e., updates to the Medicare Prescription Drug Benefit Manual and annual MA and Part D Call Letter). These clarifications would help to minimize any potential disputes over the facts and circumstances of a beneficiary's case or situation. Such clarifications from CMS would also ensure that plans can continue to offer clinically-sound formulary structures that provide high quality, cost-effective coverage for beneficiaries.

A.10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§423.38)

Currently, dual eligible beneficiaries have access to a Special Enrollment Period (SEP) that allows eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA-PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period (AEP) each fall.

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CMS proposes to specify that the Part D SEP is generally available within a two-month window of plan enrollment or eligibility change.

Centene supports this proposal with suggested modifications. As one of the largest MMP and MLTSS health plans in the country, Centene has witnessed firsthand how a continuous SEP has led to disruptions in continuity of care and difficulties with quality measurement. However, based on our experience, Centene also believes it is critical for dual members with disabilities to have the option to switch between comparably aligned and integrated products when their key disability-related providers or DME are no longer covered by their current plan (which should not, but could occur more than 2 or 3 times a year). Frequently these members have searched for years to find a particular prescription that minimizes side effects, or a particular provider that is knowledgeable about their disability. If that particular prescription is no longer on a plan's preferred drug list (PDL) or provider in a plan's network, the stability of that member's health could be at risk.

Therefore, Centene supports the proposed rule change with the stipulation that dual beneficiaries with disabilities have the option to continuously use the SEP within 2 months of notification that their "key disability or LTSS-related providers or DME" are no longer covered by their current plan. "Key disability or LTSS-related providers or DME" would only include those that are related to the disability-related diagnosis or diagnoses.

With this requested modification, new paragraph (c)(9) could read: "dual and other LIS-eligible beneficiaries who have a change in their Medicaid or LIS-eligible status or a change in coverage of their "key disability or LTSS-related providers or DME" (as defined) would have a SEP to make an election within 2 months of the change, or of being notified of such change, whichever is later." Additional statutory language or immediate regulatory guidance would be important to ensure that this particular use of the dual SEP is not used for providers or DME that are preferred but not necessary for the continued health and functioning of the member.

While enrollment brokers would be one way to educate affected populations and other stakeholders of the new SEP parameters, Centene also recommends CMS utilize the strengths and capacity of community-based organizations for this purpose. Frequently, CBOs have the trust and respect of the affected populations but are also significantly under-funded. As such, Centene recommends CMS establish community outreach grants to CBOs for the specific purpose of educating affected populations and other stakeholders of the new SEP parameters.

A.11. Star Ratings

As part of the Administration's efforts to improve transparency, CMS proposes to codify the existing Star Ratings System for the MA and Part D programs with some changes. The proposed changes include more clearly delineating the rules for adding, updating, and removing measures and modifying how CMS calculates Star Ratings for contracts that consolidate.

Centene is appreciative of the ongoing opportunity CMS provides plans to comment on current and future changes to the Star Ratings. We continue to believe that measuring and reporting quality along a variety of dimensions provides beneficiaries with meaningful information and Star Rating bonus payments work to align plan and government incentives around improved beneficiary satisfaction and improved patient outcomes. Specifically, we continue to believe that the Star Ratings are not fully reflective of the difficulties involved in treating low-income and high-disability populations.

The CAI has made some progress in this regard, but we believe the methodology still does not capture real differences in a number of measures not included in the adjustment. Additionally, we continue to encourage CMS to be conscious of the administrative burden quality reporting places on MCOs. We encourage CMS to look at measures that may be duplicative or overlapping in their scope and aim to reconcile that with an eye to capturing the necessary quality information in the most efficient way possible. We believe some progress has been made in this area, but look forward to commenting on specific measure inclusions and removals that further this goal in future responses.

We further encourage CMS to take immediate steps to remove the impact of audit findings on star measures particularly as it relates to the quality bonus calculation including the QBP calculation for 2019 payment year and going forward. CMS has already recognized that the audit findings may not be appropriate to include in the quality measures and that any adjustments related to enforcement actions should reflect the magnitude of the audit issue. Consistent with these policies and CMS' existing policy related to sanctioned plans, we recommend CMS remove CMP deductions from the BAPP calculation so plans are not penalized in the current/future year for a policy that is now in question.

A.11.e. Contract Ratings

CMS proposes to continue calculating Star Ratings at the contract level for now but solicits comments on whether this should be done at the plan level in the future.

