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Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-4182-P P.O. Box 8013 Baltimore, MD 21244-8013

RE: File Code CMS-4182-P

Filed Electronically: www.regulations.gov

Dear Sir/Madam:

Thank you for this opportunity to offer our comments on the *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 proposed rule.* HealthPartners is a not-for-profit plan sponsor and has participated in the Medicare Program since 1984. We hold five contracts with the Centers for Medicare & Medicaid Services (CMS): H2422 (MA FIDE SNP), H2462 (1876 Cost), H3416 (MA-PD PPO), H4882 (MA-PD PPO), and S1822 (Employer Group only PDP).

HealthPartners is an integrated care delivery system and is driving change that helps our members live healthier lives at lower costs. Through our unique wellness programs, innovative provider payment approaches which incent and reward quality, and convenient member tools and services, we are able to provide better value for our members. By partnering with providers, members, purchasers, and the community, we are leveraging our capabilities to develop initiatives which improve health, member experience, and affordability.

We welcome this opportunity to offer our perspective on provisions in the proposed rule. The overall direction CMS is taking will provide plans much needed regulatory flexibility and relief of unnecessary and outdated requirements.

#### **COMMENTS**

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

**1.** Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (Sec. II.A.1, page 56340). HealthPartners supports a number of components of CMS' proposed approach to implementing the CARA provisions including:



- Use of existing Medicare overutilization drug management tools, including the OMS, in the proposed program.
- Use of the current 2018 drug utilization requirements as a foundation; for example, continuing use of the OMB to identify potential at-risk beneficiaries.
- Initial limitation to opioids only and expanding the drugs in the program in future years.
- Use of the excluded exempted beneficiary categories and encourage CMS to expand to include end-stage congestive heart failure and end-stage COPD.

HealthPartners participates in the Minnesota Senior Health Options (MSHO) program, a Dual Special Needs Plan (D-SNP) that is subject to the State Medicaid Restricted Recipient guidelines. We have a robust program in place to manage drug over utilizers under this program and that experience is included in the recommendation below.

**Recommendation:** In finalizing the proposal, CMS consider the following feedback:

## A. Limitations on Access to Coverage for Frequently Abused Drugs.

- CMS implement a shorter waiting period (1 to 3 months) for prescriber lock-ins instead of the proposed 6 month timeframe. The lock-in tools should be applied as soon as confirmation is made with prescribers after completing the case management outreach but not waiting longer than 3 months. The at-risk status can be verified in much less than 6 months. Identified beneficiaries would benefit from immediate case management and the ability to apply lock-in tools. Conversely, 6 months is enough time for a beneficiary to submit requests for opioids during this time period rather than be identified and brought into the program sooner.
- Clarify how plans are to process requests for opioids for a member who is locked-in for two scenarios:
  - First, emergency situations when the member cannot use their designated pharmacy and/or prescriber.
  - Second, a request coming from a prescriber that is not aware of the beneficiaries lock-in status.

CMS provide additional information if these scenarios should be treated as exception requests, denied, or a one-time approval in cases of an emergency (e.g., emergency room visit).

- B. Case Management, Clinical Contact, & Prescriber Verification. CMS allow plans to reach out to the beneficiary as a new member and to their prescriber and confirm criteria for case management under the plan's program. This is needed because certain state privacy laws are more restrictive than Federal law and the plan cannot reach out to a prior plan to confirm at-risk status and obtain case management program details.
- C. **Chain Pharmacies and Group Practices.** CMS re-evaluate the use of TINs and offer another more feasible option. Many PBMs do not have the ability to identify prescribers with the same TIN as one prescriber or one pharmacy.



- D. **Fully Integrated D-SNPS.** CMS provide additional flexibility to dual-eligible plans already participating in State Medicaid overutilization management programs. Specifically, allow plans participating in the MSHO program to continue to follow the MN State Medicaid guidelines and have flexibility to include parameters of the CMS program that are not duplicative and add additional value to the oversight of this population of beneficiaries. Having to comply with two programs would lead to confusion among case managers, the care team, and members, especially when there are different timeframes, case management requirements, and beneficiary communication requirements. Additionally, with MSHO and D-SNPs, there is precedent to follow Medicaid and merge requirements in the integrated appeals process currently in place.
- **2.** Flexibility in the Medicare Advantage Uniformity Requirements (Sec. II.A.2, page 56360). HealthPartners strongly supports CMS' new interpretation of Federal law so plans can reduce and eliminate barriers to health care for those members who meet certain objective clinical criteria.

