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January 16, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted via www.regulations.gov

Re: CMS-4182-P: 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, November 28, 2017.

Dear Administrator Verma:

Thank you for the opportunity to comment on the proposed revisions to the Medicare Advantage and Part D programs (CMS 4182 P). Independent Health Association (IHA) is a not-for-profit health plan that continually aims to provide our Western New York community with innovative health-related products and services, which enable affordable access to quality health care. Our award-winning customer service, dedication to quality health care and unmatched relationships with physicians and providers has allowed us to be consistently recognized as one of the highest-ranked health insurance plans in the nation. IHA offers Medicare Advantage Plans and Prescription Drug Plans. Please see below for IHA's comments.

A.1. Implementation of Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

Chain Pharmacies & Group Practices – As part of expanded efforts on the OMS, CMS proposes that if a pharmacy has multiple locations that share real-time electronic data, then all locations should be treated as a single pharmacy. CMS asks for information on plan system capabilities and whether such an approach can be accounted for. We appreciate CMS attention to the feasibility of this proposal, and point out that this would require a significant system enhancement in order to operationalize this proposal. For example, new processes and claims file feeds would also be required to implement this proposal.

Exempted Beneficiaries – CMS proposes three categories of "exempt beneficiaries, including those with a diagnosis of cancer. It also asks whether other populations should be exempt, such

as those receiving end of life care. IHA would like the ability to clinically interpret the "cancer diagnosis" criteria. We would like to define specifically what is meant by an exempt cancer diagnosis. This could be done in a medical policy and would be better than using a broad term of "cancer diagnosis." For example, someone who had a cancer diagnosis several years ago and who is in remission may or may not be someone who should be getting a high level of medications. We believe that if we can identify other populations, we should be able to include these as well. We ask for the latitude to expand the exempt designation depending on medical necessity.

Case Management, Clinical Contact, & Prescriber Verification – The proposal indicates that clinical staff must reach out to prescribers of frequently abused drugs to verify whether a potentially at-risk beneficiary is in fact at-risk. We agree with the proposal for written notification via mail, however, three follow-up calls within ten days is excessive. A second notification after 10-14 days, if there is no response, would be more reasonable.

Special Requirements for Prescriber Lock-ins – The proposal is that a sponsor cannot limit access to one or more prescribers unless at least six months have passed from the date the beneficiary was first identified as a potential at-risk beneficiary in an Overutilization Monitoring System (OMS) report and beneficiary meets the clinical guidance in the last OMS report. IHA would like to include members we identify using our own internal criteria or Part D sponsor identified cases.

A.2. Flexibility in the Medicare Advantage Uniformity Requirements

The proposal permits MAO's to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for members that meet specific medical criteria, as long as all members who meet the criteria are treated the same.

The proposed rule is viewed as a positive change and we agree in concept. MA organizations need the ability to vary supplemental benefits as well as premium and cost sharing to better address the needs of members with specific conditions, such as diabetes. IHA would like to see clarification and further detail in the plan bidding process as to the medical criteria to determine eligible enrollees for tailored benefits. If the criteria are not defined up-front, then plans may be able to create adverse selection in the market and cherry-pick specific populations. We ask that CMS define whether plans can use this flexibility for Part B benefit medication copays.

A.4. Maximum OOP Limit for Parts A and B Services

MA plans are currently required under the rules to establish limits on enrollee out-of-pocket cost sharing (deductibles, coinsurance and copayments but not premiums) for Parts A and B services that do not exceed annual limits established by CMS (referred to as the MOOP amounts). These limits were intended to help ensure that enrollment by individuals who use higher-than-average levels of health care services are not discouraged from enrollment. MA plans that adopt a lower voluntary MOOP are given greater flexibility in their cost-sharing requirements. IHA agrees with the idea of implementing more than two levels of MOOP. This will encourage MA plans to offer lower MOOP limits with different cost-sharing limits. CMS should consider splitting the variance in thirds and allow for cost sharing variances at the $4,500, $5,600 levels as well as the $3,400 and $6,700 levels. Key benefits that could be varied include SNF days 1-20, IP cost levels, ER and UC, SCP and OT/ST/PT visits. We look forward to the Call Letter for more details.

