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Patrick Conway, MD
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter

Dear Acting Administrator Conway:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Advance Notice of Methodological Changes for Calendar Year 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2018 Call Letter (Call Letter). The AMA strongly supports the Centers for Medicare & Medicaid Services' (CMS) focus on strengthening beneficiary access to essential medical services and treatment through meaningful choice of health plans in the Medicare Part D prescription drug benefit (Part D) and MA programs. We applaud CMS' continued focus on essential patient protections in the areas of network adequacy, accuracy, and transparency which are necessary prerequisites to realize the promise of informed choice in the MA and Part D programs. We further urge CMS to continue requiring and monitoring that MA and Part D plan sponsors offer clear and streamlined processes for challenging determinations made by plan sponsors that have the potential to result in adverse events and poor patient health outcomes. Overall, the AMA supports CMS' efforts in a number of the areas discussed below. In addition, we urge CMS to consider the unintended consequences of some of the recommendations that may create regulatory burdens without a commensurate benefit to beneficiaries.

Network Adequacy & Current Directories

The AMA welcomes and strongly supports CMS' efforts to strengthen network adequacy standards for MA plans. We urge continued oversight of MA sponsor compliance to ensure that physicians whose practices are closed or who are otherwise unavailable cannot be used to successfully meet MA network adequacy standards, and that CMS is addressing a range of issues with online provider directories. Clearly, directories should not include physicians who are no longer contracting with the MA plan because they have retired from practice, moved, or died. We agree that network directories should also clarify when physicians who are still in the MA plan's network are not accepting new patients.

The AMA supports CMS requirements that MA plan sponsors must establish and maintain proactive, structured communications with their network physicians in order to assess their availability on a timely basis and comply with applicable network access requirements. We applaud the requirement that plans

must implement protocols to effectively address inquiries and complaints about patients being denied access to contracted physicians, and that they must provide real-time updates to their online directories.

In addition to the information that CMS has indicated it requires plans to collect on office addresses, phone numbers, and hours, the AMA recommends that plans be compelled to maintain up-to-date information on the specialty and/or subspecialty of each physician in the network, as well as whether they practice on a full-time or part-time basis. For example, over time a pulmonologist may become a sleep medicine specialist and the network directories should reflect these types of changes. In addition, even if a physician's office is open full-time, that does not mean that all physicians in the group are practicing full-time.

The AMA reiterates our support of CMS efforts to monitor compliance with these regulations, including engaging an additional contractor to verify the accuracy of online provider directories; developing a new audit protocol; and indicating to plans that failure to maintain complete and accurate directories, as well as failure to have a sufficient number of physician practices open and accepting new patients, may subject the MA plans to civil monetary penalties or enrollment sanctions. In addition, the AMA strongly supports CMS requiring plans to provide and update network information in a standardized, electronic format for eventual inclusion in a nationwide provider database. The AMA agrees that such an approach could be leveraged by application developers to create user-friendly search applications that will be more accessible, up-to-date, and useful than the current, non-standardized websites or printed directories. These applications could allow patients to make more informed decisions about their health care coverage because they would know whether or not their physicians are in the plan before they enroll, and, if their physicians are not in the plan, they could see which plans their physicians do accept.

We further support in this Call Letter the CMS proposal that MA plan sponsors adhere to a separate network adequacy evaluation for special need plans (SNPs) given these MA plans are designed to provide specialty care to special target populations based on their unique health care needs. This beneficiary population is particularly vulnerable, and it is essential that network adequacy is viewed through the lens of medical specialty care as well as particular barriers to access that large geographic distances between beneficiaries and providers will play for this patient population. In addition, we strongly support provisions in the Call Letter that require sponsors that offer plans for dually eligible Medicare-Medicaid beneficiaries to have adequate networks to ensure enrollees have timely and reliable access to providers and pharmacies. We also support that states will evaluate networks for Medicaid services providers, including long-term supports and services as this constitutes, like the beneficiaries in SNPs, a vulnerable patient population that faces significant access to care barriers that are often exacerbated by limited resources.