**Recommendation:** CMS ensure in future marketing guidance no member confusion regarding member eligibility and a level playing field with plans participating in the VBID program. This includes no marketing of reduced cost sharing or other benefit flexibility until post-enrollment and plan identification of eligible individuals. This will reduce member confusion as well as adverse selection concerns. In addition, CMS expand this flexibility and rewards and incentives to Part D benefits. We are not aware of any regulatory constraints that would prohibit this. Expansion would support a more comprehensive and holistic approach of medical and Part D coverage.

**3. Segment Benefits Flexibility** (Sec. II.A.3, page 56361). CMS' proposed flexibility in benefits rules applicable to plan segments supports a more efficient bid process.

**Recommendation:** CMS clarify in sub-guidance that plans are allowed to display multiple segments in the Evidence of Coverage, Summary of Benefits, and other coverage documents. This further supports efficiencies that segmentation provides to the bid process and coverage documents.

**4.** Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (Sec. II.A.4, page 56361) and Cost Sharing Limits for Medicare Parts A and B Services (Sec. II.A.5, page 56362). HealthPartners supports CMS' proposal to use Medicare Fee-for-Service data to establish annual MOOP limits and cost-sharing thresholds. However, we do not support the use of MA encounter data to establish these limits due to the continuing challenges and issues associated with the Encounter Data System (EDS). It would be premature to use data that is incomplete and not validated.

**Recommendation:** CMS delay the use of MA encounter data to establish MOOP or cost sharing limits until the EDS and related data issues are completely resolved.

**5.** Coordination of Enrollment/Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (Sec. II.A.7, page 56365). HealthPartners supports CMS' proposal to codify the seamless conversion rules. However, CMS should not limit by plan type and instead make it available to all plan types. We believe CMS' concerns can be addressed with other consumer protections



such as improved education, clearer advance notification about the conversion, and information on other coverage options. In addition, we do not support the proposed "opt-in" election process as a substitute for seamless conversion. It does not reduce the burden on plans and CMS can leverage current systems to exchange information with plans including the Medicare Beneficiary Identifier (MBI).

**Recommendation**: CMS reinstate the original seamless conversion policy to apply to all plan types and work closely with plans to enhance the process to address consumer protections. Furthermore, CMS leverage current systems to exchange information with plans to facilitate enrollments, including the MBI.

In regards to default enrollments into D-SNPS, CMS take into account current state processes and guidance to ensure requirements do not negate state ability to work with qualified plans to provide options to beneficiaries.

**6. Part D Tiering Exceptions** (Sec. II.A.9, page 56371). Generally, HealthPartners supports the change and supports further adjustment to the tiering exception process based on how plans structure Part D benefits and formularies.

**Recommendation:** CMS consider the following points in finalizing this section.

- A. CMS further clarify "alternative" drug. HealthPartners interprets "alternative drug" to mean a drug that is the same therapeutic class and dosage form. For example, the drug a member is asking for is in liquid form because they have trouble swallowing. All alternative drugs are tablets. Under this interpretation, would the plan approve a liquid form? Or would the plan deny because the only alternatives are in tablet form? Our interpretation is the plan would deny the tablet form.
- B. CMS allow tiering exceptions to be made to drugs in a specialty tier when it is a lower cost alternative to a drug on lower tier (e.g., non-preferred). For plans that file a 30-day supply for the specialty tier that CMS continue to allow the 30-day supply for tiering exceptions made for specialty drugs given the drug in the lower tier would be available for up to a 90-day supply.
- **7.** Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (Sec. II.A.10, page 56373). HealthPartners appreciates and supports the change to the SEP policy, as it would allow for continuity of care for the dually eligible population.

**Recommendation:** CMS allow for dual eligible beneficiaries not currently enrolled in a D-SNP, FIDE SNP, or MMP and who qualify to enroll in one of these plans for any month, not just during open enrollment or upon initial eligibility of dual status. This would enable dually eligible beneficiaries not currently enrolled in an integrated program to access these programs while still ensuring continuity for beneficiaries already enrolled in an integrated product.

**8.** Medicare Advantage and Prescription Drug Program Quality Rating System (Sec. II.A.11, page 56375). HealthPartners strongly supports the proposal to codify the Star Ratings System including the



methodology, measures and data collection. We believe this will bring more stability and predictability to the program. Our recommendations to CMS' proposal are organized around the topics CMS is interested in receiving stakeholder feedback.

