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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-4182-P

To Whom It May Concern:

I am writing on behalf of Health Care Service Corporation (HCSC) to comment on the notice of proposed rulemaking titled, "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 by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on November 28, 2017 (82 FR 56336).

HCSC is the largest customer-owned health insurance company in the United States. The company offers a wide variety of health and life insurance products and related services, through its operating divisions and subsidiaries including Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas. HCSC has established Medicare Advantage (MA) plans and Part D Prescription Drug (Part D) stand-alone plans in all five of the HCSC states. In addition, HCSC operates a Medicare-Medicaid Plan (MMP) contract in the State of Illinois.

Our comments and related recommendations are provided below.

COMMENTS

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

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (Preamble pgs. 56340-56360)

Blue Cross and Blue Shield of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas

Divisions of Health Care Service Corporation, a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association

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

CMS is proposing a regulatory framework for implementation of provisions of the Comprehensive Addiction Recovery Act of 2016 (CARA), which included new authority for establishment of voluntary drug management programs under Medicare Part D, effective on or after January 1, 2019. Under such programs, Part D plan sponsors will be permitted to limit at-risk beneficiaries' access to coverage of controlled substances designated by CMS as "frequently abused drugs," to a selected prescriber(s) and/or network pharmacy(ies). CMS proposes to implement the CARA provisions by integrating them with the agency's current Opioid Drug Utilization Review (DUR) policy and Overutilization Monitoring System (OMS) requirements.¹

HCSC is strongly committed to the prevention, detection, and resolution of prescription drug-related fraud, waste, and abuse for the benefit of the health and well-being of our members and the health care system overall. We believe permitting sponsors to establish Medicare Part D drug management programs for beneficiaries at-risk of prescription drug misuse and abuse, coupled with the appropriate beneficiary protections, will play a key role in improving quality of care and safety for affected enrollees by reducing inappropriate and unsafe utilization of prescription drugs. We have identified several issues and related recommendations regarding the proposed framework, and they are discussed below.

- ***Frequently Abused Drugs.*** For plan year 2019, CMS is proposing to only designate opioids (with the exception of buprenorphine for medication-assisted treatment and injectibles) as frequently abused drugs for purposes of Part D drug management program requirements. As CMS and sponsors gain more experience with Part D drug management programs, particularly following initial implementation, we encourage the agency to evaluate and consider whether the designation should be expanded to include other high-risk medications.
- ***Drug Management Program Appeals.*** CMS is proposing to implement the statutory requirement that the following drug management program components are subject to reconsideration and appeal: (1) identification of an individual as an at-risk beneficiary for coverage determinations made under such a program; (2) the selection of a prescriber or pharmacy; and (3) information sharing for subsequent plan enrollments. CMS indicates that the agency considers each of these aspects to be part of a beneficiary's "at-risk

¹ See CMS Web site, "Improving Drug Utilization Review Controls in Part D" at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>

determination” under a drug management program, and proposes to adjudicate at-risk determinations under the existing Part D benefit appeals processes and timeframes as established in the Part D regulations. HCSC appreciates use of and alignment with the existing Part D appeals processes and timing. We also strongly encourage CMS to communicate “at-risk determination” appeal-related information and requirements in a clear, concise and consistent manner to beneficiaries, the Independent Review Entity (IRE) and sponsors to support a uniform understanding of the agency’s rules and related expectations.

- ***Special Requirement to Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s)***. CMS indicates in the Preamble on page 56354 that the agency believes implementation of a prescriber lock-in (i.e., limiting an at-risk beneficiary’s access to coverage of frequently abused drugs to a selected prescriber), “should be a tool of last resort to manage at-risk beneficiaries’ use of frequently abused drugs.” Toward that end, CMS is proposing that a sponsor may not limit an at-risk beneficiary’s access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk individual via an OMS report. We are concerned that this extended waiting period could present a barrier to the success of Part D drug management programs given the potential challenges this limitation could create for plan efforts to address misuse and abuse in a timely manner and the potential negative consequences on beneficiaries’ health status. We recommend that CMS establish a more reasonable timeline that balances importance of timely plan action with the desire to minimize any potential impact on a beneficiary’s relationship with his or her health care providers (e.g., a period of 1 to 3 months).
- ***Limitations on the Special Enrollment Period (SEP) for LIS Beneficiaries with an At-Risk Status***. CMS is proposing to limit the availability of the ongoing SEP that permits Medicare-Medicaid dual eligible and low-income subsidy (LIS) eligible individuals to make Part D enrollment changes (enroll, disenroll from or switch Part D plans) throughout the year. Specifically, CMS proposes that once a dual-eligible or LIS eligible individual is designated as “potentially at-risk” or “at-risk” for purposes of Part D drug management program requirements, the individual will be notified that they will be unable to use the SEP due to their status. We support the proposal and agree with CMS’ statement on page 56351 of the Preamble, which notes that this proposed SEP limitation would be an important tool to reduce the opportunities for LIS-eligible beneficiaries designated as at-risk to switch plans in an effort to circumvent the drug management program and not receive the care coordination such a program provides.

- ***Termination of a Beneficiary’s “Potential At-Risk” or “At-Risk” Status.*** CMS proposes to establish that a beneficiary’s at-risk determination will terminate at the end of the 12-calendar month period calculated from the effective date of the limitation, or if earlier, as of the date the beneficiary demonstrates they are no longer at risk. To support continuity, we recommend that CMS implement a process to permit sponsors to evaluate and determine whether a continuation of the at-risk determination is warranted and allow for an extension of the determination for an additional 12-month period based on the outcome. Sponsors should be permitted to make the subsequent determination prior to expiration of the initial 12-month period.
- ***Addressing Issues Related to Data Access and Availability.*** According to the Centers for Disease Control and Prevention (CDC), Prescription Drug Monitoring Programs (PDMPs), which are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients, “continue to be among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk.”² However, although the majority of states operate PDMPs collecting dispensing data including for opioid prescriptions paid for by insurance and cash, we understand only a handful of those states provide Part D plan sponsors access to these data. Until greater advances are achieved in this area, we strongly encourage CMS to consider how issues such as Part D enrollees who pay cash for their prescriptions may impact the ability of Part D drug management programs to effectively address prescription drug overuse and abuse.

