AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–4201–P. Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the contract year (CY) 2024 Notice of Proposed Rule Making (NPRM) outlining technical changes to the Medicare Advantage (MA) and prescription drug benefit policies, published in the *Federal Register* on December 27, 2022 (87 Fed. Reg. 79452). The NPRM covers numerous topics aimed at strengthening beneficiary protections, improving access to behavioral health care, and promoting equity for millions of Americans with MA and Medicare Part D.

A number of topics that CMS includes in the proposed rule are also addressed in the AMA's March 2022 comment letter as well as our August 2022 comment letter. We encourage the agency to also consider these comments and recommendations in addition to the comments provided below.

The AMA developed our Recovery Plan for America's Physicians to address pivotal issues that hinder our physicians from providing optimal care and to seek fundamental changes to create a health system that better supports patients and the physicians who care for them. The plan outlines five pillars that strengthen our physician workforce, recover from the trauma of the pandemic, and improve health care delivery by eliminating some of the most common burdens that threaten to drive physicians from practice. These include:

- Fixing prior authorization to reduce the burden on practices and minimize dangerous care delays for patients.
- Reforming Medicare payment to promote thriving physician practices and innovation.
- Fighting scope creep that threatens patient safety.
- Supporting telehealth to maintain gains in coverage and payment.

- Reducing physician burnout and addressing the stigma around mental health.

The AMA applauds CMS for acknowledging our concerns, as well as those of our patients, in particular by including several meaningful proposals addressing significant prior authorization (PA) reforms. As commented in greater detail below, the policy changes outlined in the proposed rule align with reforms contained in the AMA PA Principles and Consensus Statement and will significantly improve PA in the MA and Part D programs. **We appreciate that CMS recognizes the burdens associated with the PA program, particularly within MA, and urge you to adopt these policies as written, or with the strengthening recommendations detailed below, to support judicious, transparent, and clinically appropriate use of PA that protects beneficiaries' access to treatment.**

This letter will address the following requested topics:

A. Ensuring Timely Access to Care: Utilization Management Requirements
B. Medicare Advantage Network Adequacy: Access to Services
C. Protecting Beneficiaries: Marketing Requirements
D. Strengthening Quality: Star Ratings Program
E. Advancing Health Equity
F. Improving Drug Affordability and Access in Part D
G. E-Prescribing and health information technology (health IT) standards

The following outlines our principal recommendations on the 2024 NPRM.

- The AMA urges CMS to finalize many proposed PA policies as written, including but not limited to codifying that beneficiaries in MA plans must have access to the same items and services as they would under Traditional Medicare; prohibiting MA plans from denying care ordered by a contracted physician unless medical necessity criteria are not met; clarifying that behavioral health services furnished as emergency services cannot be subject to PA; and requiring that PA approvals remain valid for the duration of the course of treatment.
- The AMA also supports the other proposed PA policies and makes several recommendations to strengthen them in order to support judicious, transparent, and clinically appropriate use of PA that protects beneficiaries' access to treatment. For example, CMS could further improve continuity of care protections for patients on ongoing medication therapy by requiring that Part D plans' PA approvals remain valid for the duration of prescribed course of treatment.
- The AMA supports the Medicare Advantage Network Adequacy proposals. However, we stress that such alternative arrangements should not substitute for compliance with network adequacy requirements and urge CMS to monitor the use of these alternative arrangements to ensure that MA plans are consistently providing access to in-network care.
- The AMA recommends that Part D plans be required to immediately notify both impacted patients and prescribers when an "immediate substitution" takes effect for an interchangeable biological product, instead of permitting a communication delay of up to two months.
- The AMA supports CMS' proposals to expand certain requirements for notifying beneficiaries when their physicians are terminated from an MA plan's network and agree that this provides improvements over current Medicare requirements.
- The AMA recommends that MA plan agents maintain a level of transparency such that the incidence of confusion among potential enrollees about covered and non-covered services is unmistakably clear.

