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December 20, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Attention: CMS-4185-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-P)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) in response to the Notice of Proposed Rulemaking (proposed rule or proposal) regarding the Policy and Technical Changes to Medicare Advantage (MA) and Medicare Part D published in the *Federal Register* on November 1, 2018 (CMS-4185-P). Several of the policies in this proposed rule make positive steps to improve current regulations. Specifically, the AMA supports:

- **Existing Regulation on MA Provider Directories:** The AMA strongly supports ongoing efforts by CMS to improve the accuracy of provider directories for Medicare Advantage Organizations (MAOs), as this information is essential to accessing timely and affordable medical care.
- **Medicare Plan Finder (MPF) Price Accuracy:** The AMA strongly supports CMS' proposal to enhance the MPF Price Accuracy to improve the reliability of a contract's MPF advertised prices.

The following outlines our principal recommendations with regard to the proposed rule:

- **MA Provider Directory Application in Proposed Rule:** The AMA remains deeply concerned about the persistent rate of error among provider directories, and strongly encourages CMS to implement and enact enforcement actions for MA plans that have demonstrated noncompliance.
- **MA and Part D Prescription Drug Plan Quality Rating System:** The AMA urges CMS to reevaluate and finalize a cut point methodology that ensures the Star Ratings accurately reflect plan quality and are grounded in evidence.

- **Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE:**

    - *Written Notice:* The AMA urges that the written notice to the individual or entity via letter of their inclusion on the preclusion list be sent certified mail and the letter be standard across the MA and Part D programs.
    - *Beneficiary Access:* The AMA appreciates CMS providing discretion under Part D to not include a particular prescriber on the preclusion list when CMS determines that exceptional circumstances exist regarding beneficiary access to prescriptions. However, the AMA recommends that CMS also provide similar discretion under MA to not include a provider on the preclusion list when CMS determines that exceptional circumstances exist regarding beneficiary access to items or services.
    - *Preclusion List for a 10-Year Period:* The AMA recommends that CMS should set a lower default preclusion period to three years and use aggravating factors to increase the applicable timeframe.
    - *Beneficiary Appeals and Liability:* The AMA recommends that CMS either (1) allow a beneficiary to appeal a payment denial for out-of-network providers for being on the preclusion list or (2) explicitly require language in the proposed advance written notice to any beneficiary that the beneficiary will be financially liable if the beneficiary continues to receive services from the out-of-network provider.
- **MA Coverage of Virtual Diabetes Prevention Program (MDPP) Services:** The AMA recommends that CMS encourage MA plans to offer virtual MDPP services as a supplemental benefit.
- **MA Telehealth Expansion:** The AMA recommends the finalization of the proposed requirements and regulatory definitions for the inclusion of telehealth as basic benefits for purposes of bid submission and payment. However, CMS should explicitly clarify that (1) telehealth services are precluded as a means of establishing network adequacy; (2) telehealth does not include other virtual services already permitted for inclusion as part of the basic benefits; and (3) all telehealth and virtual services, whether offered as part of the basic benefit or as a supplemental benefit, must comply with state licensure and medical practice laws where the patient is located when receiving such services.
- **Part D Exceptions:** CMS proposes that Part D plans must render a decision within the specified timeframes when prescriber determination is available, but in no case later than 14 calendar days after receipt of the request, whichever occurs first. Given the concerns we outline in detail below, we urge CMS to carefully evaluate the impact of this new 14 calendar day requirement and ensure compliance with notification of appeal rights as well as the right to submit another exception request.