2. Flexibility in the Medicare Advantage Uniformity Requirements (Preamble pgs. 56360-56361)

For CY 2019, CMS is proposing to adopt a new interpretation of the MA uniformity requirements outlined in the statute at 1852(d) and 1854(c) and the corresponding MA regulations at § 422.100, to permit MA plans to reduce enrollee cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, “provided that similarly situated enrollees (that is all enrollees who meet the identified criteria) are treated the same.” Currently, MA plans are required to offer all enrollees of the plan access to the same benefits at the same level of cost sharing (with the exception of plans participating in the agency’s MA Value Based Insurance Design (VBID) Model). CMS notes that this new interpretation would provide MA plans flexibility to vary supplemental benefits as well as premiums and cost sharing.

² See <https://www.cdc.gov/drugoverdose/pdmp/>

Under the proposal, MA plans must still ensure compliance with the statutory and regulatory non-discrimination requirements that prohibit plans from denying, limiting or conditioning the coverage or provision of a service or benefit based on health-status related factors. Specifically, the cost sharing reductions and targeted supplemental benefits must be for health care services that are medically related to each disease condition. To ensure compliance, CMS intends to monitor if a plan utilizes this flexibility for a large number of disease conditions while excluding other higher cost conditions, to make sure that “the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations.” The related Fact Sheet that CMS released along with the proposed rule states that the upcoming CY 2019 Call Letter “will address the operational details of this policy.”

We commend CMS for proposing to provide these new tools, and agree with the agency’s stated expectation that this flexibility will permit MA plans to better manage health care services, and improve care and outcomes for our most vulnerable enrollees. While we support adoption of these proposed changes, we have identified below several issues and related recommendations that we believe will further ensure the changes are implemented in a manner that best meets the needs of MA enrollees. We strongly encourage CMS to carefully consider these issues prior to finalizing the proposal.

- ***Beneficiary Communications.*** In an effort to ensure that individuals are provided with comprehensive information to make the most informed decisions about their health care coverage, we strongly recommend that the marketing and communication requirements and guidelines do not inappropriately restrict the ability of plans to provide key details, including to prospective enrollees, about benefits offered consistent with this new flexibility. We believe providing comprehensive information to support informed decision making is consistent with CMS’ stated priority to maintain and ensure beneficiary choice, and will play a critical role in how effectively this new benefit flexibility can positively impact the health care and outcomes of MA enrollees.
- ***Operational Guidance.*** As noted above, CMS intends to provide operational details regarding implementation of this new flexibility in the forthcoming Call Letter. We believe it will be important for MA plans to review and comment on the operational details and guidance before they are finalized, as these steps allow plans to provide the agency with feedback informed by practical experience and permits CMS to consider potential operational challenges before processes and guidance become final. We appreciate that CMS expects to provide a mechanism along these lines via the Call Letter process and look forward to the opportunity to comment. In addition, timely issuance of final bid-related guidance will be important to coordinate with and inform MA plan bid development processes, and we encourage the agency to issue all necessary guidance no later than release of the final Call Letter accordingly.

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100 and 422.101; Preamble pgs. 56361-56362)

CMS is proposing to revise the MA regulations at §422.100(f)(4) and (f)(5) and §422.101(d)(2) and (d)(3) to incorporate additional authority to permit the agency to make adjustments to the underlying data sources and methodology CMS uses to establish the annual maximum out-of-pocket (MOOP) limits for Medicare Parts A and B services, and to clarify and codify that CMS may use Medicare FFS data to establish the annual limits. CMS is not proposing changes to the MOOP limits at this time, but indicates that the proposed additional authority (i.e., to increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount, implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits, etc.), will provide the agency flexibility to annually adjust the mandatory and voluntary MOOP limits, as needed, based on changes in market conditions and to ensure the sustainability of the MA program and benefit options over time. In addition, CMS indicates that the agency's longer-term goal is to establish future MOOP limits based on the most relevant and/or available data, and may consider future rulemaking regarding the use of MA encounter cost data "to understand program health care costs and compare to FFS data in establishing cost sharing limits." Any changes to the MOOP limits under this proposed expanded authority would be communicated in advance of each plan year via the annual Call Letter and other guidance.

HCSC is firmly committed to ensuring our enrollees have access to quality care and benefits at an affordable cost, and we recognize the value of and support CMS' need to be afforded the appropriate level of flexibility to respond timely to changes in market conditions when determining annual MOOP limits. This is of particular importance as it relates to ensuring the sustainability of MA benefits offered to enrollees as well as the sustainability of the MA program more broadly. While we are generally supportive of the proposed changes and CMS' stated intent underlying the proposed changes, we strongly encourage the agency to ensure this additional flexibility is not implemented or utilized in a manner that would add more stringent requirements on benefits offered through MA plans than requirements in the Original Medicare program, thus impeding the ability of MA plans to effectively respond to market condition changes or diminishing the ability of beneficiaries to exercise their choice of enrollment in a plan that best suits their overall health care needs.

In addition, regarding the potential future use of MA encounter data in establishing cost sharing limits, CMS indicates in the Preamble on page 56362, that the agency "expects that MA encounter data will be more accurate and complete in the future" (emphasis added). We caution CMS to not move forward with future rulemaking that would seek to rely on use of these data to understand MA health care costs or to inform future policy regarding cost sharing and MOOP limits until the agency, in consultation with plans, is able to determine with

confidence that the data are sufficiently reliable (i.e., accurate and complete) for that purpose.

5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100; Preamble pgs. 56362-56363)

CMS is proposing to revise the MA regulations to clarify and codify that CMS may use Medicare FFS data to establish annual cost-sharing limits on Medicare Parts A and B services to prevent discriminatory benefit design. In addition, CMS is proposing to use MA utilization encounter data to inform patient utilization scenarios to help identify MA plan cost sharing standards and thresholds that are not discriminatory.