Centene is opposed to calculating Star Ratings at the plan level. The collection of plan-level data would create significant additional unnecessary administrative burden to plans—resources that could otherwise be dedicated to quality improvement activities would instead be dedicated to the administration and management of the additional reporting requirements. However, if CMS were to move ahead with plan-level measurement, we would request it first conduct a simulation with both scenarios for a year and seek comments on those processes and results. As already noted by CMS, not all plan benefit packages (PBP) could be reliably measured. This could lead to additional beneficiary confusion when evaluating and comparing plan performance since some ratings would be at the contract level and some would be at the PBP level. With that said, plans dispersed across large geographic areas should be evaluated based on their unique characteristics—those measure where regional experience is particularly impactful should be measured at the plan level and those that cannot should be measured at the contract level.

A.11.f. Contract Consolidations

CMS is proposing a change in how contract-level Star Ratings are assigned in the case of contract consolidations. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, CMS proposes to assign and display on Medicare Plan Finder Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Under this proposal, the calculation of the measure, domain, summary, and overall ratings would be based on these enrollment-weighted mean scores. This weighting would be applied for the first two years after consolidation, thus by the third year the data will be reflective of the combined contract.

Centene shares CMS' concern that low-quality plans have used consolidation to mask low performance and agrees with the proposed solution. However, consistent with HPMS guidance, we would propose that CMS use the final summary

mean (post reward factor, categorical adjustment index (CAI), etc.) rather than the rounded final star rating, or other measure of an overall star rating score, for consolidation. Additionally, we request that CMS provide clarity on when this change would take effect (e.g., with the issuance of the 2019 Call Letter, etc.).

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

To address continued anticipated changes in the world of quality measures, CMS proposes specific rules to govern the addition, update, and removal of measures. CMS proposes to apply these rules to the measure set proposed in this rulemaking, to the extent that there are changes between the final rule and the Star Ratings based on the performance periods beginning on or after January 2019. Several of CMS' proposals are outlined below and Centene has provided their comments as relevant.

Addressing Data Quality Issues

For data quality issues identified during the calculation of the Star Ratings for a given year, CMS proposes to continue its current practice of removing the measure from the Star Ratings.

Centene recommends that CMS add a hold harmless provision to this requirement. Plans that have worked hard to perform well on a measure should not be penalized if an error is detected in the data. For example, when the measure related to providing translation services (TTY/LEP) was removed due to data integrity issues it harmed the overall ratings of some plans—those plans were unable to get credit for the good results they had achieved on the measure.

Displaying Measure Changes

CMS proposes that new measures and measures with substantive changes would be kept on the display page for a minimum of two years—measures with non-substantive changes would not be moved to the display page.

Centene supports this approach.

Updating the National Drug Code (NDC) for use in Quality Measures

Pharmacy Quality Alliance (PQA) updates its NDC lists biannually, usually in January and July.

Centene suggests that CMS require PQA to update their NDC lists more frequently, at least quarterly, or rely on the Generic Product Identifier (GPI) or similar method to allow plans to identify new NDCs for existing drugs of interest earlier in the year.

Removing Measures

CMS will remove measure due to changes to clinical guidelines or when a measure shows low statistical reliability. Centene agrees that if measures are no longer clinically relevant they should be removed from the Star

Rating system. The agency should allow at least one Star Rating period to pass before removing measures deemed to be clinically irrelevant. This will provide plans with adequate time to alter their internal processes so valuable time is not lost to advancing measures that are no longer relevant. In addition, CMS will remove measures which have shown high performance across all contracts which decreases the variability across contracts and makes the measure unreliable, also known as "topping out."

Centene advocates that if a measure is determined to be "topped out", but is valuable clinically, it should be retained so that plans are rewarded for maintaining the level of effort required to be successful on the measure. If CMS opts not to take this approach, the agency should allow for at least two Star Rating periods to pass before removing measures which are deemed topped out.

A.11.i. Measure Set for Performance Periods Beginning on or After January 1, 2019

CMS proposes that several measures be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part C and D Star Ratings. One of these measures is on Special Needs Plan (SNP) care management. The guidance and technical specifications released thus far on the SNP care management measure have been inconsistent. Auditors have been known to contradict CMS' interpretation of the specifications.

Centene recommends that this measure be retired until clear guidance can be issued by the agency. If the measure is reintroduced, the cut points should be stratified based on SNP type (e.g., C-SNP, D-SNP, etc.), since the various SNP types have different outcomes on this measure. In addition, Centene advocates that the measure on statin use in person with diabetes (SUPD) be included in the coverage year 2019 Star Rating at the weighting of a first-year measure and categorized as a process measure rather than an outcome measure.