A. Opportunities to improve measures to further reflect quality of health outcomes. HealthPartners continues to strongly believe that survey measures such as the Health Outcomes Survey (HOS) measures that are self-reported and are not objectively reflective of health outcomes. Furthermore, it is inappropriate to assign self-reported measures the weight of 3x and we do not support increasing the weight of measures that are self-reported. The HOS questions related to these measures are based on members' experiences and thus should be categorized as experience measures. Members may be receiving appropriate health care services; however, their responses regarding their physical health and mental status are based on experience and personal benchmark rather than on medical measures of functionality. Self-reported survey responses are often affected by the beneficiaries' feelings at the time they fill out the survey. For example, if a member doesn't feel well at the time s/he fills out the survey, the response tends to be more negative. If the person feels good at the time, then the response tends to be more positive.

#### **Recommendation:**

- CMS eliminate the HOS-based measures for star ratings because the information obtained from the surveys is not actionable. As an alternative, if CMS is not ready to remove all HOS measures from the star ratings, we recommend that two measures C04: Improving or Maintaining Physical Health and C05: Improving or Maintaining Mental Health be weighted as experience measures at 1x. These are too generic for star ratings and are not true outcomes measures.
- CMS work with industry on the development, testing and refinement of patient-reported outcomes measures, recognizing the difficulty in constructing reliable measures.
- **B. Establishment of cut points.** The current methodology for establishing cut points allows for large year-over-year changes (up or down) when there is relatively little change in the distribution of scores. This is contrary to CMS goals of stability over time and putting improvement in ratings under the control of the plan. Also the measure cut points need to reflect meaningful differences in plan performance.

**Recommendation:** CMS implement the following changes:

- Set caps to the range of cut point changes to limit volatility.
- Set predetermined cut points so plans and providers have targets to strive for.
- Retire measures when there are 1 percentage point differences in the same direction between cut points year over year (e.g., 3 years).
- **C. Measurement of overall improvement across measures.** We support the use of improvement measures but not the weighting of 5x. This higher weighting diminishes the value and importance of clinical measures and misleads beneficiaries about which are the highest quality health plans.

In addition, the application of both Part C and Part D improvement measures penalizes plans that have significant gains in one Part of Medicare. Allowing for the inclusion of either the Part C or Part D improvement measure acknowledges and rewards a plan's improvement and is a reasonable extension and application of CMS' hold harmless provision.



**Recommendation:** CMS implement the following changes:

- Reduce the weight of improvement measures to 3x.
- Allow for the inclusion of either the Part C or the Part D quality improvement measure if including only one of the measures would improve the plan's overall score.
- Correct Appendix 1 Improvement Measures (Part C & D) so measures Getting Needed Care and Customer Service reflect they are not included in the Improvement Measure.
- **D. Categorical Adjustment Index (CAI).** The CAI was intended as an interim adjustment to account for disparities in a plan's performance associated with social economic status tied to contract level enrollment of LIS/dual individuals and disabled individuals. As CMS has noted the CAI has had minimal impact on plan star ratings and we have experienced firsthand a negative adjustment that lowered our overall star rating from 5 stars to 4.5 stars. CMS should not penalize high-performing plans for lower population of LIS/dual individuals and disabled individuals.

**Recommendation:** CMS not codify the CAI and continue work on a long-term solution. In addition, CMS recalibrate the CAI so that the lowest adjustment is zero and the maximum adjustment is increased accordingly. Alternatively, CMS hold plans harmless from reductions in star ratings due to the CAI.

**E. Non-substantive updates to measures.** Non-substantive changes to reporting requirements involve advance evaluation, planning and implementation. Plans and their partners need sufficient time to prepare for the changes.

**Recommendation:** CMS announce any changes to measures prior to the measurement period so plans have an opportunity to make changes/updates to internal processes.

**F.** Adding measures that evaluate quality from the perspective of adopting new technologies. HealthPartners does not support this concept. The use of new technology does not directly correlate to high member satisfaction or high plan performance. It is more reflective of the geography and make-up of the plan membership. It does not align with the goals CMS has set for the star ratings program.

**Recommendation:** CMS not add measures related to new technologies.

**G. Including survey measures of physicians' experiences.** It's been our experience that physicians have a hard time differentiating between health plans. They concentrate on the patient and providing care, not which plan the patient is covered under. In addition, we are concerned with the burden on physicians if they are required to complete a survey for every contracted plan. Plus we are concerned about potential bias in responses given it is difficult for physicians to distinguish plan types and contracting entities. This type of survey doesn't fit under the stars methodology of quality of care for the member.