As noted in the comment above, CMS indicates in the Preamble on page 56362, that the agency “expects that MA encounter data will be more accurate and complete in the future” (emphasis added). We are concerned that CMS’ proposal to use these data to inform analysis before that time could potentially distort the agency’s understanding of MA enrollee utilization and result in potentially inaccurate assumptions on which CMS would rely as part of the agency’s efforts to evaluate cost-sharing standards and thresholds. To ensure accuracy, HCSC recommends that CMS refrain from moving forward with the proposal to utilize these data to inform patient utilization scenarios until the agency, in consultation with plans, is able to determine with confidence that the data would provide an accurate and complete picture of MA enrollee utilization and would be sufficiently reliable for that purpose.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256; Preamble pgs. 56363-56365)

Beginning with MA bid submissions for CY 2019, CMS is proposing to eliminate the “meaningful difference” requirement, under which approval of an MA organization’s bid is conditioned upon whether the plan is substantially different from those of other plans offered by the organization in the same service area with respect to certain characteristics (i.e., benefits, cost sharing, etc.). The agency believes it is challenging to apply the current standardized meaningful difference evaluation in a manner that accommodates and evaluates important considerations objectively, and is proposing this change “to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation.”

HCSC strongly supports the proposed change, which will provide greater flexibility to develop and offer innovative benefit designs that best meet the needs of our enrollees. In addition, we agree with CMS’ statement on page 56365 of the Preamble, that eliminating the meaningful difference requirement can permit organizations “to offer a portfolio of plan options with clear differences between benefits, providers, and premiums which would allow beneficiaries to make more effective decisions if the MA organizations are not required to change benefit and

cost sharing designs in order to satisfy” this standard. Accordingly, we recommend that CMS finalize the proposed change, and ensure the needed operational guidance is provided to plans as quickly as possible to support CY 2019 bid development and submission.

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68; Preamble pgs. 56365-56368)

- **“Default Enrollment.”** CMS proposes to significantly revise and codify the existing “seamless conversion” rules that permit individuals to be converted from a non-MA plan to an MA plan when the individual becomes Medicare eligible. Under the proposal, “default enrollment” (previously “seamless conversion”) would apply only to dual eligible beneficiaries (i.e., Medicaid managed care enrollees newly eligible for Medicare), who could be automatically enrolled into a Dual Eligible Special Needs Plan (D-SNP) operated by the same parent organization as the Medicaid managed care plan in which the beneficiary was enrolled. The default enrollment process would be subject to certain specified conditions, including: the state approves use of the default enrollment process and provides Medicare eligibility information to the MA organization; the MA organization provides an opt-out notice informing the beneficiary of their right to decline the deemed enrollment no later than 60 days prior to the effective date of the enrollment; the beneficiary does not decline or opt-out of the default enrollment; and CMS has approved the MA organization to use the default enrollment process before any enrollments are received.

HCSC agrees with CMS’ statement on page 56366 of the Preamble that the default enrollment option can be particularly beneficial for dual eligible individuals as it “promotes enrollment in a plan that offers some level of integration of acute care, behavioral health and, for eligible beneficiaries, long-term care services and supports.” While we support the proposed approach, we strongly encourage CMS to minimize complexity of the process, including to avoid deterring state interest in and ability to work with applicable plans to make this option available to beneficiaries. In addition, it will be of critical importance for CMS (in consultation with states, plans and other key stakeholders) to develop clear and concise implementation guidance, including to support timely and transparent communication to facilitate successful implementation. We note that timely, accurate and complete Medicare eligibility data from the state via the Medicare Modernization Act (MMA) file will be a key factor in ensuring operational success.

- **“Opt-In” Enrollment for Newly Medicare Eligible Beneficiaries.** CMS proposes to discontinue “seamless conversion/default enrollment” in all other instances, and instead establish a new and simplified process through sub-regulatory guidance that would be available to all MA organizations and would permit beneficiaries to “opt-in” to (“actively request”) MA coverage from non-

MA coverage (i.e., commercial, etc.) offered by the same organization. If CMS moves forward with finalizing this proposed approach, HCSC strongly recommends that the agency work in close collaboration with plans and other key stakeholders to develop requirements for the new streamlined process, and provide a meaningful opportunity for review and comment on the related operational guidance before it is finalized. We believe these steps will assist the agency in identifying and resolving any potential operational issues and/or challenges in advance of implementation. In addition, it will be important for CMS to ensure the requirements are developed and implemented in a manner that minimizes enrollee burden and provides a true “streamlined” pathway for eligible beneficiaries interested in utilizing the “opt-in” process.

8. Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g); Preamble pgs. 56369-56371)

CMS is proposing to revise the MA regulations at §422.60(g) to incorporate a limited expansion of the agency’s current authority to initiate passive enrollment for full-benefit dual eligible beneficiaries enrolled in an integrated D-SNP. Under the proposal, CMS could passively enroll eligible individuals into a different integrated D-SNP in instances where the agency determines, after consulting with the State Medicaid agency, that the individual’s integrated care coverage and continuity of care would otherwise be disrupted (e.g., non-renewals of the current D-SNP, state re-procurements of Medicaid managed care contracts). Passive enrollments would be permitted only when the receiving plan meets certain specified conditions. We are firmly committed to efforts to better integrate care for dual eligible beneficiaries and appreciate the role this limited expansion of CMS’ passive enrollment authority can play in advancing that goal.

For clarity and to facilitate a consistent understanding, we encourage CMS to ensure the criteria for plans to receive passive enrollments under this proposal and the steps the agency will take to determine whether those criteria have been satisfied are clearly communicated in any implementation guidance released by the agency. We also recommend that CMS consider making the following revisions to clarify the MA regulations at 422.60(g)(2)(ii):

“Have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the **immediately prior** plan (or plans) ~~from **in** which the beneficiaries are passively **were** enrolled.~~”

9. Part D Tiering Exceptions (§§ 423.560 and 423.578 (a) and (c); Preamble pgs. 56371-56373)

CMS is proposing to clarify and revise the regulatory requirements that establish how Part D enrollee tiering exceptions (i.e., enrollee requests to obtain an alternative non-preferred drug at the lower cost sharing terms applicable to drugs in a preferred tier), are to be adjudicated and effectuated. Specifically, the proposed revisions would establish rules that more definitively base eligibility for

tiering exceptions on the *lowest* applicable cost sharing for the tier containing the preferred alternative drug(s) for the treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels (e.g., "generic", "brand", etc.). The agency also proposes to clarify that an "alternative drug" for purposes of a tiering exception is a preferred drug (i.e., a drug on a lower cost sharing tier) that is appropriate in treating the condition as it affects the enrollee, "taking into consideration the individual's overall clinical condition, including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen."