A.11.j. Improvement Measures

CMS proposes to continue the current methodology for calculating the improvement measures. For a measure to be included in the improvement calculation, the measure must have numeric value scores in both the current and prior year and not have had a substantive specification change during those years. In addition, the improvement measure will not include any data on measures that are already focused on improvement (e.g., Health Outcome Survey (HOS) measures focused on improving or maintaining physical or mental health). The Part C improvement measure includes only Part C measure scores, and the Part D improvement measure includes only Part D measure scores.

Centene agrees with this approach.

A.11.k. Data Integrity

CMS proposes specific rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. Data may be determined to be incomplete, inaccurate, or biased based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that impacted specific measure(s).

In two instances, a plans Star Rating on a measure will automatically be reduced to one Star: (1) HEDIS measures will be reduced to one Star when audited data are submitted with a designation of "biased rate" or when a plan does not report data; and (2) Part C and D Reporting Requirements data will be reduced to one Star when a contract did not score at least 95 percent of data validation for the applicable reporting section or was not compliant with data validation standards.

Centene believes that an automatic reduction to one Star should be limited to systematic issues only, rather than a single episode of a data integrity issue. Additionally, as it relates to CMS' second approach previously described, we request that CMS review the clarity of guidelines presented to plans when it is identified that a large number of plans are having data integrity issues related to reporting a specific measure (i.e. SNP Care Management measure). It may be that confusing instructions are the root cause rather than plan error.

As part of the review process CMS proposes to use multiple data sources whenever possible, such as findings obtained from audits. Centene recommends that CMS not use the findings from audits as part of the data integrity review process for Star Ratings because CMS cannot conduct audits on all Medicare Advantage plans each year, thus plans that are not audited may have an undue benefit. We suggest instead that other enforcement actions be used where there is cause to believe results are inaccurate (e.g., suspension of enrollment or some other tool).

Lastly, CMS proposes to reduce a contract's Part C or Part D appeal measure Star Ratings in instances of data integrity issues. Given that there are varying degrees of this type of data issue, CMS proposes a scaled approach which is intended to reflect the degree of the data accuracy issue rather than a "one size fits all" approach.

Centene is supportive of CMS' proposed scaled approach methodology.

A.1.l. Measure-Level Star Ratings

CMS proposes that if the reliability of a CAHPS measure score is very low for a given contract, less than 0.60, the contract would not receive a Star Rating for that measure.

Centene requests that CMS evaluate the use of CAHPS data in the Star ratings program and at the very least provide additional transparency on the validity of the case mix adjustment methodology. Additionally, we would request that CMS address regional variations in response rates and outcomes that are a result of the geographic differences in the healthcare delivery system. Additionally, Centene supports CMS providing a simulation of the cut points based on two and three years of data. Since star ratings influence payment and, subsequently, benefits CMS should seek to make the movement of cut points less volatile.

A.11.q. Measure Weights

CMS is proposing to continue the current weighting of measures in the Part C and D Star Ratings program by assigning the highest weight (5) to improvement measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1). CMS is considering increasing the weight of the patient experience/complaints and access measures and are interested in stakeholder feedback on this potential change in order to reflect better the importance of these issues in plan performance.

Centene strongly disagrees with making this change—we do not believe CMS has adequately demonstrated the validity of the patient experience/complaints and access measures to justify increasing their weight at this time. In particular, we question the validity of the CAHPS measures in identifying true differences in patient experience, given that that distance between thresholds is often narrow and the case mix adjustment is not inclusive of many factors that are tied to experience and out of the plan's control (e.g., geography).

Additionally, CMS has proposed that the two HOS measures that ask beneficiaries to rate their physical and mental health have been given a weight of three.

Centene requests that CMS re-evaluate this value for HOS 'outcomes' measures. High performing plans perform at the same or similar levels as lower performing plans and the measures are subjective and do not provide real measurement of plan's quality. We are also concerned that these measures are not true measures of health outcomes, but rather mortality outcomes since the regression model underlying these measures is based on mortality risk.

A.11.r. Application of the Improvement Measure Scores

Consistent with current policy, CMS proposes a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest rating (4 stars or higher) and welcomes comments on these requirements, including any clarifications in how and when it should be applied.

Centene recommends that the hold harmless provision not be applied in scenarios where without the quality improvement measure a plan rated 4 stars or higher would see a decrease in its overall rating. We also suggest that plans that would be at risk of receiving a low performing icon due to application of the quality improvement measure be held harmless.