A.6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review

CMS proposes eliminating the MA meaningful difference standard 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." IHA agrees with this objective, which in the past was applied using a calculated amount of a $20 variance between plans for specific key benefits. We believe beneficiaries should have as much choice as possible. However, it is possible that eliminating meaningful differences could cause confusion for beneficiaries when selecting a plan, due to increased complexity and similarity of offerings. If substantive changes are made to assist beneficiaries with choosing plans and plans include benefits such as preventive dental, vision, network tiering and network affiliations that meet certain needs, then this would be a fair way to offer additional choice. Further, IHA believes there should be clear and objective criteria used for determining which plans are going to be offered. If CMS finalizes the proposed change, there should be published criteria in place to ensure that bid review determinations are being made objectively based on known decision making criteria. This will allow for fair competition that will then lead to the most innovative plan designs and greatest beneficiary choice.

A.9. Part D Tiering Exceptions

The proposal revises the Part D tiering exceptions policy, including limitations that Part D plans may apply to tiering exception requests. The provision allowing plans to exclude a dedicated

generic tier from the tiering exceptions process would be eliminated. IHA believes the proposed changes will deter plans from offering a $0 generic prescription tier. In that eventuality, this would have the unintended effect of adding cost to beneficiaries and not reflect the intent of a $0 generic tier. Currently, many plans offer this $0 generic tier, which is beneficial to members as an incentive for medication adherence and quality of care. IHA does not support eliminating the generic-only tier exemption, which we believe would adversely affect a no cost tier for generic drugs and disadvantage members.

A.11. MA and PDP Quality Rating System - *Data Integrity*

IHA urges CMS to follow a scaled approach to star reduction due to data integrity, which is a better approach than an automatic reduction to one star. The one aspect that is not accounted for in the current approach is the number of appeal decisions actually made timely. Because the equation only bases the calculation on the number of untimely IRE forwarded decisions divided by the number of cases not forwarded, it does not take into account all of the decisions made timely. Although we appreciate that the intent is to promote data integrity, it may have the unintended consequence of making a very good plan with many timely decisions appear as though they have a more significant issue in this area than they really do. If the effort is simply an attempt to make sure the plan is auto-forwarding cases, then this may serve well. If the real intent is to make sure that the plan is making timely decisions, this measure does not adequately assess this intent.

A.12. Any Willing Pharmacy Standard Terms and Conditions and Better Definition of Pharmacy Types

CMS proposes to clarify that the "any willing pharmacy" requirement applies to any "similarly situated" pharmacy that "has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy. The proposal also provides definitions for different pharmacy types and provides deadlines for the provision of standard terms and conditions to a requesting pharmacy.

IHA is concerned that if applied broadly, this proposal might deter a plan's ability to meet requirements of fraud, waste, and abuse (FWA) in instances where a pharmacy may have a unique or innovative business or care delivery model that doesn't fit a commercially or community acceptable practice.

We do not support applying this to Specialty Pharmacies. These pharmacies treat complex disease states and conditions and dispense drugs of high dollar value. We recommend that specialty pharmacies be defined separately through licensing and certification requirements.

We believe that any willing provider should be based on MA-PD and PDP regions. Local MA-PD plans should have the latitude to exclude certain national pharmacies ability to bill for services for a beneficiary located within the MA-PD region where services are readily available. This would represent a significant FWA deterrent. Pharmacies may claim AWP under retail provisions, but then provide mail order services, which can be a potential source of FWA. This could help with FWA prevention among pharmacies. The exception would be in the cases of limited distribution drugs or member emergency.

For Mail Order – we recommend adding a licensed pharmacy that dispenses and delivers extended day supplies of covered part D drugs **primarily** via a common carrier at a mail order cost share.