- Illustrative Examples.** We appreciate CMS' clarification of what constitutes an alternative drug for the treatment of an enrollee's condition for Part D tiering exception purposes. To further ensure a consistent understanding and uniform implementation across all sponsors of this policy and the proposed clarifications and revisions to the tiering exceptions process more broadly, we recommend that CMS provide several examples that effectively illustrate the various steps of a tiering exception, including steps to determine the lowest applicable tier and appropriate "alternative" drug.
- Specialty Tiers.** CMS notes in the Preamble on page 56372 that the agency is proposing to add a definition of "Specialty Tier" to the Part D regulations at §423.560, and also proposes to clarify that "if the specialty tier has cost sharing more preferable than another tier, then a drug placed on such other non-preferred tier is eligible for a tiering exception down to the cost sharing applicable to the specialty tier if an applicable alternative drug is on the specialty tier" and all other applicable regulatory requirements are met. We note that currently, Part D sponsors may choose to designate one formulary tier as their Specialty Tier, on which Part D drugs with sponsor negotiated prices that exceed the dollar per month threshold established annually by CMS may be placed. However, in an effort to address changes in the prescription drug landscape, including the considerable impact of high-cost drugs on the Part D program (as noted by CMS throughout the Preamble discussion on this provision), as well as maintain an affordable and accessible Part D program for beneficiaries, HCSC continues to believe that CMS should permit sponsors to designate two separate specialty tiers, a preferred specialty tier with lower cost sharing and a non-preferred specialty tier.

As we have indicated previously, an approach along these lines could provide sponsors with greater leverage in negotiations with manufacturers for certain high-cost drugs, as well as encourage and increase competition among existing specialty drugs. In addition, as more biosimilar products are approved by the Food and Drug Administration (FDA), this two-specialty tier structure could encourage Part D enrollees to substitute lower-cost biosimilar products for the corresponding reference product. This could result in more affordable care for Part D enrollees and lower costs for the Part D program more broadly. As you know, in their June 2016 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended that CMS revise

their Part D guidance to allow for two specialty tiers, and indicated that if used appropriately, this tier structure could reduce the need for non-formulary exceptions as less cost-effective options could be placed on the non-preferred tier rather than excluded from the plan's formulary.³ HCSC continues to strongly recommend that CMS revise the Part D formulary tier model options to include an additional 6-tier structure that would allow for a preferred and non-preferred specialty tier as described above. We note that in conjunction with this recommendation, we also previously recommended that if this specialty tier option is permitted, CMS revise the tiering exception guidance to permit enrollees to obtain a 6th tier non-preferred drug at the 5th tier preferred drug cost sharing level when the 6th tier drug is medically necessary, and it appears that the agency's proposed clarification highlighted above would establish a pathway for such exceptions to occur.

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38; Preamble pgs. 56373-56375)

CMS is proposing to revise the Part D regulations at §423.38(c)(4) to limit the continuous special election period (SEP) that permits dual eligible and low-income subsidy (LIS) eligible individuals to make Part D enrollment changes throughout the year. Specifically, under the revised SEP, a beneficiary would have one opportunity to change plans per calendar year. In addition, a beneficiary may change plans (1) if they have been assigned to a plan by CMS or a state, in which case they may use the SEP before that election becomes effective, or within 2 months of their enrollment in that plan; or (2) if they experience a change in Medicaid or LIS-eligible status, in which case they may use the SEP to make an election within 2 months of the change, or of being notified of such change (whichever is later).

While we recognize the intent underlying CMS' proposed change, we are concerned that the proposal could inadvertently hinder continued progress toward achieving greater integrated care for dual eligible beneficiaries by limiting their ability to switch to an integrated plan option or to align enrollment with a corresponding Medicaid plan offered by the same plan sponsor. In addition, the continuous SEP is important to consumer choice in states where integrated care options through D-SNPs and MMPs are supported. We recommend that CMS revise the proposal to continue to extend the SEP to dual eligible beneficiaries for the purpose of moving to an integrated plan option, including for the purpose of aligning enrollment with a corresponding Medicaid plan offered by the same sponsor.

³ See MedPAC June 2016 Report to the Congress: Medicare and the Health Care Delivery System at <http://www.medpac.gov/-documents/-reports>

11. Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (Preamble pgs. 56375-56407)

- ***Guiding Principles (Preamble; 56377)***. CMS outlines a set of guiding principles the agency has used historically in making enhancements to the MA and Part D Star Ratings, and that CMS expects to use to guide future changes. We believe use of guiding principles in this manner helps to ensure and maintain the integrity and effectiveness of the Star Rating system, as well as assist plan efforts to set goals and work toward well-defined standards that clearly reflect CMS priorities. To further improve the utility of the guiding principles, we recommend that CMS incorporate an additional principle establishing that the measure cut-points should reflect meaningful differences in performance.
- ***Contract Consolidations (Preamble; 56380)***. CMS is proposing to establish and codify a new set of rules for how contract-level Star Ratings are calculated and assigned for consolidated contracts. Currently, CMS assigns the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place. However, the agency proposes to assign and display on Medicare Plan Finder (MPF), 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 involved in the consolidation. CMS would use this approach to calculate the Star Rating for the first and second years following consolidation. The agency also proposes a similar approach for calculation of related Quality Bonus Payment (QBP) ratings.

We believe this proposed revised approach to calculating Star Ratings for consolidated contracts results in a more accurate representation of plan quality and enrollee experience, which are both important factors for beneficiaries who rely on the Star Ratings for plan comparison purposes to make informed decisions about their health care coverage. In addition, the proposed approach aligns with several of CMS' principles for the Star Ratings system, including that ratings treat contracts fairly and equally. For these reasons, we recommend that CMS finalize the revised approach as proposed.