Network Adequacy and MA Provider Directories

Existing Regulation on Provider Directories

The **AMA strongly supports ongoing efforts by CMS to improve the accuracy of provider directories for MAOs, as this information is essential to accessing timely and affordable medical**

care. CMS first addressed provider directories in the context of network adequacy in the CY2016 Call Letter requiring MA plans to disclose their provider directories, maintain and monitor the network of providers, and to provide adequate access to covered services.[1,2] In the guidance, providers whose practices were closed or otherwise unavailable could not be used to successfully meet network adequacy standards. Additionally, CMS stated that it did not have the authority to require providers to notify MA plans of their current status, but strongly encouraged them to be responsive to MA plan inquiries and notify them on pertinent changes in network status.[3]

To maintain and monitor adequate networks, CMS requires that MA plans establish and manage proactive and structured communication with providers, the purpose of which is to ensure availability of and access to covered services for all MA enrollees.[4] Widely inaccurate provider directories can negatively impact access to care, by preventing beneficiaries from effectively and efficiently identifying in-network providers. The **AMA appreciates CMS' multi-faceted approach to improving provider directories and recommends continued maintenance of these communication structures, in order to safeguard patient access to necessary health care services.**

The AMA also applauds the three-pronged approach by CMS to monitor compliance of provider directories by (1) direct monitoring of MAOs' online provider directories; (2) developing new audit protocols to enhance CMS' oversight of the validity and accuracy of MAOs' online directories; and (3) enacting compliance and/or enforcement actions that penalize MAOs failing to maintain complete and accurate directories with civil money penalties or enrollment sanctions.[5]

CMS Online Directory Audit Results

The AMA remains deeply concerned about online provider directory accuracy, given the results from three CMS reports, performed from February 2016 to July 2018. In the corresponding audits, CMS surveyed 108 physician providers selected from the online directories of 54, 64, and 52 MAOs in 2016, 2017, and 2018, respectively.[6,7,8] The results showed that, **45 to 52 percent of all provider directory locations contained at least one inaccuracy during these three independent audits**. The types of inaccuracies included the following: (1) the provider was not at the location listed; (2) the phone number was incorrect; or (3) the provider was not accepting new patients when the directory indicated they were. Of greater concern, these errors were found to create significant barriers to access to health care services by MA patients and beneficiaries. Despite far-reaching inaccuracies in online provider directory information, CMS failed to issue any civil money penalties or enrollment sanctions. Instead, the agency decreased total compliance action taken over the three-year time period.

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[1] 42 CFR § 422.111.
[2] 42 CFR § 422.112.
[3] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2016.pdf
[4] 42 CFR § 422.1(b).
[5] 42 CFR § 422.1(b).
[6] https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf
[7] https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Year2_Final_1-19-18.pdf
[8] https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Round_3_11-28-2018.pdf

Provider Directory Application in Proposed Rule

In the Proposed Rule, CMS suggests that MA plans utilize their provider directories to identify "providers offering services for additional telehealth benefits and in-person visits, or offering services exclusively for additional telehealth benefits."[9] However, as demonstrated above, approximately 50 percent of MA plan online provider directories contain inaccuracies that create significant barriers in access to care. The AMA believes that the identification of qualifying providers that offer necessary and beneficial telehealth services will be compromised if dependent on widely inaccurate online provider directories.

Online provider directories have a tremendous impact on overall access to health care services for MA plan beneficiaries, with this information source a principal touchpoint in connecting patient to physician. However, **accurate provider information has more far-reaching effects on the success of value-based care delivery in modern physician practice**. In an interview about online provider directories and network adequacy, Vice President of Stars for Gorman Health Group, Melissa Smith stated:

> Accurate provider data is a mission-critical foundation for a strong Star Rating. If provider data is inaccurate, members will likely struggle to access providers or may actually show up at the wrong location for an appointment. These issues influence all Star Ratings measures; they directly impact clinical quality measures and indirectly impact member survey and administrative measures. In addition, inaccurate provider data jeopardizes the success of numerous key health plan business functions and minimizes the return on investment of supplemental investments in Star Ratings, Risk Adjustment, and Quality Improvement (QI).[10]

Evidence from three separate audits conducted by CMS from 2016 to 2018 exhibit ongoing inaccuracies in online provider directory information, with the lack of improvement in this critical information source globally affecting patient access and quality care delivery. **The AMA remains deeply concerned about the persistent rate of error among provider directories, and strongly encourages CMS to implement and enact enforcement actions for MA plans that have demonstrated noncompliance**.