Overall, we strongly urge CMS to outline the systematic process for validation of and update to the provider networks and the assessment of the adequacy of the network. The Part D and MA programs were designed to provide beneficiaries greater choice based on their needs and preferences. Therefore, it is a basic design requirement of the MA plan sponsors to ensure these fundamental requirements are met.

Removal of Measures from Star Ratings: High Risk Medication

The AMA strongly supports and urges CMS to finalize its proposal to remove the high risk medication (HRM) measure for Part D plans. The placement of a medication on the high risk list is not a

contraindication to its use, but rather an encouragement for prescribing decisions to consider risks and benefits for the senior population based on individual patient characteristics.

Physicians who care for aging patients agree that there are times when a HRM is the only reasonable option for a patient. A commonly cited example of appropriate use is when a patient is being provided end-of-life or palliative care, and the benefits of providing a drug to an older patient outweigh the risks associated with prescribing it. In such a situation, the drug should be made available to the patient and neither the physician nor the Part D plan should be penalized or inappropriately burdened for prescribing it.

Formulary Administration Analysis Measure (Part D)

The AMA strongly supports the CMS proposal to adopt a new display measure using the results of the Formulary Administration Analysis program by which CMS evaluates whether Part D sponsors are appropriately adjudicating drug claims consistent with Part D requirements and plan design. This is the type of information that beneficiaries need in order to understand whether or not a plan is more or less likely to provide access to medically necessary treatment, and we would urge CMS to expedite the inclusion of this critical information in the scope of items that beneficiaries have available when they are making plan elections.

CMS Star Ratings

We remain concerned that CMS' Star Ratings program is impeding clinical care and leading to increased administrative burden on physicians, and thus does not provide a beneficiary benefit. A large percentage of the measures within the MA Star Ratings program are based completely on physician action and compliance. In order for plans to comply and earn incentives from CMS, plans must often set within their physician contracts unrealistic targets on physicians for the plan to score well due to the Star Rating cut points. 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. There may be instances when compliance with a measure is contrary to appropriate care, but plans do not incorporate exceptions or suitable exclusions related to the measures due to the requirements CMS has set up for Star Rating compliance. It does not make sense to assume that all care should 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 one hundred percent adherence to a measure and in some cases the highest compliance may be eighty-percent or ninety-percent since there is a lack of data on what optimal performance should be for every measure.

If the Star Ratings program is designed to ensure and incentivize plans to provide high quality care to beneficiaries, then better alignment is needed between Star Ratings and Medicare physician quality programs, such as the Physician Quality Reporting System and now transitioning to the Quality Payment Program (QPP). There is no guarantee that a physician is adequately compensated, receives credit or aligns with a physician's QPP requirements for any of the activities a physician must engage in and adhere to for a plan to earn an incentive. This divide leads to increased administrative burden and competing priorities on physicians and hinders patient care, as opposed to improving the quality of care. At a minimum, the Star Ratings measures need to be aligned with the AHIP-CMS Core Measure Collaborative activity.

Furthermore, many of the measures, particularly the *HEDIS Effectiveness of Care* measures, have more to do with physician quality than assessment of a health plan. The *Effectiveness of Care* measures are really targeting clinical quality, which is a physician or facility issue—and therefore physicians and facilities have the data. Star Ratings should be refined to better measure the quality of plans and things over which the plan has control and the supporting data (for example, access). Without a better focus the MA ratings program is just one more burden on physicians and does not provide beneficiaries with the best information they need to determine the most appropriate and high quality Medicare Advantage or drug plan.

Administrative Burden: As the Star Ratings program has expanded and plays a larger financial role on health plans' bottom lines, the administrative demand has simultaneously increased on physicians. Specifically, as the HEDIS standards continue to evolve, laboratory data are playing an increasingly critical role in increasing HEDIS scores. In order for health plans to increase their HEDIS scores and earn greater incentives from CMS, plans are requiring practices as part of their clinical data submission requirements to submit data on all patient lab results. Often the plans require this information to be submitted within 30 days and state it is due to the Star Ratings HEDIS requirements.