For Retail Pharmacy – we recommend "any licensed pharmacy that is primarily opened to dispense prescription drugs to the walk-in local general public from which a sponsor's enrollees can participate". Additionally we recommend adding "Retail pharmacy does not include a pharmacy that dispenses prescription medication to patients primarily through mail or other courier service."

Standard Terms and Conditions – we believe that two business days within receipt is too short of a turn-around time. We recommend a longer timeframe as a fair turnaround time. This will allow a plan to validate the requesting provider and that they are truly a "willing pharmacy."

Further, the specific terms should not be disclosed before the conditions are met. We are concerned that a pharmacy could ask for proprietary information prior to proving they can meet the conditions of a contract. It is in the best interest of beneficiaries that specific terms are not disclosed before conditions are met.

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

IHA supports the CMS proposal to change the outpatient days' supply from "30 days" to "a month's supply." We also support the proposal to change the transition days' supply for LTC setting from 91+ days to the same as in the outpatient setting.

A.14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

IHA supports the CMS proposal for more timely substitutions of certain generics. We believe this to be a positive change that would benefit the member through reduced cost and allow plan flexibility.

A.17. RFI Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at POS

IHA urges CMS not to move forward with this proposal to apply manufacturer rebates and pharmacy price concessions to drug prices at the point of sale (POS).

We believe that such a proposal raises multiple operational concerns. Due to the many various contractual terms and conditions with many manufacturers, certain claims may be non-eligible and there would be instances where we offer the POS rebate when in fact we will never be paid on the claim. Many of our current contracts are performance based and actual concessions and rebates are not known until certain thresholds are met. Since rebate amounts are not received by Part D plans until several months after the sale, the Part D plan would have to "front" the rebate discounts at the POS and then later recoup these from manufacturers. Estimating these up-front is virtually impossible. Also, it is usually not our intent to put higher costing drugs on the formulary over lower costing drugs, so members are always receiving the best value in the tier. Members are getting the benefit of manufacturer rebates in the overall benefit that is being calculated.

The increased operational burden and additional administrative costs associated with this proposal would cause Part D premiums to increase significantly. Premiums are a key factor in a beneficiary's plan decision. Significantly increased Part D premiums could create fewer choices and reduced access for beneficiaries.

Competitive market forces are beginning to reduce the role that rebates have on pharmaceutical pricing and formulary development. If rebates are locked into place at the point of sale, pharmaceutical manufacturers would lose any incentive to price products at a low starting price, instead starting drugs at higher prices with rebates.

B.1. Restoration of MA Open Enrollment Period

The proposal which implements provisions in the 21st Century Cures Act restores an open enrollment period from January 1 until March 1 of each year, to allow beneficiaries to correct a

plan decision they are not satisfied with. However, it should not be a time for aggressive marketing tactics or a time in which broker agents are incentivized to promote beneficiaries to switch plans. Therefore, CMS should consider monitoring for churn and possible beneficiary confusion during this open enrollment period.

B.2. Improving the CMS Customer Experience - *Reducing the Burden of Compliance Program Training Requirements (§§422.503 and 423.504)*

IHA agrees with the elimination of the compliance training requirement for FDR's. There is not the ability to enforce such requirement over and above private contracts that exist between the plan sponsor and the first tier, downstream or related entity. Additionally, mechanisms used to administer such requirements have evolved into overly burdensome processes administratively, frustrating particularly medical and hospital professionals as well as plan network administrators. We have a robust oversight program already including a robust oversight program for FDR's, particularly those that provide an administrative or delegated function on behalf of the Plan.

B.4. Timing and Method of Disclosure Requirements

IHA agrees with making the Evidence of Coverage (EOC) available electronically rather than mailing paper copies. We recommend that CMS allow MA plans to have the EOC generated electronically as the "default" and have members "opt-in" to request paper copies of the documents. As more beneficiaries have access to on-line material and portal accounts, there is less need to do full printed mailings. This will impact the MA administrative costs that we can better use to offer enhanced benefits and improved access to care.