MA and Part D Prescription Drug Plan Quality Rating System

Improving Program Quality and Accessibility

Measure-Level Star Ratings

We support CMS' efforts to gather further stakeholder input on MA Star Ratings cut point methodologies for non-Consumer Assessment of Healthcare Providers and Systems measures. The AMA has previously expressed concerns that the current program often impedes clinical care, leads to increased administrative burdens on physicians, and does not provide much in the area of a beneficiary benefit. Therefore, we appreciate CMS' request for comments on revisions to the cut points methodology.

[9] 83 FR 54990.
[10] https://www.gormanhealthgroup.com/blog/the-importance-of-accurate-provider-data-and-network-adequacy/

As the AMA has noted in previous comment letters, many of the measures within the MA Star Ratings program are based completely on physician action and compliance. For plans to comply with and earn incentives from CMS, plans must often set unrealistic targets within their physician contracts in order for the plan to score well due to the Star Ratings cut points. While the AMA does not have a preference on the proposed methodologies CMS has put forward for comment, we urge CMS to consider as it finalizes changes to the methodology that the finalized policy does not impede clinical judgement.

Often physician compliance with a measure must be at 100 percent regardless of whether it would, in all cases, constitute appropriate and medically necessary care. For example, for the Diabetes Care—Blood Sugar Controlled measure, it is not reasonable to assume that every physician could achieve an A1c less than nine percent in every patient. The American Diabetes Association and the national medical specialty societies whose members manage patients with diabetes are moving toward more patient-centered individualized A1c goals, which allow for patients to keep their A1c closer to eight but not exactly eight. In the absence of such an approach, if an MA plan's physicians treat more elderly or sicker patients, it might be unfairly rated if the A1c target is less than nine and the compliance with the measure is set at 100 percent. In addition, there may be instances when compliance with a measure is contrary to appropriate care, but plans do not incorporate exceptions, suitable exclusions or risk-adjustment models related to the measures due to the requirements CMS has set up for Star Rating compliance. All care should not be the same for all patients because no measure is precise enough to account for all the nuances in practice, patient adherence, and other relevant factors that impact patient care and health outcomes. It is not possible to achieve 100 percent adherence to a measure, and there is a lack of data on what optimal performance should be for every measure. Therefore, we urge CMS to reevaluate and finalize a cut point methodology that ensures the Star Ratings accurately reflect plan quality and are grounded in evidence.

Additions and Updates to Individual Star Rating Measures

Controlling High Blood Pressure (Part C)

The AMA is supportive of the structural changes NCQA has made to the measure to allow for use of telehealth services and remote monitor device readings, as well as updating the specifications to follow the latest scientific guideline recommendations. However, given the broad denominator population, it is not reasonable to assume that every health plan can expect that all physicians or practices can achieve a blood pressure target of less than 140/90 mmHg in every patient. When this measure was first developed, the assumption was that many physicians and other health care providers would not be able to achieve 100 percent since the measures were broadly defined and some imprecision in defining the patient population was deemed acceptable. This approach does not work well when performance is assigned to cut points with an assumption that top performance should eventually reach 100 percent; yet, at the same time, there is no evidence to demonstrate what scores should be defined as top performance in measures that have some degree of imprecision. In addition, the 2017 American College of Cardiology guideline for high blood pressure, on which this measure is based, cautioned that achievement of these targets must be balanced with the patient's risk tolerance and clinical factors such as advanced cognitive impairment and multiple co-morbidities.[11] Treatment that requires multiple blood pressure lowering agents may not

[11] Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. JACC. 2018; 71:e127-e248. doi: 10.1016/j.jacc.2017.11.006.

be possible without risk of adverse outcomes, such as acute kidney injury or failure. For physicians and practices that treat greater numbers of the elderly or those with multiple chronic conditions, each will be at risk to be penalized if the blood pressure target is less than 140/90 mmHg and the top decile set at 100 percent.