A.11.t. Categorical Adjustment Index (CAI)

Beginning with the 2017 Star Ratings, CMS implemented a CAI that adjusts for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low-income subsidy and/or are dual eligible (LIS/DE) and/or have disability status. CMS developed the CAI as an interim analytical adjustment while it developed a long-term solution. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and beneficiaries with disabilities.

Under the existing policy and the proposed rule, certain measures would not be candidates for the adjustment, including those measures that CMS believes are already case-mix adjusted for socioeconomic status (e.g., CAHPS and HOS outcome measures). For the measures that meet the inclusion criteria, CMS proposes to identify measures for the adjustment by using the following decision criteria: (1) a median absolute difference between LIS-DE and non-LIS-DE beneficiaries for all contracts analyzed is five percentage points or more; (2) the LIS/DE subgroup performed better or worse than the non-LIS-DE subgroup in all contracts. CMS proposes to codify the CAI calculation methodology, while it considers other alternatives for the future, but notes in the preamble that they believe that the difference in quality ratings between plans that serve a disproportionate share of this population and those who do not are "quite modest."

Centene appreciates CMS' efforts to date to account for differences that naturally occur when a plan serves a disproportionate share of more vulnerable populations, but believes there is more CMS can do as they continue with the

CAI and give thought to a longer-term solution. Plans incur additional costs when serving LIS/DE beneficiaries—these investments must be made if plans are going to provide the same quality outcomes as other plans that serve fewer of LIS/DE beneficiaries. Additional services include the increased need for case management as well as the time and investment needed to locate and contact members who are disproportionately unreachable through contact information provided to the plan. While CMS believes that that the quality ratings between those plans that serve a disproportionate share of the LIS/DE population and those that don't are modest, in Centene's experience serving beneficiaries across the country, the investments that must be made and the variance between LIS/DE and non-LIS/DE beneficiaries is significant. Existing research is not conclusive on this point, but challenges persist for those plans that serve a disproportionate share of this population. Thus, Centene recommends that CMS conduct further research on how best to recognize quality efforts made by plans serving a predominately LIS/DE population, rather than settling for the CAI approach long-term.

As it relates to CMS' current approach, Centene believes that it's significantly insufficient in recognizing differentiation and that CMS needs to conduct this research and move to a longer-term solution that more accurately reflects the variance as soon as possible. While we have concerns about the existing approach generally, in particular we encourage CMS to further examine the current SES adjustment applied to CAHPS and HOS measures, which has led CMS to exclude these measures from the CAI, in the near-term. We have concerns about the adequacy of the existing adjustment and requests that CMS demonstrate that the case mix methodology for the adjustment applied to these measures is sound and truly offsets differences in performance.

Specifically, we recommend CMS pursue evaluation of a number of approaches to closing the remaining adjustment gap the CAI does not address. First, while LIS and disability status are readily available factors on which to base the CAI, we encourage CMS to determine if other factors tied to social determinates like transportation access, health literacy, and economic status, may be better indicators of the true differences that exist with serving of vulnerable populations. Additionally, CMS does its measure evaluation for CAI for looking at within contract differences—in an effort to hold all else equal. Nonetheless, we encourage CMS to evaluate the possibility that the contracts being used as the basis for this assessment are actually different from contracts that have higher concentrations of LIS/DE beneficiaries. This difference may include geography, provider networks, and differences within the LIS/DE classifications. We believe this may be one reason CMS thus far has only found small differences in its analyses, which is not reflective of our organization's experience. Finally, we encourage CMS to continue to advance work with the appropriate measure stewards to determine how adjustments could be made at a measure-level basis to account for difference in serving vulnerable populations."

PART D

A.12.a. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)

CMS proposes to make clarifying changes by providing definitions for a mail order pharmacy and a retail pharmacy and establishing deadlines for making standard terms and conditions available to requesting pharmacies. CMS also describes in the Preamble several interpretations of the existing requirement that standard terms and conditions be "reasonable and relevant," including language reflecting prior sub-regulatory guidance relating to specialty pharmacies and credentialing requirements exceeding state and federal mandates.

Centene is concerned that the interpretation provided in the Preamble that prohibits credentialing standards exceeding state and federal mandates may be overly broad. Though we agree that duplication of and redundancy with nationwide

accreditation criteria is not warranted, we recommend that the policy should offer sponsors with the flexibility to develop criteria they can demonstrate is both reasonable and relevant for the Part D program, such as provisions targeted at preventing specific types of fraud, waste, and abuse, which may exist in specific regions and may vary by region.