- ***Data Integrity (Preamble; 56394)***: CMS is proposing to codify the existing data integrity policy, under which a contract's measure rating is reduced to 1 star if the agency determines that the underlying measure data are incomplete, inaccurate, or biased. In addition, CMS is proposing a new rule to authorize scaled reductions in Star Ratings for the Part C and Part D appeal-related measures. Specifically, the proposed methodology would employ scaled reductions to account for the degree to which Independent Review Entity (IRE) data are missing, ranging from a 1-star reduction to a 4-star reduction, with a 4-star reduction being the most severe and resulting in a measure-level Star Rating of 1 star for the associated appeal measures. CMS plans to utilize findings from the agency's industry-wide appeals Timeliness

Monitoring Project (TMP) or audit data to inform the data integrity reviews and ultimately the scaled reductions, when applicable.

We believe the proposal to implement scaled reductions for the appeal measures is a reasonable approach that will permit CMS to consider the degree and severity of the issues identified, rather than a one-size fits all approach. In addition, we note that the TMP, which was first initiated in 2017, is still in the initial years of implementation. We continue to encourage CMS to ensure the agency and plans have had sufficient time to gain experience with the monitoring effort, to refine the approach and underlying processes as needed, and to ensure the data and approach are stable and appropriately reliable for data integrity purposes.

- **Measure Cut-Points (Preamble; 56399).** CMS is requesting comments on methods to determine measure cut-points, including comments on whether CMS should return to the agency's previous policy of establishing pre-determined 4-star thresholds for certain measures. The agency also requests suggestions on how to minimize generating Star Ratings that do not reflect a contract's "true" performance" (i.e., the risk of misclassifying performance).

HCSC continues to strongly encourage CMS to reinstate the previous policy of providing pre-determined 4-star thresholds under the Star Ratings system, which allows us to set goals, both internally and for our contracted providers, and to work efficiently toward well-defined standards that reflect key CMS priorities. Further, pre-determined cut points provide greater transparency in the Star Ratings system and facilitate our ongoing assessment of the effectiveness of our efforts to achieve or maintain the highest level of ratings.

We appreciate CMS' willingness, as noted in the Preamble, to consider methodologies to minimize year-to-year changes in the cut-points, which make it challenging for plans and our contracted providers to set goals and make progress toward achieving them. To address this concern, we recommend that CMS evaluate whether establishing measure cut-points based on industry performance over a period of time, rather than a specific point in time, results in improved stability by minimizing year-to-year fluctuations. In addition, to ensure that measure cut-points result in ratings that reflect meaningful differences in performance across contracts, we recommend that CMS evaluate whether establishing cut-points based on quadrants between whole stars (e.g., 3, 3.25, 3.5, 3.75) results in ratings that more accurately reflect distinctions in quality and performance. We also recommend that CMS make available to plans, the results of the agency's evaluation/analysis (and the underlying methodology applied), and provide a subsequent opportunity for further review of and feedback on proposed approaches.

- **Measure Weights (Preamble; 56401).** CMS is proposing to codify the agency's existing approach to weighting of Part C and Part D measures in the Star Ratings System, including assigning a weight of 5 to improvement measures, a weight of 3 to outcome and intermediate outcome measures, a weight of 1.5 to patient experience/complaints and access measures, and a weight of 1 for process measures. In addition, in the Preamble, CMS indicates that the agency is considering increasing the weight of patient experience/complaints and access measures and solicits comments on this potential change.

We continue to have concerns that measures based solely on survey data have the potential to yield unreliable results. For example, due to concerns raised about the reliability of using survey data for the Part C pneumococcal vaccine measure, in the 2018 Call Letter CMS indicated that the agency is exploring non-survey based methods "to assess pneumococcal vaccination status and guideline adherence." In addition, increasing the weight of these measures does not align with CMS' guiding principles for the Star Ratings System, which indicate that future measures for the system should be focused on health outcomes. For these reasons, we do not support increasing the weights of the patient experience/complaints and access measures and recommend that CMS maintain the current weights accordingly.

- **Categorical Adjustment Index (Preamble; 56404).** For the 2019 Star Ratings and beyond, CMS is proposing to continue the use of the interim analytical adjustment, the "Categorical Adjustment Index (CAI)," to account for the average within-contract disparity in performance associated with a contract's percentage of beneficiaries with low income subsidy and/or dual eligible (LIS/DE) and disability status. HCSC continues to believe that serving and enrolling a population comprised disproportionately of individuals with complex needs (including beneficiaries with LIS/DE and disability status), presents unique challenges that have not been accounted for in the Star Ratings System and are only minimally addressed by the CAI. While HCSC supports CMS' proposal to continue to apply the CAI to the Star Ratings, we look forward to working with the agency to develop a meaningful long-term approach and solution to these issues. To that end and as quickly as possible, we strongly urge the agency to establish and implement a framework to facilitate ongoing, transparent and collaborative efforts that would include CMS, plans and other key stakeholders, with the goal of developing a robust solution for implementation in future years.

12. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types (§§ 423.100 and 423.505; Preamble pgs. 56407-56411)

CMS is proposing to revise the Part D regulations at §423.100 to modify the definition of "retail pharmacy" and add a definition of "mail order pharmacy." The agency also proposes to revise §423.505 to codify existing guidance with respect to when a requesting pharmacy must be provided with a sponsor's standard

terms and conditions. Lastly, in the Preamble discussion, CMS proposes to clarify that the Part D “any willing pharmacy” requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business. The agency is proposing to take these steps “to ensure that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement.”

We recommend that CMS defer further consideration of these proposed clarifications and modifications until the agency engages in additional detailed discussions with Part D plan sponsors and other key stakeholders to permit CMS to understand the full range of sponsor experiences with these requirements. We believe this approach will permit the agency to better evaluate whether the proposed modifications and clarifications to the any willing pharmacy requirements are necessary and appropriate, while also ensuring CMS does not inadvertently restrict sponsors’ ability to establish and implement appropriate safeguards (e.g., quality, etc.) when developing pharmacy networks best suited to provide services to our Part D members, in accordance with CMS rules.