Some of the measures that are leading to this tedious and time consuming demand on physicians are the following:

- NCQA 0575: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0 percentage)
- NCQA 0057: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Testing
- NCQA 0062: Comprehensive Diabetes Care: Medical Attention for Nephropathy NCQA
- NCQA 0018: Controlling High Blood Pressure

Plans have also expressed an intention to expand these requests to additional types of clinical data to support other HEDIS measures, including those addressing blood pressure control and BMI assessment.[1,2] Practice burdens will continue to grow as plans ask for more types of clinical data to support increased Star Ratings.

We therefore urge CMS to require health plans to allow practices to respond *at-will* at a time of their choosing, at a minimum allow for at least 90 days to respond, support use of electronic methods of data submission, **and** adequately compensate physicians for the time and burden. We also urge CMS to refocus Star Ratings on metrics over which health plans have direct control and access to supporting data, as continued inclusion of clinical quality measures in the program will invariably burden physicians with data requests from health plans.

Display Measures

- *CAHPS measures (Part C & D):* The AMA is supportive of CMS removing the following measures within CAHPS because the following are not relevant to assessing health plan

[1] United Healthcare (UHC). Outreach Efforts to Begin July 1 to Support Care Providers with Continued Adoption of Clinical Data Submission Protocol. Clinical Data FAQs. 2015 *Accessed Feb. 24, 2017.*
[2] United Healthcare (UHC). Physician, Healthcare Professional, Facility, and Ancillary Provider 2016 Administrative Guide - For Commercial and Medicare Advantage Products. *Accessed Feb. 24, 2017.*

performance: reminders for appointments, computer use during office visits, computer use by provider helpful, computer use made talking to provider easier. However, we are disappointed that CMS has eliminated the "Getting Information from drug plan" measure from CAHPS because we frequently hear from physicians and beneficiaries that it is extremely difficult to access accurate and timely information on drug plans.

- *Non-Recommended PSA-Based Screening in Older Men (Part C):* The measure Non-Recommended PSA-Based Screening in Older Men (Part C) as currently drafted would be detrimental to patient care, and the AMA strongly recommends against it. While the AMA appreciates the addition of several exclusions, the measure may incentivize physicians and plans to disregard patient and clinician discussions about PSA screening or simply deter screening all together and obviate the patient's right to information about risks and benefits. Most critically, this measure hinders shared decision making (SDM), which is in stark contrast to the vision set forth in CMS' Quality Strategy to emphasize person-centered care, and harkens back to an era when decisions were made for the patient rather than with the patient. Measures that ignore the established role of SDM will make it more difficult for providers to help patients make important decisions that align with their personal preferences. The discussion of the risks and benefits of PSA screening in targeted populations is supported by many leading societies, including American College of Physicians, American Society of Clinical Oncology, American Cancer Society, and the American Urological Association (AUA).

  Recent evidence also points to a decline in screening. *JAMA* has published two peer-reviewed studies documenting that fewer men are being screened for prostate cancer, and fewer early-stage cases are being detected.[3] These studies highlight that the number of cases has dropped not because the disease is becoming less common, but because there is less effort being made to find it. Any measures aimed at reducing access to screening would be detrimental to efforts to give patients greater control of their healthcare decisions and hinder endeavors to catch earlier stage cancers before they progress to a stage beyond effective treatment.

  There are several exclusions listed for the measure in question, but the measure does not account for comorbidities, individualized risk for prostate cancer, prolonged life expectancy, and patient preferences. Exclusions should be provided for men at high risk, including African Americans, men with a family history of the BRCA gene and those with a family history of prostate cancer. These high risk groups are a critical population that many medical societies, including the AUA, specifically state should be considered distinct from the broader population. Additionally, the measure should distinguish screening from diagnostic PSA testing. Exclusions should include symptoms that may be suggestive of benign prostatic hyperplasia, such as frequency and nocturia or dysuria, but which may in fact point to prostate cancer. Furthermore, prostatitis and chronic pelvic pain should be excluded as they necessitate PSA testing to ensure that cancer is not an explanation for the symptoms.