In addition, Centene believes that the two-business day deadline for responding to requests for the sponsor's standard terms and conditions may be too limited and would not allow for potential extenuating circumstances that can arise. Centene recommends that CMS use instead a longer timeframe (e.g., five business days upon receipt of the request) for responding to requests for standard terms and conditions.

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

CMS proposes to change the outpatient transition days' supply from "30 days" to "a month's supply" and to change the long-term care (LTC) setting required minimum transition days' supply from between 91 and 98 days to "a month's supply."

Centene appreciates and supports the conforming changes to the minimum transition days' supply for the outpatient and LTC setting. However, we request that the regulation include language from the Preamble which clarifies that "a month's supply" corresponds to the number of days the Part D sponsor attributed as its retail month's supply for a given drug in its Plan Benefit Package, as submitted to CMS, for the relevant plan year.

A.14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

CMS proposes to allow sponsors to immediately add or substitute first-to-market therapeutically equivalent generic drugs to its formulary and to immediately remove or change the preferred or tiered cost sharing of the corresponding brand drug without providing notice ahead of time.

We appreciate and support the change in policy as it would provide beneficiaries with earlier access to lower cost therapeutically equivalent alternatives to more expensive brands.

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

Under current policy, CMS requires that follow-on biological products be subject to the higher Part D maximum copayments for LIS beneficiaries and for non-LIS beneficiaries during the catastrophic portion of their benefit. CMS is proposing to revise the definition of a generic drug at §423.4 to include follow-on biologic products for the sole purpose of allowing the lower copay option to LIS beneficiaries and the lower coinsurance option to non-LIS beneficiaries during the catastrophic coverage phase.

We appreciate and support changes in policy that incentivize the use of lower cost biologic follow-on options.

A.16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (§423.265)

CMS proposes to modify the meaningful difference requirement for Part D plans by eliminating threshold differentials used to distinguish two alternative plans offered by the same parent organization in the same region. CMS is also proposing to maintain the requirement that enhanced plans be meaningfully different from the basic plan offered by the same plan in the service area.

Centene appreciates and supports this change in policy as it would provide more meaningful options and choices for beneficiaries and incentivize market innovations.

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

CMS is seeking comment on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale.

Under current law, when not explicitly required to do so for certain types of pharmacy price concessions, Part D sponsors can choose whether to reflect various price concessions, including manufacturer rebates, they or their intermediaries receive in the negotiated price. However, when manufacturer rebates and other price concessions are not reflected in the negotiated price at the point of sale, beneficiary cost-sharing, which is generally calculated as a percentage of the negotiated price, becomes larger, covering a larger share of the actual cost of a drug.

Centene agrees with CMS that high cost-sharing can be a barrier to care; however, we have serious concerns about the proposal to require point-of-sale price modifications described by CMS. While we believe that efforts need to be taken to address rising drug prices and their effect on providing affordable treatments for beneficiaries, this proposal fails to address the main driver of beneficiary unaffordability: list price. Lower list prices would reduce cost sharing to individual beneficiaries who need high-cost medication, but also would reduce health care costs overall leading to overall increases in the affordability of health care services. To this end, we believe such a program, if implemented, would produce little net-benefit to beneficiaries as it would decrease barriers to further price increases that would be reflected in higher premiums and benefit changes.

Furthermore, we have serious concerns about the ability to efficiently implement such a program, which could drive administrative costs that may surpass any benefit.

B. Improving the CMS Customer Experience

B.1. Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40)

CMS is proposing to make to certain changes to the regulations related to the open enrollment period to comply with the 21st Century Cures Act which changes the open enrollment period to be held from January 1 to March 31 each year beginning in 2019. This new OEP allows individuals enrolled in an MA plan to make a one-time election during the first

3 months of the calendar year (i.e., January through March) to switch MA plans or to disenroll from an MA plan and obtain coverage through Original Medicare. In addition, an MA organization has the option to voluntarily close one or more of its MA plans to OEP enrollment requests.

Centene supports CMS making these changes.

B.2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

CMS proposes to remove the regulatory requirement that first-tier, downstream and related entities (FDR) complete a CMS compliance training, which lasted one hour—Medicare Advantage and Part D sponsors thus would no longer be required to ensure that FDRs completed such trainings. Plan Sponsors would continue to be responsible for FDRs' compliance with the relevant Medicare requirements, despite this change.

Centene supports this change and agrees with CMS' conclusion that the existing training program is unnecessary.