13. Changes to Days’ Supply Required by the Part D Transition Process (Preamble page 56411-56412)

CMS is proposing to revise the Part D regulations at §423.120(b)(3) to make a technical change to the current required days’ transition supply in the outpatient setting, from the current “30 days” to “a month’s supply”, and to shorten the required transition days’ supply in the long-term care (LTC) setting from between “91 to 98 days” to “a month’s supply”, consistent with the proposed technical change for the outpatient setting. CMS indicates that the agency is proposing the technical change to the required days’ supply in the outpatient setting in response to inquiries from sponsors regarding scenarios involving medications that do not easily add up to a “30 days” supply when dispensed (for example, drugs typically dispensed in 28-day packages).

We support the proposed change and agree that the clarification should help mitigate the challenges described above. However, we note that while the Preamble includes language on page 56412 indicating that “the supply would have to be for at least the days’ supply that the applicable Part D prescription drug plan has approved as its retail month’s supply in its Plan Benefit Package submitted to CMS for the relevant plan year” the agency is not proposing to incorporate similar language into the regulation text. HCSC recommends that CMS incorporate the language above into the relevant section of the regulation text to ensure clarity and to facilitate a consistent application of the agency’s policy across all Part D plan sponsors.

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120 and 423.128; Preamble pgs. 56413-56416)

CMS proposes to revise the Part D regulations to provide sponsors additional flexibility to implement generic substitutions, including by permitting sponsors to immediately substitute or add newly approved therapeutically equivalent generic drugs to the formulary, and remove or change the preferred or tiered cost sharing of the corresponding brand name drugs. The proposed revisions also would permit sponsors to make these changes at any time of the year, and reflect additional beneficiary protections, including to address safety and transparency concerns. We appreciate and support the additional flexibility, and recommend that CMS finalize the proposed changes accordingly.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing (Preamble pgs. 56416-56417)

Page 56417 of the Preamble indicates that follow-on biological products are subject to the higher Part D maximum copayments for LIS beneficiaries and non-LIS beneficiaries in the catastrophic portion of the Part D benefit. However, CMS is proposing to revise the definition of a generic drug at §423.4 to include follow-on biological products, although the proposal to treat these products as generics is limited to purposes of non-LIS catastrophic cost-sharing and LIS cost sharing only. CMS is proposing this change in an effort to lower cost sharing for these drugs to incentivize enrollees to choose follow-on biological products over more expensive reference biological products, and to reduce costs to both Part D enrollees and the Part D program. We support CMS' goal of incentivizing use of lower cost biological products and reducing costs for Part D enrollees and the Part D program overall. We note that the Regulatory Impact Analysis on page 56488 of the proposed rule estimates that this proposed change would provide savings of \$10 billion in 2019, with savings increasing by approximately \$1 million each year through 2028. Accordingly, we recommend that CMS finalize the change to the regulatory definition of a generic drug as proposed.

16. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences (§§ 423.265; Preamble pgs. 56417-56419)

Effective for CY 2019, CMS is proposing to revise the Part D regulations at §423.265 to eliminate the stand-alone Prescription Drug Plan (PDP) Enhanced Alternative to Enhanced Alternative (EA to EA) meaningful difference requirement, under which two EA plans offered by the same parent organization in the same region must provide different and distinct coverage options determined by specific threshold differentials that are established by the agency on an annual basis. We note that CMS is proposing to maintain the current requirement that EA plans must be meaningfully different from the basic plan offered by a sponsor in a service area. However, the agency intends to reexamine in the future, how CMS defines the meaningful difference requirement

between basic and EA plans, including investigating whether the current Out-of-Pocket-Cost (OOPC) model or an alternative methodology should be used to evaluate differences. CMS plans to seek stakeholder input on this topic as part of that process.

HCSC strongly supports the proposal to eliminate the PDP EA to EA meaningful difference requirement, and we agree with CMS' assessment that the proposed revisions will strike an appropriate balance between encouraging competition and plan flexibilities, while still providing PDP choices to beneficiaries that represent meaningful choices in benefit packages. In addition, we appreciate that CMS intends to reexamine how this requirement is defined between basic and EA plans in the future and whether the OOPC model or another alternative should be used in the evaluation. We look forward to the opportunity to provide input on these topics and potential future improvements.

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale (Preamble pgs. 56419-56428)

HCSC is firmly committed to providing high-quality coverage, care and services to our members and to ensuring an affordable and accessible Medicare Part D program for our enrollees and taxpayers more broadly. That commitment includes working together with CMS to address issues that pose challenges to achieving these goals and that threaten the continued success of Part D, including in more recent years, challenges resulting from the considerable impact of high-cost drugs, including the increased market entry of new high-cost drugs, on the program.

CMS has included in the proposed rule, a Request for Information (RFI) that discusses considerations related to and solicits comment on potentially requiring Part D plan sponsors to reflect in the price of a covered Part D drug at the point-of-sale, at least a minimum percentage of manufacturer rebates and all pharmacy price concessions negotiated by the sponsor or their contracted pharmacy benefit manager (PBM). CMS indicates that feedback received in response to the RFI will be used for consideration in future rulemaking on this topic.

We appreciate that *before* taking steps to pursue policy changes related to the potential application of manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale, CMS utilized the RFI process to solicit feedback from stakeholders as an initial step to inform future rulemaking. However, we are seriously concerned that the RFI does not provide sufficient opportunity or the most appropriate framework to facilitate consideration of these issues at this time, given their complexity, the vast scale and scope of the topics on which CMS is seeking feedback, the significant time and resources required to conduct the detailed actuarial and other analyses of these issues, and most importantly, the desire of the agency, sponsors and other key stakeholders to ensure the

ideas evaluated would provide the most appropriate path forward for the Part D program and the members we serve. We are particularly focused on avoiding any path that could potentially result in unintentional consequences for our members and the program, and impede our ability to perform in a manner that best serves Part D program goals. Specifically, it will be of critical importance to avoid pathways that could lead to increasing overall beneficiary out-of-pocket and government costs, decreasing manufacturer liability (i.e., in the coverage gap), compromising proprietary details of pricing arrangements and significantly stifling competition under Part D; creating operational, resource, compliance and administrative challenges for sponsors and our contracted PBMs; creating barriers to preserving beneficiary choice; and causing the Part D program to function in a less efficient and effective manner. CMS also acknowledges many of these issues as potential concerns throughout the RFI discussion in the Preamble.