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[3] Sammon JD, Abdollah F, Choueiri TK, Kantoff PW, Nguyen PL, Menon M, Trinh QD. Prostate-Specific Antigen Screening After 2012 US Preventive Services Task Force Recommendations. JAMA. 2015 Nov 17;314(19):2077-9; Jemal A, Fedewa SA, Ma J, Siegel R, Lin CC, Brawley O, Ward EM. Prostate Cancer Incidence and PSA Testing Patterns in Relation to USPSTF Screening Recommendations. JAMA. 2015 Nov 17;314(19):2054-61.

Stratification by age is a critical element of the AUA's 2013 Guideline on the Early Detection of Prostate Cancer, which does not recommend routine PSA screening in men age 70+ years or any man with less than a 10-15 year life expectancy. However, the panel noted that some men age 70+ years who are in excellent health may benefit from screening. Seventy-year-olds in the United States currently have a median life expectancy of 84 years, and this figure is not uniform. Therefore, for healthy men at that age, PSA screening may be appropriate. Additionally, the AUA emphasizes the importance of SDM, a key component of high-quality health care, and advocates for adoption of SDM into routine clinical practice. The screening decision should be shared between patients and their physician and should consider the tradeoff between length and quality of life inherent in PSA screening. Therefore, the measure is inappropriate, and will penalize physicians and patients who choose PSA screening and interferes with the patient-physician relationship and should be removed from the program.

Forecasting to 2019 and Beyond

CMS has proposed changes to existing measures and potential new measures. The AMA offers the following feedback on specific measures:

- *Telehealth and Remote Access Technologies:* The AMA supports including telehealth and/or remote access technology encounters as "eligible encounters" in various Part C quality measures to the extent the telehealth services are allowed under the current statutory definition of Medicare covered telehealth services and/or as a provided by the MA sponsor as a MA supplemental benefit. Telehealth and remote access technology while very limited under Medicare currently and still quite limited under MA, increasingly provide access to services that currently are equivalent to in-person care and services.

- *Cross-Cutting Exclusions for Advanced Illness*. The AMA supports excluding individuals with advanced illness from selected Part C measures. The health status of these individuals often makes compliance with the measure difficult and/or inappropriate. **We also recommend that CMS allow for more general exclusions for patients with specific conditions, comorbidities or allergies from Part C measures to ensure patient and clinical differences are accounted for and do not interfere with clinical decision making, and for denominators of quality measures to be appropriately defined to ensure patients for whom the treatment may not be appropriate are excluded.** As we mentioned earlier, many of the measures within the Star Ratings program are heavily reliant on physician action and data and there are instances where strict adherence to a measure interferes with patient preferences and/or is clinically inappropriate. For example, the *Medical Attention to Nephropathy measure* that is part of the Comprehensive Diabetes Care composite requires a physician to prescribe an ACE inhibitor or ARB, and we have heard of instances where a physician must deviate from the measure due to patient allergies. But the measure does not account for this type of exclusion, and the plan and physician are penalized. Broadening exclusions may also assist with dealing with the cut point issue because not all care can be completed at a hundred-percent level and allow for encounters that warrant physician non-conformance with measure specifications.

Changes to the OMS Opioid Overutilization Methodology

CMS is proposing several changes to the methodology used in the Part D Opioid Overutilization program that the AMA agrees are reasonable and will improve administration of the program:

- The measurement period would be shortened to 6 months from 12 months to better focus on current potential overutilization and reduce the number of repeat cases.
- Average Morphine Equivalent Dose (MED) will be used instead of a count of 90 consecutive days MED in order to lessen the impact of gaps in prescription fills and days' supply in identifying potential overuse.
- Physicians prescribing opioid analgesics will be grouped in their practices to eliminate false positives that occur when two or more prescribers in the same practice issue opioid prescriptions to the patient.