B.4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)

CMS proposes to change the Medicare Advantage plan disclosure requirements by, (1) requiring that both Medicare Advantage and Part D Sponsors provide certain information by the first day of the annual enrollment period (information outlined in paragraph (b)), rather than 15 days beforehand as was previously required; and (2) allowing certain documents to be provided electronically rather than requiring print versions, including the Summary of Benefits, Explanation of Coverage, and provider network information.

Centene strongly supports both of these proposals. Providing hard copies of plan information, in particular the Explanation of Coverage, can be very costly and the majority of beneficiaries access these types of documents online. Thus, this flexibility will lower the associated administrative costs, allowing plans to reallocate that money towards initiatives that are more impactful to beneficiaries.

Nonetheless, we also wish to ensure that the change will not adversely impact beneficiaries who need these materials in other languages or formats (i.e. Braille, large print, etc.), which typically takes 15 days to process. Therefore, Centene respectfully requests that CMS add language to the final rule clarifying that beneficiaries who require plan content information in another language or format have the right to request it 15 days before the first day of the annual enrollment period. This will ensure these beneficiaries have access to the same information at the same time as other beneficiaries, and the same amount of time to process it and make informed decisions.

B.5.b. Amending the Regulatory Definition of Marketing and Marketing Materials

CMS proposes that the term "marketing" would be defined as the use of materials or activities by the sponsoring organization or downstream entities that are intended to draw a beneficiary's attention to the plan or plans and influence a beneficiary's decision-making process when making a plan selection; this last criterion would also be met when the intent is to influence an enrollee's decision to remain in a plan (that is, retention-based marketing). In conjunction with the proposed new definition of marketing, CMS proposes to remove from the list of examples items such as membership

communication materials, subscriber agreements, member handbooks, and wallet card instructions to enrollees, as they would no longer fall under the proposed regulatory definition of marketing.

Centene support this proposed change to the definition of "marketing." This change provides needed clarity as to what types of materials are considered "marketing" and therefore what level of review and scrutiny certain materials fall under.

B.6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§423.590 and 423.636)

CMS is proposing to change the timeframe for issuing decisions on Part D payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request—this timeline would also apply to an independent review entity (IRE) reconsideration request.

Centene supports this change and agrees that it will likely reduce the volume of untimely payment redeterminations that must be auto-forwarded to the IRE.

B.7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§422.590)

As it relates to the appeals process for coverage determinations, CMS sub-regulatory guidance (Chapter 13 of the Medicare Managed Care Manual) specifically directs plans to mail a notice to the enrollee informing the individual that the plan has upheld its decision to deny coverage, in whole or in part, and thus is forwarding the enrollee's case file to the IRE for review. CMS proposes that the IRE would be responsible for notifying enrollees upon receiving cases, including both standard and expedited case.

Centene supports this change and believes it could help alleviate unnecessary duplicative notices that may cause beneficiary confusion.

B.9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§422.502 and 423.503)

CMS denies contract qualification applications from organizations that have failed to comply with Medicare Advantage or Part D requirements, using a 14-month look-back period. CMS proposes to reduce the past performance review period from 14 months to 12 months to avoid some instance of double-counting non-compliance in two consecutive cycles depending on the timing/date of the underlying non-compliance incident.

Centene supports this change as proposed.

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B.10-11. Part D Prescriber Preclusion List & Preclusion List—Part C/Medicare Advantage Cost Plan and PACE Provisions

Current regulation states that for a prescription to be eligible for coverage under the Part D program, the prescriber must have (1) an approved enrollment record in the Medicare fee for service program (that is, original Medicare); or (2) a valid opt out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC). Full implementation of these requirements has been delayed several times, most recently until January 1, 2019 given the large number of providers who have yet to enroll or opt-out. Similar provisions and concerns exist for providers and suppliers for MA, Cost and PACE plans.

CMS proposes eliminating the prescriber and provider enrollment requirement and instead compiling a "Preclusion List" of individuals and entities that fall within either of the following categories: (a) are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or (b) have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. Under this option, CMS would make the Preclusion List available to Part D prescription drug plans and Medicare Advantage plans. Plans would then be required to deny claims from or written by prescribers and providers on the list.

Centene strongly supports this change for both Parts C and D. In regard to the actions that are referenced in §424.535(a) that may cause a provider to be included on the preclusion list, of the 14 reasons listed, three appear to be specific to enrolling and maintaining active enrollment status in the Medicare program (6, 9, and 10). We recommend excluding these as reasons for a provider or supplier to be included on the preclusion list as it would not apply to those who are not enrolled with Medicare. To ensure Medicare Advantage plans have appropriate processes in place to screen providers, suppliers, and prescribers against the preclusion list, we recommend including review as part of CMS' ongoing audit and monitoring activities, potentially as part of the Program Audits or the Industry Wide Timeliness Monitoring. Alternatively, prescription drug events and/or risk adjustment data might be used as a means to confirm plans are not paying providers and suppliers on the prelusion list.