In addition, to further highlight challenges associated with utilizing this RFI as the vehicle for consideration of these issues, we note that the proposed rule in which the RFI is included contains nearly forty provisions impacting the MA and Part D programs, which required careful review and detailed analysis to support our efforts to provide meaningful and actionable feedback to CMS.

As a result, we believe a more appropriate and reasonable approach to facilitate sufficient opportunity and time for careful consideration of these issues and their underlying causes, would be for CMS to establish a separate stand-alone process and framework outside of the proposed rule that better supports the conversations and analytical work that must occur to best inform the agency's potential future direction in this area. We envision that a stand-alone process and framework could include CMS facilitated multi-stakeholder discussions, listening-sessions, and an expanded opportunity (similar to the RFI) to provide feedback. In addition, we emphasize the need for this process and framework to be stand-alone for maximum benefit and note that utilizing other vehicles, such as the forthcoming draft Part C and Part D Call Letter, would pose timing and resource challenges similar to the RFI contained in this proposed rule. It also will be important for CMS to take into consideration the broader issue of increasing drug prices in the prescription drug marketplace overall and the need for solutions that are not limited to the Part D program or health plans to effect meaningful change.

B. Improving the CMS Customer Experience

2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504; Preamble pgs. 56429-56431)

CMS is proposing to revise the MA and Part D regulations to eliminate the requirement for plan sponsors to provide compliance training to first-tier, downstream and related entities (FDRs). The agency believes this proposed change will allow sponsoring organizations and the FDRs with which organizations are contracted, “the maximum flexibility in developing and meeting

training requirements associated with effective compliance programs.” HCSC supports this proposed change and appreciates CMS’ interest in reducing the burden of the training requirement. We recommend that as CMS updates the Compliance Program Guidelines (i.e., Chapter 9 of the Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual), and the relevant Audit Protocols to reflect these changes, that the agency provide a meaningful opportunity for plans to review and comment on revised draft versions of these important guidance documents before they are finalized.

4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111, and 423.128; Preamble pgs. 56431-56433)

CMS is proposing to separate the delivery date of the Annual Notice of Change (ANOC) from the Evidence of Coverage (EOC), by requiring that plans provide the EOC and other specified disclosure materials by the first day of the annual enrollment period, rather than 15 days before. In addition, CMS proposes to permit plans to provide certain materials, such as the EOC, Summary of Benefits, and provider and pharmacy directories electronically (e.g., via posting on a website) instead of in hard copy, although hard copy materials must be available and provided “upon request.”

HCSC appreciates and supports the proposed change to the EOC delivery timeline, which provides an additional two weeks for plans to prepare, review, conduct quality assurance checks, and ensure the accuracy of these materials. We also support the agency’s proposal to permit greater flexibility for plans to provide certain materials electronically, which improves the ability of enrollees to more easily navigate these documents (e.g., due to word search functionality, ability to magnify text, etc.). The proposed change also reduces administrative burdens, particularly due to the reduced time, effort and cost of not producing and mailing these materials to all enrollees. Our understanding is that if finalized, CMS expects to implement these proposed changes for CY 2019 (in 2018). For clarity, we request that CMS confirm whether our understanding is accurate. In addition, we strongly recommend that the agency issue any related operational guidance as quickly as possible after the rule is finalized to ensure plans have the information needed to comply with CMS’ disclosure requirements in a timely manner.

5. Revisions to §§ 422 and 423 Subpart V, Communications/Marketing Materials and Activities (Preamble pgs. 56433-56437)

CMS is proposing several changes to the MA and Part D regulations, including changes to narrow the definition of “marketing” and the scope of materials that fall under that definition, and to establish and incorporate a definition of “communications” intended to address the current regulatory void regarding requirements that pertain to beneficiary materials that are not marketing-related. HCSC supports CMS’ proposed efforts to clarify and more effectively distinguish marketing materials and related activities from more general beneficiary

communication materials and related activities. Our understanding is that if finalized, CMS expects to implement these proposed changes for CY 2019 (in 2018). For clarity, we request that CMS confirm whether our understanding is accurate. In addition, we strongly recommend that the agency issue any related operational guidance as quickly as possible to ensure plans have the information needed to comply with CMS' disclosure requirements in a timely manner.

To facilitate implementation of these proposed changes, and to ensure a consistent understanding across all plans, we recommend that as quickly as possible after the rule is finalized CMS provide comprehensive sub-regulatory guidance that clearly outlines the requirements that would be applicable to materials categorized as communications, and includes an exhaustive list of materials categorized as marketing. If time permits, we recommend that CMS provide an opportunity for review of and comment on a draft version of the operational guidance before it is finalized.

6. Lengthening the Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636; Preamble pgs. 56437-56438)

CMS is proposing changes to the adjudication timeframe for Part D standard redetermination requests for payment at §423.590(b) and the related effectuation provisions at §423.636(a)(2). Specifically, the agency proposes to change the timeframe for issuing decisions on 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. HCSC firmly believes an extended opportunity for sponsors to obtain the needed documentation to support payment redetermination requests has the potential to reduce the need to deny payment redetermination requests due to missing information and result in more fully informed decisions. HCSC supports this proposal and recommends that CMS finalize the changes accordingly.

9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§ 422.502 and 423.506; Preamble pgs. 56440-56441)

CMS is proposing to reduce the look-back period, from 14-months (i.e., January 1 through February 28 of the following year) to 12-months (i.e., March 1 through February 28 (or 29 in a leap year) of the following year), for which a contract's prior performance is reviewed for purposes of the Application Cycle Past Performance Review methodology. HCSC appreciates and supports the proposed change, which mitigates the potential for certain instances of non-compliance to be "double-counted" if those instances occurred in January or February of a given year. To further refine the methodology, we recommend that CMS consider establishing the 12-month review period as a calendar year review, that is, from January 1 through December 31 of the year preceding the application submission deadline.