CMS suggests exempting from the program patients with cancer diagnoses and those in hospice. The AMA recommends that exemptions should also be considered for the following patients: those receiving palliative care, those with a terminal condition who may not have elected hospice care, those in a long-term care facility, and those receiving medication-assisted treatment for substance use disorders. These additional exemptions would be especially important if CMS adopts the change to target patients with more than three prescribers regardless of the number of opioid dispensing pharmacies.

The AMA also agrees that the hard edit threshold be set no lower than 200 mg MED and appreciates the instructions to plans regarding the need to take steps to avoid false positives.

Pharmacy Quality Alliance Opioid Measures

The revisions being made to the Opioid Overutilization program, particularly the change to use of average MED instead of 90 consecutive days, are inconsistent with the language in the opioid utilization quality measures (on page 102) in the draft Call Letter, which include the 90 consecutive days language. Also, we note that these measures exclude patients on buprenorphine, which is consistent with our recommendation that the Opioid Overutilization program also needs to exempt these patients. Access to medication-assisted treatment for opioid use disorder is already negatively affected by stigma and prejudice towards these patients. Being targeted by plans for suspected overuse could lead to interference with medication adherence and lead to relapse.

Prior Authorization Requirements

Since the inception of the Part D prescription drug benefit, the AMA has frequently raised concerns about plans' use of prior authorization and other drug utilization management (DUM) requirements as a means to reduce utilization and spending, even when there are no valid patient safety reasons for requiring these extra steps. DUM demands impose unnecessary administrative burdens on prescribers and unjustified access delays on patients. Patients are enrolled in an enormous number of different Part D plans, each with their own formularies and prior authorization requirements. Physicians receive no compensation for the many hours of frustrating administrative time they spend trying to overcome hurdles that plans have placed before their patients' rapid access to their medications.

A recent AMA survey found that 75 percent of respondents described the burden associated with prior authorization on physicians and staff in the practice as "high" or "extremely high," with 22 percent estimating they and their staff spend over 20 hours a week processing prior authorizations. An overwhelming 90 percent reported that prior authorization delays access to necessary care, even though 79 percent of prior authorization requests are eventually approved. Furthermore, 80 percent reported being sometimes, often, or always required to repeat prior authorizations for medications after a patient is stabilized on a medication to manage a chronic condition.

As an example, physicians who treat patients with glaucoma experience numerous prior authorization and other DUM demands that detract from their patients' care, which can have serious effects when they prevent patients from adhering to their drug regimen. Several of them are outlined below:

- Brimonidine (for glaucoma)
  Alphagan P 0.1 percent and 0.15 percent brand, versus Brimonidine 0.15 percent generic that has an acceptable preservative, versus Brimonidine 0.2 percent that has a 25 percent or more rate of developing chronic allergy over time. A number of Part D plans consider Brimonidine 0.2 percent the only generic they will supply and ophthalmologists are forced to use it, despite the high risk of allergy. Once patients become allergic to the 0.2 percent solution, they can no longer use any of the alternatives because they will be allergic to those also.

- TravatanZ versus Travaprost
  TravatanZ uses a very gentle preservative and for some patients with dry eye, it is better for them than the generic. However, it is difficult to get authorization for TravatanZ, and even when patients have been on that version for years, they are forced to switch to a generic. Also, recently, Travaprost generic became unavailable, leading to patient and pharmacist inquiries about whether they could switch to another drug, rather than providing the patient with the brand TravatanZ. If the generic is unavailable, it should be standard policy that patients get the brand name medication instead of being forced to switch.

- Combination agents that are currently brand name only
  Combigan (brimonidine + timolol) and Simbrinza (brimonidine + brinzolamide)
  These drugs are often denied for patients who are already on the component medications or who need an escalation of therapy with an additional medication. This means patients must continue to use the multiple bottles and multiple administrations rather than the more convenient combination dosing that improves adherence, as patients who have fewer bottles and fewer times that they have to accurately apply their drops can more easily administer their medications.