- The AMA encourages CMS to work with the Agency for Healthcare Research and Quality (AHRQ) to update the Health Plan Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey.
- The AMA urges caution in adoption of new quality measures outlined below and requests that CMS ensure, if the quality measures are adopted, that plans cannot impose PA or other administrative burdens or financially penalize physicians to enforce measure compliance.
- The AMA recognizes the importance of using medical interpreters as a means of improving the quality of care provided to patients with limited English proficiency (LEP) including patients with sensory impairments and supports that MA organizations and cost plans should cover the full cost of language services and directly pay interpreters for such services to ensure that proper and effective care can be provided.
- The AMA recognizes that in order for the requirement that linguistic and cultural care information be included in provider directories to be truly beneficial for providers and patients, MA provider directories must be accurate and complete.
- The AMA strongly supports the CMS proposal to require that MA provider directories assist beneficiaries in identifying which network physicians prescribe medications for opioid use disorder (MOUD).
- The AMA recognizes that in order to increase access and truly provide culturally competent care commensurate with higher spending per beneficiary, MA plans need to change their incentive structure.
- The AMA applauds CMS' initiative to bring forward the health equity implications as it extends to digital health literacy and the need for improvements in the MA beneficiaries' experience with understanding and being able to fully realize the telehealth benefits afforded in each plan.
- The AMA supports CMS' proposal to make the Limited Income Newly Eligible Transition (LI NET) Program a permanent part of Medicare Part D, as required by the Consolidated Appropriations Act (CAA). The AMA also supports the proposal to implement section 11404 of the Inflation Reduction Act (IRA), which expands eligibility under the low-income subsidy program in 2024.
- The AMA urges both the Office of the National Coordinator for Health IT (ONC) and CMS to ensure that updated SCRIPT and Real-Time Prescription Benefit (RTPB) standards are widely available in the electronic health record (EHR) vendor market prior to placing any requirements on physicians for adoption (e.g., ONC EHR certification or CMS Promoting Interoperability measures). We urge ONC and CMS to monitor the availability of these standards in physician-facing products to ensure the feasibility of any future physician-facing requirements.
- The AMA supports CMS' proposed new approach to standards adoption through which the Secretary of Department of Health and Human Services (HHS) would adopt health IT standards under the authority of the Public Health Service Act and agrees that it will support greater alignment between ONC and CMS, improve the ability to synchronize timelines, reduce confusion, and minimize regulatory burdens.

Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program

A. Ensuring Timely Access to Care: Utilization Management Requirements

I. Streamlining Prior Authorization (PA)

Current PA Landscape

Several recent studies describe the harmful impact of PA on both patients and physician practices. In a 2021 AMA survey of over 1,000 practicing physicians, 93 percent of physicians reported care delays because of PAs, with 82 percent indicating that patients abandon treatment due to PA struggles with their health plans.[1] Not surprisingly, 91 percent of physicians reported that PA has a negative effect on their patients' clinical outcomes, with this impact sometimes being severe: 34 percent of physicians said that PA has led to a serious adverse event (e.g., hospitalization, permanent impairment, or even death) for a patient in their care. Beyond these alarming effects on patient health, AMA survey data also capture the administrative waste associated with the PA process: practices reported completing an average of 41 PAs per physician, per week, with this workload for a *single physician* consuming nearly two business days of physician and staff time.

Physicians' experiences with PA align with the findings of the HHS Office of Inspector General (OIG) 2022 report,[2] which found that 13 percent of PA requests denied by MA plans met Medicare coverage rules, and 18 percent of payment request denials met Medicare and MA billing rules. The report included disturbing case studies describing how MA beneficiaries were denied treatment—care that would have been *covered under Traditional Medicare*—due to opaque, proprietary MA plan clinical criteria.

Most recently, a Kaiser Family Foundation analysis found that MA plans denied two million PA requests in whole or in part in 2021, representing about six percent of the 35 million requests submitted that year.[3] While only about 11 percent of PA denials were appealed, the vast majority (82 percent) of appealed denials were fully or partially overturned, raising serious concerns about the appropriateness of many of the initial denials.

Calls for PA Reform

With mounting concerns regarding the clinical validity of MA plans' PA criteria and the resulting adverse impact on patients, many stakeholders have called for PA reform. In 2017, the AMA, along with a coalition of organizations representing physicians, medical groups, hospitals, pharmacists, and patients, released the Prior Authorization and Utilization Management Reform Principles, which outlined critical improvements needed to protect patients' access to necessary treatment.[4] These principles spurred an industry dialog that culminated in the January 2018 publication of the Consensus Statement on Improving

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[1] 2021 AMA Prior Authorization Physician Survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[2] Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[3] Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021. https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021.

[4] Prior Authorization and Utilization Management Reform Principles. https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

the Prior Authorization Process.[5] **Notably, the Consensus Statement represented agreement between health care professional organizations and insurer trade associations on the need for PA reform.** Unfortunately, subsequent AMA physician survey data illustrate that health plans' progress in voluntarily making the agreed-upon changes has been disappointingly slow.[6]

In addition, OIG called upon CMS to issue new guidance that would ensure MA beneficiaries' timely access to medically necessary care and appropriate physician payment following the concerns identified in its 2022 report. Specifically, OIG instructed CMS to address appropriate use of clinical criteria in medical necessity reviews and system vulnerabilities that can lead to errors in PA determinations.