B.5. Revisions to Communication/Marketing Materials and Activities

IHA agrees with this change to reduce administrative burden while still providing clear communication with members. We believe CMS should—perhaps through sub-regulatory guidance—establish clear and specific guidelines as to what is considered "marketing" versus "communications" to avoid an uneven playing field in which plans may creatively construct materials that take advantage of a broad definition and ultimately allow for cherry-picking populations. Plans that play by the rules should not be adversely impacted by other plans' ability to creatively market because the rules are too broadly defined.

B.6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and Independent Review Entity (IRE) Reconsiderations

IHA supports increasing enrollee payment appeal requests at the redetermination and IRE reconsideration levels to a maximum of 14 calendar days. Particularly these allowances would help improve timely outcomes for effectuation of payment after a decision is made. Often plan sponsor payment processes do not allow for enough time to make payment through normal automated processes thereby resulting in an overly burdensome administrative process that may be manual in nature just to ensure payments are made within the required time frame. There is little adverse effect on the enrollee and it is consistent with the timeframe for requests for reimbursement coverage determinations set forth in Chapter 18 (Prescription Drug Benefit Manual), Section 30.3.

B.7. Reducing Burden on Plans by Eliminating Medicare Advantage Plan Notice of Forwarded Appeals/Cases sent to the IRE

IHA agrees with this change from the standpoint that it can be very confusing to the beneficiary to receive multiple notices regarding this type of action. However, we would also like to continue to have the option to send a letter to the member advising of the case status. In accordance with the Medicare Managed Care Manual, Chapter 13, Section 70.7.4 and 80.2, an untimely reconsideration affirms the adverse organization determination. Therefore, the plan should advise the enrollee of the affirmation of the adverse organization determination; the health plan would not have the opportunity to do this if a letter is not sent.

B.10. Preclusion List

IHA does not support the proposed preclusion list at this time. Operational aspects of this preclusion list for Part C and Part D appear to be problematic and not functional given the timeframe needed to implement. In addition, we disagree with providing a 90 day fill from a provider who is on the list. A "bad-actor" should not be entitled to payment, nor enable receipt of a medication for such a long period of time that may harm a beneficiary. CMS should work with plans to work-out operational details to address those situations when a prescriber who is on the list is requesting a member receive a script. We also ask that CMS define who notifies the member that their provider is on the preclusion list. And, we also seek clarity or guidance on how this proposed preclusion list would work with the OIG list and how vendors (and which type of vendors) are to comply with this list. These are among the many unanswered operational questions that make this proposal not feasible for 2019.

B.12. QIP Removal

IHA agrees with this change and supports the CMS direction to eliminate redundancies with other plan efforts. This will allow for re-distribution of resources to positively impact beneficiaries with better care and improved benefits.

B.13. Reducing Provider Burden

To ensure that a plan is submitting the most accurate diagnosis codes for care management risk adjustment, the plan must request medical records to validate claims encounters. This varies from time to time based on claim volume and provider reviews. RADV audits are a requirement of the MA program and the plan must comply with multiple record requests to find the best medical record to support the submission. We do everything we can to reduce the provider burden, especially using electronic access to records where possible. In certain cases, providers will not allow a plan to have electronic access and there is no incentive for them to do so. We believe that any limitation placed on the plan to perform this work will limit our ability to validate the accuracy of the diagnosis submissions, which can lead to inaccurate plan reimbursement and false-positive care management programs reliant on this information. Limitations placed on the RADV scope are counter-productive with mandated compliance requirements and the CMS authorization that was designed to maintain the integrity of the MA program. This proposal undermines the ability to be good stewards of public funds and therefore urge CMS not to finalize this proposal.

Thank you again for the opportunity to comment and thank you for considering IHA's views on the proposed revisions to the Medicare Advantage and Part D programs (CMS 4182 P). If there are any questions or additional information is needed, please contact Jeremy Laubacker at Jeremy.Laubacker@independenthealth.com.

Sincerely,

Robert Tracy
Vice President, Medicare Products