- Prostaglandin analogs
  Latanoprost or brand Xalatan; travaprost or brand TravatanZ; Lumigan; Xioptan (preservative free)
  Patients continue to have to use a generic prostaglandin before being allowed to use any of the brands. Even patients who have been documented to do well during the previous year (or more) on a particular drug are forced to switch or pay higher copays because their plan has negotiated a better price on a different drug and the formulary has changed.

- Classification as "Anti-Glaucoma Agents"
  Many Part D plans do not understand that there are different classes for glaucoma drugs, so physicians who prescribe multiple medications to manage patients' glaucoma are warned against prescribing "duplicate" therapy and face coverage restrictions.

The AMA urges CMS to require MA and prescription drug plans to sharply curtail their use of prior authorization and other DUM requirements. The AMA also recommends that policies be established to ease the process of complying with prior authorization requirements. Standard electronic transactions for prescription prior authorizations have been available since 2013 and are already mandated for use in certain states (e.g., Minnesota). These transactions allow physicians to prospectively complete pharmacy prior authorizations as part of the e-prescribing process, support significantly faster response times, avoid the hassles associated with re-entering data and remembering passwords for proprietary portals, and reduce administrative burdens for physicians and staff. **A federal requirement for Part D plans to support these transactions could ensure faster patient access to medications and reduce substantial practice burdens across the country.**

Furthermore, transparency of these requirements should be improved by requiring all MA and Part D plans, as well as pharmacy benefit managers, to: (1) publicly disclose to both patients and physicians in a searchable electronic format all drugs and medical services that are subject to coverage restrictions (prior authorization, step therapy, formulary restrictions, quantity limits); and (2) provide this information to vendors to be displayed in electronic health record systems. This increased transparency will ensure that physicians are aware of any restrictions when prescribing/ordering therapy and allow patients to make informed choices when enrolling in health care coverage.

Medicare Advantage Seamless Conversions

The AMA urges CMS to eliminate the so-called "seamless conversion" policy. To date, CMS has placed a temporary moratorium on new applications for a policy that allows MA plans to submit proposals to CMS, which are then reviewed at the CMS Regional Office level, to automatically enroll patients who are in commercial, exchange, or Medicaid insurance plans operated by the organizations into the MA plans offered by these same organizations once the patients become eligible for Medicare based on their disability or age. Patients in the non-Medicare plans receive a letter indicating that they will be automatically enrolled once they are Medicare eligible. If they do not want to participate in the organization's MA plan, they must take action to opt out of the seamless conversion. Serious problems arise, particularly when patients are not adequately informed about their choices and/or do not understand how to avoid the conversion. Problems also arise when the physician networks for the MA plan are narrower than those for the pre-Medicare health insurance. In light of the documented widespread deficiencies in health plan provider network directories, it is highly unlikely that patients could even make an accurate comparison between the physician networks for the different plans. **The temporary moratorium on new applicants should be replaced with a permanent cancellation of the MA policy on seamless conversions.**

Provision of Annual Wellness Visit Services

The AMA has heard numerous complaints regarding the manner in which MA plans are handling delivery of Annual Wellness Visit (AWV) services. MA plans frequently contract with outside vendors for these services, instead of having them provided by patients' primary care physicians. Some of these outside vendors use deceptive marketing tactics, such as holding "wellness fairs" and then billing for an AWV. Most of the time that AWV services are provided by outside vendors, there is no report to the patients' primary care physician nor any follow-up on the findings from the screening. This practice impedes continuity of care and prevents the AWV from realizing its potential contribution to preventing illness and identifying previously undiagnosed conditions requiring treatment plans or additional diagnostic work-ups. **The AMA strongly urges CMS to modify federal policy to promote provision of the AWV by the patient's regular physician instead of as a one-time-only service from an outside vendor.**

CMS Monitoring and Compliance Activities Regarding Encounter Data

The AMA understands that CMS has transitioned to new blended methods for calculating beneficiary risk scores. The AMA also appreciates that such methods and data must be complete and accurate. As CMS implements increased monitoring and compliance activity in this area, the agency is strongly urged to consider that physicians bear a significant administrative burden because plan sponosors focus on optimizing payment through risk scores. We urge CMS to evaluate the impact of these activities on the additional documentation and record production and other administrative activities physicians will be asked to shoulder by plan sponsors as this will detract from time and opportunity to render patient care.