MPF Price Accuracy (Part D)

CMS proposes to make enhancements to the Medicare Plan Finder (MPF) Price Accuracy measure in order to enhance the reliability of a contract's MPF advertised prices. The AMA strongly supports the proposed updates to the measure. The changes would factor both how much and how often prescription drug event prices exceeded the prices reflected on the MPF. This is critical to provide enrollees with information they have confidence is reliable and accurate. The AMA continues to strongly advocate for price transparency; and updates to this measure ensures that contract performance is (1) measured in a meaningful and useful manner, and (2) available to enrollees.

Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

The AMA appreciates the actions of CMS in reducing the burden of the MA and Part D provider-and-prescriber enrollment requirements by preventing payment for items, services, or prescriptions furnished or prescribed by demonstrably problematic providers and prescribers rather than requiring the enrollment of providers and prescribers regardless of the level of risk posed. As CMS implements the preclusion list, the AMA stresses that the process be transparent, applied in a fair and uniform manner, and not negatively impact beneficiary access to medically needed items, services, and prescriptions.

Written Notice

CMS proposes to send written notice to the individual or entity via letter of their inclusion on the preclusion list.[12] **The AMA urges that this written notice be sent certified mail and the letter be standard across the MA and Part D programs.** In other contexts of payment suspension, revocation, and revalidation, the AMA has heard concerns about clinicians not being properly notified, letters being lost in transit, or going to an incorrect office or staff member. Requiring certified letters for the notice of preclusion can help demonstrate the chain of custody and potential weak points in sending and receiving the notice. Additionally, given the various communications from CMS, Medicare Administrative Contractors, Part D plans, and private payers, the AMA recommends that the preclusion notice be uniform in format and with standard language where appropriate. Thus, a clinician can easily identify the notice and its purposes from other communications.

Beneficiary Access

The AMA appreciates CMS providing discretion under Part D to not include a particular prescriber on the preclusion list when CMS determines that exceptional circumstances exist regarding beneficiary access to prescriptions.[13] This discretion is similar to the Office of the Inspector General's (OIG) ability to waive exclusion when it imposes a hardship on beneficiaries, such as being the sole community physician or

[12] Proposed 42 CFR § 422.222(a)(2)(i) and § 423.120(c)(6)(v)(A).
[13] Proposed 42 CFR § 423.120(c)(6)(vi).

sole source of essential specialized services in a community.[14] The AMA does not understand why CMS only provides this discretion under Part D and not under MA. **Thus, the AMA recommends that CMS also provide similar discretion under MA to not include a provider on the preclusion list when CMS determines that exceptional circumstances exist regarding beneficiary access to items or services.**

Preclusion List for a 10-Year Period

The AMA is concerned that under the proposal any felony conviction automatically defaults to a preclusion period of 10 years.[15] As stated in the proposed rule, the 2016 proposed rule regarding revocations has a **maximum** reenrollment bar of 10 years. Thus, for preclusions the maximum should also be for 10 years unless OIG excludes someone for a longer period. Ten years should not be the automatic default of all felonies for a preclusion. Additionally, CMS should provide parameters regarding what types of felonies fall under this section. This would be consistent with the revocation rule and could include crimes against persons, such as murder, rape, or assault; financial crimes, such as extortion or embezzlement; any felony that places a patient at immediate risk; and any felony that would result in a mandatory exclusion.[16]