**Recommendation:** CMS not include survey measures of physicians' experiences. Instead CMS provide beneficiaries a standardized provider compare tool.

**9.** Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (Sec. II.A.12, page 56407). While it is important to be timely and responsive to a requesting pharmacy, a two



business day response timeframe is not adequate for addressing questions, follow ups, or other unexpected circumstances. More time is allowed in many other Part D beneficiary-related requirements involving timeframes to process coverage requests that impact beneficiary health and well-being.

**Recommendation:** CMS extend the timeframe to provide the standard terms and conditions to five business days upon receipt of the request. This is a reasonable amount of time for this type of request and is not more restrictive than other requirements and timeframes that directly impact beneficiaries.

**10.** Changes to the Days' Supply Required by the Part D Transition Process (Sec. II.A.13, page 56411). HealthPartners supports CMS alignment of the transition days' supply for LTC and outpatient settings. However, it is not clear that the "months' supply" corresponds to the number of days filed in the Plan Benefit Package (PBP) under retail month's supply. Furthermore, it is not clear that employer group waiver plans follow the group's benefit design and retail month's supply.

**Recommendation:** CMS modify the regulation to include the supply is at least the days' supply approved by CMS as the retail month's supply in the PBP or for EGWP's, the group's benefit design for retail month's supply.

**11. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes** (Sec. II.A.14, page 56413). HealthPartners appreciates CMS' proposal to enable plans to immediately substitute newly released equivalent generics for brand name drugs at the same or lower cost sharing, if they meet revised requirements.

**Recommendation:** CMS provide plans the opportunity and adequate time to evaluate the generic drug and consider cost, availability, and other factors before substituting newly released equivalent generics. Plans need flexibility to add the generic to their formularies when they believe it is appropriate and practicable.

**12.** Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale (Sec. II.A.17, page 56419).

Pharmacy price concessions at point of sale. Performance-contingent pharmacy payment arrangements have become a highly contentious issue between pharmacies and PBMs, and as an integrated care delivery organization that owns our own pharmacies, HealthPartners has experience as both a plan and a pharmacy. These arrangements that involve recouping sums from network pharmacies after the point of sale for "poor performance" relative to standards defined by the PBM result in lack of price transparency, allow unfair competitive advantages to certain plans based on technical differences in how costs are reported, and shifts costs to beneficiaries and taxpayers.

The simplest and most direct way to address this matter is for CMS to amend the definition of "negotiated prices" at §423.100 to eliminate the reasonably determined exception and require all pharmacy price concessions to be applied at point of sale.



To achieve this, HealthPartners supports requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a Part D drug. Any additional amounts (bonus payments) that could flow to network pharmacies would be reported as negative DIR.

We believe this approach supports price transparency and a level playing field amongst plans. Also it helps to eliminate concerns that Part D sponsors have been effectively gaming the Part D reimbursement system to shift drug costs to beneficiaries, drug manufacturers, the government and tax payers.

## Manufacturer rebates at point of sale.

HealthPartners appreciates the opportunity to provide input on how to design a policy to require the pass through at the point of sale (POS) manufacturer rebates. In theory, CMS' proposed methodology to calculate the average rebate amount applied at the POS makes sense; however, we have significant concerns with how it would work and don't believe it addresses the core issue — **high cost drugs and increasing drugs prices**. There is increasing lack of affordability of many Part D drugs for members, plans, and the federal government, and CMS' projections of the financial impact of the proposed point of sale policy include higher beneficiary premiums, increased government spending and increased revenues for drug manufacturers. These financial effects combined with administrative complexities and operational burdens on plans has given us great pause in supporting this approach. Below is an outline of our concerns.