Additionally, we have several concerns around the need for and burdens of the provisional fill policy for the Part D preclusion list. The provisional fill requirement was included in the current prescriber enrollment provision (which, as noted above, is proposed to be eliminated) to preserve access to drugs for beneficiaries whose prescribers were not necessarily found to have engaged in any problematic behavior, but rather, had not enrolled in Medicare. It was designed to minimize potential disruptions in access to needed drugs while prescribers were enrolling into Medicare. The requirement as proposed here would instead require sponsors to fill prescriptions written by prescribers that CMS has identified as "demonstrably problematic" after a review process. Provisional fills are not available for prescriptions written by excluded prescribers; Centene is unaware of any policy justification for having provisional fills for prescribers who have engaged in similar "demonstrably problematic" activities. Therefore, Centene recommends that the provisional fill requirement be eliminated.

Centene is also concerned around the burdens of operating and administering the provisional fill policy. Due to the time and resources required to make necessary updates required to sponsors' and their contracted PBMs' IT systems, policies and procedures, and operational policies, Centene believes that the 2019 start date would not be feasible. Therefore, if

CMS were to retain the requirement, Centene strongly recommends that the implementation date be delayed to a date determined to be feasible after consultation with sponsors and their contracted PBMs.

B.12. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

Continued evaluation through annual review of plan reported updates of the Quality Improvement Programs (QIPs) has led CMS to believe that the existing QIP regulatory requirements do not add significant value. Therefore, CMS is proposing to remove the QIP regulatory requirements—plans would still be required to meet the quality improvement requirements outlined in statute under 1852(e) of the Social Security Act.

Centene agrees with the proposal to eliminate the QIP requirements. As CMS states, we find that the QIP is often redundant with many of the quality improvement activities that are already underway. We would further suggest that CMS also remove the activities of the Chronic Care Improvement Program (CCIP) as they are also redundant to ongoing chronic care improvement efforts. Chronic conditions are the leading driver of health care costs, leading many organizations to focus their health improvement activities on members with chronic conditions regardless of whether the CCIP is a mandated project. In addition, Star metrics also prioritize the outcomes of members with chronic conditions which also incentivizes plans to develop initiatives focused on improving health care outcomes for those with chronic conditions.

B.13. Reducing Provider Burden – Comment Solicitation

CMS is interested in stakeholder feedback on the nature and extent of the burden to providers of producing medical record documentation and ideas to address the burden.

We appreciate the opportunity to provide comment and looks forward to working with CMS to determine a viable solution to reducing provider burden, a joint goal. We feel strongly that any process devised must be done so judiciously, recognizing the essential role that medical record documentation plays in a myriad of existing requirements including as they relate to quality and risk adjustment reporting requirements. Plans must receive accurate and complete medical documentation from providers in a timely way to ensure they can be responsive to CMS requests and requirements. The reality of this need must be carefully balanced with reducing provider burden.

Plans that are not fully integrated with their providers (i.e., share a joint electronic medical record (EMR) system) must make requests to view medical records—providers are asked to produce the records and may have to address plans' follow-up questions which can be time consuming. Providers receive these types of requests potentially from multiple plans. As providers increasingly moved towards using EMRs, one potential solution is that providers allow health plans access into those systems—this would allow health plans to search for the necessary documentation rather than make requests of the provider. CMS should consider ways to support providers in making the administrative changes that would be required to grant health plans such access. Another potential solution would be to further encourage the use of Health Information Exchange (HIE) systems and health plans' access to such systems—the data found in the HIE would then need to be able to count towards meeting medical record documentation requirements.

We would also suggest that CMS review the increasingly significant burden on providers in supplying provider directory-related information. While we support providing extensive and useful information in the directories so members can

make informed choices, the process of having multiple plans continually approaching providers for the same information is burdensome. This adds to the frustration of providers in constantly responding to administrative and clinical requests from multiple parties. We suggest that CMS look for ways to alleviate the burden on providers in supplying provider directory information by perhaps consolidating the process for CMS and plans into a single data source.