While the AMA understands that CMS can weigh certain factors to determine the applicable timeframe, the 10-year default is greater than the amount of a "default" OIG mandatory exclusion of five years and the general default of three years of permissive exclusions. Moreover, OIG mandatory exclusions only cover specific conduct and not all felonies. Furthermore, rather than set an arbitrary default of 10 years, OIG considers aggravating and mitigating factors to determine the length. **Thus, the AMA recommends that CMS should set a lower default preclusion period to three years and use aggravating factors to increase the applicable timeframe.**

Beneficiary Appeals and Liability

The AMA is concerned about the potential financial liability of beneficiaries for out-of-network providers who are on the preclusion list. We fully support the CMS proposal of requiring a MA contract with CMS to specifically state that a MA enrollee must not have any financial liability for items or services furnished to the beneficiary by a MA-contracted individual or entity on the preclusion list. CMS does note, however, that this proposal would only extend to MA-contracted providers and would not extend to out-of-network providers.

The proposed rule also does not allow a beneficiary to appeal a payment denial based upon a provider's inclusion on the preclusion list. Thus, coupled together, a beneficiary may be left with financial liability and no administrative recourse regarding services rendered by an out-of-network provider on the preclusion list. **Accordingly, the AMA recommends that CMS either (1) allows a beneficiary to appeal a payment denial for out-of-network providers for being on the preclusion list or (2) explicitly require language in the proposed advance written notice to any beneficiary that the**

[14] 42 USC § 1320a–7(c)(3)(B).
[15] Proposed 42 CFR § 422.222(a)(5)(iii) and 423.120(c)(6)(vii)(C).
[16] 42 CFR § 424.535.

beneficiary will be financially liable if the beneficiary continues to receive services from the out-of-network provider.[17]

MA Telehealth Benefit

The AMA strongly supports the proposed implementation of section 50323 of the Bipartisan Budget Act (BBA) of 2018 related to telehealth services in the MA Program. Section 50323 allows MA plan sponsors to provide "additional telehealth benefits" to enrollees starting in plan year 2020 and treat the telehealth services as basic benefits for purposes of bid submission and payment by CMS. **However, the AMA strongly urges CMS to clarify, as required by the BBA, that telehealth services cannot be used to establish network sufficiency**. As discussed below, the BBA makes clear that the Medicare enrollee must have the option to receive medical services in-person even when the option of telehealth services is offered. While the AMA continues to strongly support expansion of the telehealth benefit in the Medicare program before Congress and CMS, there is no evidence base or empirical studies demonstrating that compelling patients to obtain medical care virtually is clinically valid or equivalent in all instances relative to in-person care. The AMA has worked closely with a broad array of health care stakeholders including through national experts as part of the AMA Digital Medicine Payment Advisory Group to identify evidence-based expansions of virtual care services and we have strongly advocated for the expansions of such services in all Medicare programs (Part A, Part B, and Part C). But, we strongly oppose the use of such services to meet network adequacy requirements in the Medicare program as this undermines essential patient protections, patient choice, and lacks evidentiary support.

The AMA supports the proposed definition of additional telehealth benefits. We agree that these should be defined as services furnished by a MA plan for which benefits are available under Medicare Part B but which are not payable under section 1834(m) of the Social Security Act and have been identified by the MA plan for the applicable year as clinically appropriate to furnish through electronic exchange.[18] We specifically support providing MA plan sponsors with the discretion to make the determination that the telehealth services are clinically appropriate as opposed to limiting coverage to only those services CMS covers under the telehealth benefit.

The AMA strongly supports the requirements for telehealth services included in the base bid as outlined in proposed 42 CFR section 422.15. However, we do not support permitting the inclusion of such services as a supplemental benefit subject to CMS approval when a plan does not comply with a number of the proposed requirements as discussed below. MA plan sponsors are required to comply with state laws governing licensure and state medical practice without regard to whether these are offered in the base benefit or as supplemental services. The AMA supports the CMS requirements that MA plan sponsors offering telehealth services must:

- furnish in-person access to the specified Part B service(s) at the election of the enrollee;
- advise each enrollee, at a minimum in the MA plan's Evidence of Coverage, that the enrollee may receive the specified Part B service(s) through an in-person visit or via telehealth;

[17] Proposed 42 CFR § 422.222(a)(1)(ii)(A).