10. Preclusion List – Part D Provisions (§423.100, §423.120; Preamble pgs. 56441-56447); and

11. Preclusion List – Part C (§422.2, §422.222; Preamble pgs. 56447-56454)

CMS is proposing to revise the Part D regulations at §423.120(c)(6) to eliminate the requirement that prescribers of Part D drugs must enroll in or opt out of Medicare for a pharmacy claim (or beneficiary request for reimbursement) for a Part D drug prescribed by the individual to be covered under Part D. The agency also proposes to eliminate a corresponding definition of “other authorized providers” from §423.100. To replace this requirement, CMS is proposing instead to require sponsors to reject claims for Part D drugs prescribed by individuals identified by CMS as “demonstrably problematic prescribers” (e.g., prescribers recently convicted of a felony that CMS determines is detrimental to the best interest of the Medicare program, prescribers whose reenrollment bars have expired, etc.) who will be included on a new “preclusion list,” that would be created and maintained by the agency. CMS is proposing to maintain, but revise, the requirement that sponsors furnish beneficiaries with a provisional supply of a drug and related notice upon receipt of a pharmacy claim (or beneficiary request for reimbursement) for a drug prescribed by an impacted prescriber.

We also note that CMS is proposing to make similar revisions to the MA regulations at §422.222 that would eliminate the requirement for contracted providers and suppliers that furnish health care items or services to an MA enrollee, to be enrolled in or opted out of Medicare in an approved status. The agency is proposing instead to require that an MA organization may not make payment for an item or service furnished by an individual or entity identified by CMS as “demonstrably problematic prescribers” who will be included on the new “preclusion list,” referenced in the Part D discussion above.

HCSC has expressed long-standing concerns that the Part D prescriber enrollment requirement could result in unintended beneficiary access issues and pose significant operational and timing challenges for implementation. We appreciate that CMS is taking further steps to address these concerns and to reduce the overall burden of this requirement as well as the related provider enrollment requirements under MA, on beneficiaries, prescribers and Part D plan sponsors. We strongly support CMS’ proposal to eliminate the Part D prescriber and Part C provider enrollment requirement, and to replace these requirements with more streamlined and targeted risk-based approaches. We have identified issues and related recommendations below intended to assist CMS efforts to further refine the agency’s approach.

- ***OIG Exclusion List.*** We recommend that CMS clarify whether and how the proposed “preclusion list” relates to the exclusion list maintained by the HHS Office of Inspector General (OIG) that Part D plan sponsors are required to review to identify providers excluded from participation in Medicare and deny claims written by these prescribers accordingly.

- **Operational Guidance.** We recommend that CMS develop and provide as quickly as possible, draft operational guidance with a meaningful opportunity for review and comment. Guidance should include details on implementation of the preclusion list, related beneficiary communications and other key issues. As always, to support successful implementation and compliance with CMS requirements, we would appreciate receiving *final* guidance as far in advance of the implementation effective date as possible, but no later than 6-9 months prior to that time.

12. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152; Preamble pgs. 56454-56455)

CMS is proposing to eliminate the regulatory requirement for MA organizations to develop and implement Quality Improvement Projects (QIPs), due to the agency's determination that the QIP is duplicative of activities MA organizations already have underway to meet other program requirements and beneficiary needs. MA organizations would continue to be required to develop and implement Chronic Care Improvement Programs (CCIPs), and the proposed removal of the QIPs would allow organizations to focus on this single project that supports improving management of chronic conditions, as well as reduce duplication with other initiatives. We support this change and recommend that CMS finalize the proposal accordingly.

In addition, we recognize that pending the outcome of this proposed change, CMS is taking interim sub-regulatory steps to streamline QIP and CCIP reporting requirements and reduce burden on both MA organizations and the agency (i.e., for reporting associated with 2018 QIPs and CCIPs). Specifically, CMS is transitioning to an annual attestation process (replacing the annual requirement for submission of CCIP and QIP progress reports) and requiring only a subset of organizations (no more than 5 annually) to upload information about the results and status of each program. We appreciate these interim steps and encourage CMS to continue to evaluate whether any additional steps can be taken for 2018 QIPs and CCIPs to further streamline reporting and reduce burden.

13. Reducing Provider Burden—Comment Solicitation (Preamble pgs. 56455-56456)

In the Preamble discussion on pages 56455 to 56456, CMS indicates that the agency is exploring ways to reduce burden on providers arising from requests for medical record documentation by MA organizations, particularly in connection with MA program requirements, and is interested in stakeholder feedback on this topic, including "ideas to address the burden." While we appreciate and generally support the agency's commitment to reducing provider burden where possible, we strongly encourage CMS to ensure that these efforts are appropriately balanced with supporting the important purposes for which medical records are needed and do not inadvertently impact the ability of MA organizations to comply

with key CMS program requirements (e.g., submission of diagnoses data for risk adjustment purposes, etc.).

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§422.2420, §423.2430; Preamble pgs. 56456-56460)

CMS is proposing to significantly reduce the amount of Medical Loss Ratio (MLR) data that MA organizations and Part D plan sponsors are required to submit to CMS on an annual basis. In addition, the agency is proposing to revise the MLR calculation to include in the numerator, expenditures related to fraud reduction activities (including fraud prevention, fraud detection, and fraud recovery) and Medication Therapy Management (MTM) programs. CMS indicates in the Preamble on page 56457, that the agency is proposing these rules because “limiting or excluding amounts invested in fraud reduction undermines the federal government’s efforts to combat fraud in the Medicare program, and reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide.” We agree and support the proposed changes.

7. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e); Preamble pg. 56465)

CMS is proposing to revise the MA and Part D regulations to eliminate provisions that limit the actions MA organizations and Part D plan sponsors are able to take when they discover that a previously licensed agent/broker becomes unlicensed. Specifically, plans are currently required to terminate any employed agent/broker who becomes unlicensed; however, CMS believes sponsors should have the flexibility to determine the level of disciplinary action to take against agents/brokers in these instances. We agree and support this proposed change, and recommend that CMS finalize the proposal accordingly.

We appreciate the opportunity to comment. If you would like additional information or have questions about our feedback, please contact me at 202-249-7214 or Dana_Mott-Bronson@hcsc.net.

Sincerely,



Dana Mott-Bronson
Divisional Vice President, Health Policy – Government Programs