Specialty Tiers

Health plans are using various benefit design strategies to control their costs associated with the coverage of specialty drugs. One of the leading strategies, four-tier pharmacy benefit design, has become common in Medicare Part D. With a four-tier design, many specialty drugs are assigned to the fourth tier, also called a "specialty tier," which generally has much higher cost-sharing for beneficiaries. Patients in need of fourth tier drugs commonly have to pay coinsurance – and pay a percentage of the total drug costs – versus defined copayments. Coinsurance in the fourth tier can range from 10 percent to 35 percent of the cost of the specialty medication. Although out-of-pocket maximums are often in place, and some subsidies may be provided by drug companies, transitioning from the third to the fourth tier represents a significant increase in cost-sharing for patients. We remain concerned with the impact of specialty tier co-insurance on beneficiary access and health outcomes. We strongly urge CMS to consider this practice on patients, particularly those who have difficulty obtaining subsidies or who are not well-positioned to advocate for them.

Formulary Submissions

The AMA strongly supports CMS direction to plan sponsors on permissible and prohibited modifications during the summer formulary update window. The finalization of these provisions is key to benenficiary access to medically necessary treatment and safeguarding beneficiary informed decision-making and notice of formulary design. We support the directive that enhancement to formularies must be included in the sponsor's marketing materials, and the AMA urges CMS to require sponsors (as opposed to simply

encouraging them) to notify beneficiaires of formularly additions in a timely manner, since in some cases an earlier conversion could lead to cost savings for the beneficiary and overall health care costs.

Tiering Exceptions: Policy Clarifications

The AMA applauds the clarification to address non-compliance by Part D plan sponsors that have failed to establish and maintain reasonable and complete exceptions procedures when including a tiered formulary in the plan's benefit design. Given the well-documented difficulty beneficiaries and their physicians face navigating the appeals, exceptions, and complaint processes established by MA and Part D plan sponsors, it is troubling that certain plans, due to confusing and elaborate plan design, have rejected tiering exception requests for technically convoluted and legally inappropriate reasons. We strongly support the numerous clarifications that CMS has provided to appropriate handling of tiering exception requests. In the same vein, the AMA also strongly supports the clarification of how plan sponsors are required to define preferred drugs as well as the appropriate disposition of an approved tiering exception request to mean that the lowest cost sharing level applies. These are troubling examples because of the difficulty and administrative burden of navigating a confusing exceptions request process and the needless obfuscation by plan sponosrs that diverts limited physician and staff time from direct patient care to assist beneficiaries mired in these processes. Furthermore, plan noncompliance negatively and directly impacts patient health outcomes because it may undermine patient adherence. We support CMS oversight and ongoing assessment of compliance with these policy clarifications.

Conclusion

The AMA appreciates the opportunity to provide comments on the 2018 Call Letter. In order to promote patient improved health outcomes, it is axiomatic that beneficiaries must have access to medically necessary services and treatments. We appreciate the CMS efforts to improve the MA and Part D programs and urge the agency to consider additional strategies to streamline and improve the quality and usability of the information that beneficiaries rely upon when making plan elections and when pursuing appeals and exception requests. We also reiterate the need to ensure and assess regularly compliance with network adequacy and up-to-date and accessible provider directories. Finally, we strongly urge CMS to consider the areas discussed above that create administrative burdens on physician practices, and do not improve patient access or care.

Sincerely,

James L. Madara, MD