[18] The AMA has noted previously that other virtual services such as remote patient monitoring are not considered telehealth. As a result, MA plan sponsors are already able to include other virtual services, including remote patient monitoring, in the basic benefits as long as considered clinically appropriate.

- identify, in the MA plan's provider directory, any providers offering services for additional telehealth benefits and in-person visits or offering services exclusively for additional telehealth benefits; and [19]
- comply with the provider selection and credentialing requirements and when providing additional telehealth benefits, ensure through its contract with the provider that the provider meet and comply with applicable state licensing requirements and other applicable laws for the state in which the enrollee is located and receiving the service.

With regard to the last requirement, the AMA strongly supports the patient protections that would ensure enrollees are not left without recourse when the licensure, medical practice legal requirements, and other state laws where the enrollees receive their medical care have not been met. Thus, MA plan sponsors must adhere to state laws where patients receive telehealth services when provided as part of the base benefits **and when offered as supplemental benefits**. The AMA, therefore, strongly urges CMS to clarify the proposed regulatory language to ensure that any ambiguity is removed. (The AMA continues to strongly support the adoption of the Federation of State Medical Board [FSMB] Interstate Medical Licensure Compact to facilitate expedited licensure and adherence to essential patient protections afforded by the state medical boards where the patient is located.)

The AMA also conditionally agrees that MA plans furnishing additional telehealth benefits may only do so using contracted providers. We urge CMS to evaluate if this requirement facilitates care coordination and continuity of care. While we appreciate that it will enable MA plan sponsors to assess whether a contracted provider has complied with the proposed regulatory requirements, it will be important to evaluate whether this provision fragments and bifurcates care delivered in-person and services delivered via telehealth. It is critical that CMS prioritize this evaluation to ensure that telehealth implementation advances improved patient outcomes which rests in significant part on continuity of care and effective communication among the extended health care team.

The AMA also supports the proposed requirement that MA plan sponsors must make information about coverage of additional telehealth benefits available to CMS upon request. The scope of possible information sought such as statistics on use or cost, manner(s) or method of electronic exchange, evaluations of effectiveness, and demonstration of compliance with the regulatory requirements are essential to ensure compliance, but will also provide essential evidence with regard to the overall benefit to the Medicare program. This information will be relied upon by policymakers considering expansion of the telehealth benefit; therefore, we urge CMS to prioritize this requirement with specific timelines for submission of such information to CMS throughout the 2020 Cost Year.

MA Coverage of Virtual Diabetes Prevention Program (MDPP) Services

The 2018 Call Letter clarified several policies pertaining to MA plan coverage of MDPP services. MA plans must provide in-network coverage of MDPP services in accordance with the MDPP regulations with zero cost sharing. In addition, MA plans may provide coverage of MDPP services in a 100 percent virtual format as a supplemental benefit through the Remote Access Technology supplemental benefit.

[19] As outlined in this letter, the AMA believes that MA plan directory accuracy is an essential element of providing beneficiaries with fair notice and ensures that they are able to make informed decisions when they make a plan election. As the telehealth benefits expands, it is essential that CMS ensure compliance with this provision.

The virtual format MDPP coverage does not count as the Part B covered service for purposes of the basic benefit bid but may still be offered by plans.