C. Implementing Other Changes

C.1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§§ 422.2420, 423.2430)

CMS proposes to significantly reduce the burden of medical loss ratio (MLR) requirements while also recognizing that plans should not be penalized for fraud prevention and Medication Therapy Management (MTM) activities designed to provide more efficient care to their members. In particular, CMS proposes the following:

- Changing the calculation of the numerator of MLR to include all expenditures for fraud prevention;
- Clarifying that compliant Medication Therapy Management (MTM) programs can be included in numerator; and
- Reducing MLR reporting to four data elements: Organization Name, Contract Number, Adjusted MLR percentage, Remittance Amount (if MLR is under 85 percent).

Centene fully supports these proposed changes. Insurers' anti-fraud programs play a key role in contributing to improving the quality of health care for enrollees, while MTM activities are a critical tool for plans to improve medication adherence and outcomes.

C.2. Medicare Advantage Contract Provisions (§ 422.504)

CMS may enter into a contract with a MA organization subject to certain standards. The rule proposes to rectify an inconsistency in the rule that addresses the contract provisions that are material to the performance of an MA contract. The proposed rule would correct the inconsistency and state that all contract terms listed in the proposed rule's introductory text is material to the performance of the contract.

Centene supports this technical change.

C.3. Late Contract Non-Renewal Notifications (§§ 422.506, 422.508, and 423.508)

CMS proposes that a request of a contract non-renewal by either CMS or the Medicare Advantage organization or Part D plan sponsor after the first Monday in June be considered a termination by mutual consent.

Centene supports this change as proposed.

C.4. Contract Request for a Hearing (§§ 422.664(b) and 423.652(b))

Organizations have the right to appeal CMS' decision to deny their application to hold an MA contract. CMS proposes to modify the inconsistencies found in §422.664(b)(1) to § 423.652(b)(1) to align with CMS' modified deadline of issuing a determination on the appeals application by September 1—currently, both to § 422.664(b)(1) and § 423.652(b)(1) reference July 15.

Centene supports this technical change as proposed.

C.5. Physician Incentive Plans - Update Stop-Loss Protection Requirements (§ 422.208)

CMS proposes to change the stop-loss protection requirements under a physician incentive plan (PIP) in the following three ways: (1) updates the stop-loss deducible limits and use a new methodology developed by CMS to update the stop-loss deductible limits in the future to account for changes in medical cost and utilization; (2) allows Medicare Advantage organizations to use actuarially equivalent arrangements to shield them from financial loss of serving certain patients under the PIP; and (3) authorizes non-risk patient equivalents who receive some services from the physician or physician group to be included when calculating the deductible.

Centene is generally supportive of both CMS' reasoning and associated changes to the stop-loss program.

C.6. Changes to Agent and Broker Compensation Requirements (§422.2274 and §423.2274)

CMS is proposing to remove the requirements associated with aggregate compensation as it relates to agent and broker compensation.

Centene supports this change as proposed.

C.7. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e)

CMS proposes to eliminate the requirement that Medicare Advantage and Part D sponsors terminate, upon discovery, any unlicensed broker or agent employed as a marketing representative. Even though this requirement would be eliminated, CMS notes that beneficiaries would still qualify for an SEP when it is discovered that their agent or broker was unlicensed at the time of enrollment.

Centene is supportive of this change—it provides the necessary flexibility to plans to allow them to address these situations on a case-by-case basis while protecting enrollees.

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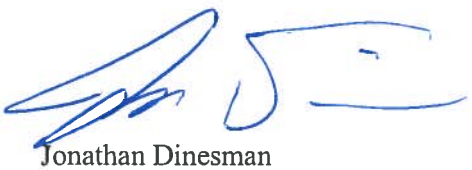
C.9. Eliminate Use of the Term "Non-renewal" to Refer to a CMS-Initiated Termination (§ 422.506, 422.510, 423.507, and 423.509)

CMS is proposing to clarify its use of the term "non-renewal." Under the proposed rules, non-renewal would reference situations in which an MA organization is electing to no longer provide coverage, not a CMS initiated contract termination. Relatedly, CMS is proposing to require that in both instances of non-renewal and CMS-initiated contract terminations, enrollees be notified 90 days prior to the end of the coverage year (December 31) of the change so they can select a new plan, assuming the decision to end the contract has been made prior to August 1.

Centene agrees with both of the proposed changes—the first provides a helpful clarification and the second provides enrollees with more time to examine their available options and select a new plan in the instance a contract is unavailable to consumers in the upcoming year.

Centene appreciates the opportunity to provide feedback on this proposed rule. We welcome the opportunity to work with CMS to discuss any of the issues described above in further detail. If you have any questions, please contact me at jdinesman@centene.com.

Sincerely



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