- Administrative burden. Today's rebate process is quite complex and there are significant challenges to apply rebates at the point of sale.
  - Rebates are challenging to project accurately. They are dependent on a number of factors including achieving certain product utilization targets. Contracts with drug manufacturers are updated numerous times over the course of a year and the amounts can fluctuate dramatically and are not stable. Rebates often apply across a group of drugs and generally are not applicable to a single claim.
  - Significant and costly system changes would be needed including the drug claim adjudication system and the Medicare Plan Finder Price file. In addition, some plans directly negotiate their rebates with drug manufacturers and would need to develop new functions to share the information with their PBM. The change would also results in amendments to PBM and network pharmacies contracts.
- New, lower cost drugs. There is evidence that competitive market pressures have helped reduce
  or eliminate the use of rebates. An example is new products to treat hepatitis C. The products
  have been priced by drug manufacturers more competitively up front and reduce the impact
  rebates have on pharmaceutical pricing and formulary development. CMS' proposal could
  interrupt this trend and the plan's ability to incorporate, new lower-cost products into formularies
  when they come to market. Also, biosimilars are on the horizon and would need to be considered.
  They have the potential to be rebate-eligible.
- Transparency. Today drug manufacturer rebates are spread across all members and reflected in reduced member premium. This approach would re-direct the rebates to the individuals using the drug and raise premium for all members. Also plans submit very detailed, drug information on Part D rebates and other components of DIR to CMS. There is some concern that more public availability of rebate data across Part D plans may be used by drug manufacturers to reduce rebates.



**Recommendation:** CMS continue to separately address manufacturer rebates and pharmacy price concessions as outlined below.

- All pharmacy price concessions pass through to beneficiaries at the point of sale at the lowest possible reimbursement level. CMS apply an effective date for plan 2019 as there are no reasons to delay implementation of this policy change as it is straight forward.
- Applying manufacturer rebates at point of sale is a much more complicated proposal and does not directly address the core issue – high cost drugs and increasing drug prices. These need to be more directly addressed by CMS and the federal government.

## Section II. B. Improving the CMS Customer Experience

**13. Restoration of the Medicare Advantage Open Enrollment Period** (Sec. II.B.1, page 56428). HealthPartners understands that unsolicited marketing to individuals eligible for the new Medicare OEP is prohibited by statute; however, the definition of unsolicited marketing is unclear. We support CMS applying a "knowing standard" to effectuate the statutory provision versus applying an overly broad marketing prohibition to all potential beneficiaries during the new OEP.

**Recommendation:** CMS clarify in sub-guidance allowable marketing during the new OEP and provide examples of what would be considered unsolicited marketing.

**14. Medicare Advantage Plan Minimum Enrollment Waiver** (Sec. II.B.3, page 56431). HealthPartners supports CMS' proposal to remove the requirement for MAOs to submit an additional minimum enrollment waiver annually for the 2<sup>nd</sup> and 3<sup>rd</sup> years of the contract. This change removes an unnecessary and burdensome requirement.

**Recommendation:** CMS move forward with the proposal to remove the requirement.

**15.** Revisions to Timing and Method of Disclosure Requirements (Sec. II.B.4, page 56431). HealthPartners strongly supports plan flexibility to provide certain disclosure materials including the Evidence of Coverage by the first day of the annual election period as well as distributing certain documents electronically (i.e., website or electronic delivery) if notice is provided on how to request paper copies. These changes better reflect how individuals access information and reduces plan costs.

**Recommendation:** CMS move forward with the changes as outlined as we have seen huge success in the implementation of similar process for other lines of business (e.g., Medicaid). Additionally we respectfully request CMS to consider the following:

- Clarify how the EOCs will be treated in regards to the pre-approval process in HPMS. Specifically, since plans no longer need to submit the EOC at the same time as the ANOC, CMS create new or additional material look up codes in HPMS for ANOCs and EOCs.
- Remove the requirement to enter annual mail dates (AMD) for EOCs in HPMS. Under this
  proposal, plans will have the flexibility to provide the EOCs electronically; therefore, AMDs for
  EOCs would no longer be applicable.



- Provide a 5 business day turnaround timeframe for mailing materials that can be made available electronically. This provides plans adequate time to print and fulfill the request.
- No longer require plans to produce a printed version of the full provider/pharmacy directory. We
  have learned that members are only interested in knowing if a specific provider/pharmacy is in
  their network and do not want a full listing of the network. Instead the individual would obtain the
  information online (the most up-to-date information) or request from the plan a customized
  directory to only include network providers/pharmacies within a certain radius from a member's
  residence. These options better meet the member's needs, save significant time and resources,
  and is less wasteful.
- CMS allow plans the flexibility to only include a notice of how to request a hard-copy SB with an enrollment form. SBs have been a long-standing required document with the enrollment forms and it is not clear in the proposal how impacted by the change.

**16.** Revisions to §§422 and 423 Subpart V, Communication/Marketing Materials and Activities (Sec. II.B.5, page 56433). HealthPartners strongly supports CMS' proposal to revise the definition of marketing and create a definition for communications. We understand that under the new definition of marketing, many of the member materials (e.g., EOC) would no longer be considered marketing and would be treated as a communications material.