The AMA strongly supports expanding provision of MDPP services in a virtual format through MA plans. Humana and Omada have partnered since 2015 to provide virtual MDPP services to MA patients, and published literature describes cost savings that the MA plans achieved (e.g., see V. Chiguluri et al., "Virtual Diabetes Prevention Program–Effects on Medicare Advantage Health Care Costs and Utilization," *Diabetes* 2018 Jul; 67 (Supplement 1), and C.M. Castro Sweet et al., "Outcomes of a Digital Health Program with Human Coaching for Diabetes Risk Reduction in a Medicare Population," *Journal of Aging and Health* 2018 Jun; 30:5, pp. 692-710). For example, data from the Humana experience found that a cohort of 491 Humana MA patients achieved clinically-meaningful engagement and weight loss outcomes. With an average participant age of nearly 70 in this "Prevent" MA program, six months after beginning the program, more than 85 percent of participants remained active–an engagement level among the best-in-class for intensive behavioral counseling–and during this timeframe Prevent graduates lost an average 8.7 percent of their body weight.

Some MA plans, such as Regence, have issued public statements about the availability of virtual MDPP services as supplemental benefits for patients in 2019. As there are a limited number of in-person MDPP providers, availability of the virtual MDPP services through MA plan coverage can help to fill a significant gap between the number of Medicare patients with prediabetes and the number and distribution of in-person suppliers. The AMA recommends that CMS encourage MA plans to offer virtual MDPP services as a supplemental benefit.

The AMA further recommends that CMS gather information from MA plans that offer virtual MDPP services as a supplemental benefit regarding patient and supplier experience with the services, patient health outcomes, and cost savings achieved. Despite substantial literature documenting the effectiveness of DPP services provided in a virtual format, some policymakers have raised questions about whether Medicare patients are as likely to see beneficial health outcomes and the program is as likely to secure savings from provision of virtual MDPP services as with in-person services. The evidence gleaned from the MA experience could inform these questions about effectiveness, utilization, and cost savings that policy makers may have regarding virtual MDPP in the Medicare population. The MA experience could also inform questions about practical implementation, including concerns about program integrity, which could further facilitate expansion of coverage for virtual MDPP services to patients in the traditional Medicare program. Particular topics that MA plans could address include coaches providing the virtual services, digital tracking of coaches' interactions with patients, coach-to-patient ratios, accuracy and uniformity of weight verification and other measured outcomes, and response times to patient questions.

Part D Exceptions

When a Part D drug plan provides for tiered cost-sharing for drugs on a formulary and provides for lower cost-sharing for preferred drugs on a formulary, a Part D enrollee may request an exception to the tiered cost sharing. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the enrollee or would have adverse effects or both. Currently, for applicable exception requests, the Part D plans must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 72 hours (or 24 hours

in the case of an expedited decision) of receipt of the prescriber's supporting statement. However, if the Part D plan does not receive the prescriber's determination—an essential requirement, the exception request may remain pending for an extended period of time. CMS proposes that Part D plans must render a decision within the specified timeframes when prescriber determination is available, but in no case later than 14 calendar days after receipt of the request, whichever occurs first. Thus, CMS is proposing an outside limit to the timeframe to address instances in which a prescriber's supporting statement is not timely received. In the latter case, CMS proposes that on the 14th calendar day, the plan would be required to issue the standardized denial notice and explain with specificity the reason for the denial, the documentation needed to approve coverage of the requested drug, and the enrollee's right to request an appeal. However, CMS should also specify that in addition to notifying enrollees of appeal rights, the MA plan is required to notify enrollees that they are also entitled to submit a new exception request. It would not be appropriate for an enrollee to be denied a medically necessary and appropriate exception because an arbitrary deadline has been missed. Further, CMS should require MA plans to streamline, simplify, and provide automated and standardized methods for submission of required documentation and determinations and appropriate flexibility. The administrative burdens of utilization management documentation requirements continue to divert physician and health care team limited resources and time away from direct clinical care. We urge CMS to carefully evaluate the impact of this new 14 calendar day requirement and ensure compliance with notification of appeal right as well as the right to submit another exception request.

The AMA appreciates the opportunity to provide our comments and thanks CMS for considering our views. If you should have any questions regarding this letter, please feel free to contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,

James L. Madara, MD