**Recommendation:** CMS move forward with the changes as outlined. Additionally, we offer the following recommendations for consideration:

- Provide expanded guidance and clear examples of communication and marketing materials to
  ensure there is consistent use and understanding of the two different type of categories across
  the industry.
- Create appropriate look up codes for submission of communication materials in HPMS (or provide clarification that submission is no longer needed) so plans are not left guessing which "marketing code" to apply to the communication material.
- Clarify how this change will impact D-SNPs and MMPs with integrated materials (Medicare and Medicaid) and how the coordinated regulatory review process will be conducted.
- Provide a clear and concise definition of "unsolicited marketing" during the Open Enrollment Period (OEP). Clarify in sub-guidance, allowable marketing during the OEP and specifically define activities that would be considered unsolicited marketing.
- Allow for all digital marketing (i.e., online banner ads and social media ads) to be subject to sameday approval in HPMS. The 5-day waiting period for digital marketing does not add value as CMS does not conduct a review of these digital ads prior to plans pushing them live.

**17.** Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (Sec. II.B.6, page 56437). HealthPartners fully supports CMS' proposal to lengthen the adjudication timeframe for Part D Payment redeterminations from 7 to 14 calendar days.

**Recommendation:** CMS move forward with the proposal to lengthen the timeframe.



**18.** Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (Sec. II.B.9, page 56440). HealthPartners supports CMS' proposal to limit the lookback period to 12 months as it would eliminate the flaw with the current 14-month review period that could result in the double counting of compliance or performance issues carried over to a second application cycle.

**Recommendation:** CMS reduce the past performance review period from 14 to 12 months for MA and Part D plans.

19. Preclusion List – Part D Prescriber Provision (Sec. II.B.10, page 56441) and Preclusion List – Part C/Medicare Advantage, Cost Plan, and PACE Provisions (Sec. II.B.11, page 56447). HealthPartners supports the elimination of the provider and prescriber enrollment requirements, as the process raised concerns about access issues and increased administrative burden. However, we have concerns with the new preclusion list as proposed. CMS is not clear how providers would specifically be identified or how the list will be created or maintained. It is unclear whether or not the Office of Inspector General (OIG) exclusion list would intersect with or be separate or different from the preclusion list. The proposal as written also does not clearly define the scope of the payment prohibition. Regarding appeals, it would be pre-mature to add the individual or entity on the preclusion list until the appeal is final. Claims for services rendered would not be denied until the appeal is completed and the provider is listed on the preclusion list.

**Recommendation:** CMS consider the following feedback:

- Define how individuals/entities would be identified by CMS to add to the preclusion list and how
  the list will be created and maintained, followed by a comment opportunity for the industry to
  provide feedback.
- Clarify whether or not the OIG exclusion list will intersect with or be different from the CMS preclusion list. If different, then re-evaluate what additional value the preclusion list adds and address the scenario of an individual or entity being on one list but not the other.
- Include language to clearly identify the scope of the payment prohibition to individuals/entities on the preclusion list.
  - Clarify which payments to individuals/entities are permissible and which are not permissible (health care services only or is it inclusive of administrative services);
  - Clarify how and in what instances CMS would apply sanctions to a plan who pays an
    individual/entity on the preclusion list.
- Postpone or delay implementation of an individual or entity on the preclusion until their appeal is final.

**20.** Removal of Quality Improvement Project for Medicare Advantage Organizations (Sec. II.B.12, page 56454). We agree that there are redundancies with the Quality Improvement Project (QIP) and other quality improvement initiatives by plans.

**Recommendation:** CMS delete QIPs from the MA Quality Improvement Program requirements.



# **Section II. C. Implementing Other Changes**

**21.** Changes to the Agent/Broker Requirements (Sec. II.C.7, page 56465). HealthPartners supports more plan discretion with regards to how to treat agent/brokers who become unlicensed. Plans are best situated to determine the most effective and appropriate level of disciplinary action based on the given facts and circumstances of an agent/broker.

**Recommendation:** CMS implement the change as proposed.

Thank you for the consideration of our comments. If you have any questions regarding our comments, please feel free to contact me at 952-967-5117 or <a href="mailto:Amy.L.Schultz@HealthPartners.com">Amy.L.Schultz@HealthPartners.com</a>.

Sincerely,

Amy L. Schultz Sr. Medicare Programs Manager HealthPartners