Feedback on CMS' PA Proposals

The AMA applauds CMS for listening to our physician members, their patients, the OIG, and many other stakeholders and recognizing the need for important guardrails in PA programs to protect beneficiaries from unreasonable barriers to medically necessary care. The policy changes outlined in the proposed rule align with reforms contained in the PA Principles and Consensus Statement mentioned above and will significantly improve PA in the MA and Part D programs. **We urge CMS to adopt these policies as written, or with the strengthening recommendations detailed below, to support judicious, transparent, and clinically appropriate use of PA that protects beneficiaries' access to treatment.**

Clinical validity and transparency of coverage criteria

Physicians want nothing more than to provide the most clinically appropriate care for their patients. The proposed rule would make significant improvements to the coverage criteria used in medical necessity determinations and ensure a clinically sound foundation for PA programs, and **we urge CMS to finalize the following provisions as written:**

- Allowing MA plans to only use PA to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service, to ensure medical necessity based on newly specified standards, or to ensure that the furnishing of supplemental benefits is clinically appropriate. **In other words, PA is not a tool to be used to delay or discourage care.**
- Codifying that beneficiaries in MA plans must have access to the same items and services as they would under Traditional Medicare. MA plans must use applicable Medicare statute, regulation, National Coverage Determinations (NCDs), or Local Coverage Determinations (LCDs) rather than internal or proprietary coverage criteria. When no such statute, regulation, NCD, or LCD exists, MA plans must use current evidence in widely used treatment guidelines or clinical literature when creating internal clinical coverage criteria, which must then be made publicly available.
- Prohibiting MA plans from denying care ordered by a contracted physician unless medical necessity criteria are not met, thus preventing intrusion into the beneficiary-physician decision making process by restricting plans' ability to steer patients to providers or settings that may not be the most appropriate based on individual factors.

[5] Consensus Statement on Improving the Prior Authorization Process. https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.
[6] 2021 update: Measuring progress in improving prior authorization. https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

- Clarifying that an emergency medical condition can be physical or mental, and, as such, **behavioral health services furnished as emergency services cannot be subject to PA.**

The AMA supports CMS' proposal that would require an MA plan to establish a Utilization Management (UM) Committee to review policies annually to ensure consistency with NCD and LCD guidelines and to review the plans' clinical coverage criteria. We recommend that CMS strengthen this provision with the following enhancements, many of which were already suggested by CMS, by requiring the following:

- Inclusion of **more than one independent physician** on an MA plan's UM Committee, as impartiality and freedom from conflict of interest are key to ensuring unbiased plan oversight;
- Participation of at least one physician with expertise regarding a particular item/service and its associated medical condition during UM Committee review of such item/service;
- Review of all internal coverage criteria (not just related to UM) by the UM Committee, as other coverage rules can negatively impact beneficiary access to care;
- Regular solicitation of input from network physicians on UM Committee decisions;
- Ongoing, active oversight of MA plans' UM decisions throughout the year;
- Removal of PAs and other UM requirements for items and services that no longer warrant restrictions, due to high approval rates or changing clinical guidelines;
- Involvement of the UM Committee in developing processes and procedures that will prevent manual and system errors in MA plans' PA programs, as described by the OIG report; and
- Regular submission of UM Committee determinations and associated documentation to CMS to allow for CMS audit and oversight.

The AMA also appreciates CMS' proposal to require that any physician or health care professional issuing an adverse determination have expertise in the field of medicine that is appropriate for the requested service, as our member physicians regularly express frustration that health plan "peer" reviewers do not have the appropriate clinical background or expertise to render a correct decision regarding an individual patient's treatment. **However, we urge CMS to strengthen this provision by specifying that such decisions be made by a licensed physician in the state where care is being provided, of the same specialty as the physician who typically manages the medical condition or disease or provides the health care service involved in the request, and with experience in the treatment being recommended.** We believe these changes will achieve CMS' underlying intention of ensuring the appropriate qualifications of reviewers, supporting thorough clinical review, and preventing inappropriate PA denials.

Continuity of care and reliance on approvals

Once a PA approval has been received, it is important that patients and physicians be able to rely on that determination and maintain access to that medically necessary care. Too often, disruptions in care caused by repetitive PA requirements result in loss of function, increased pain, or other adverse outcomes for patients. **The proposed rule would protect MA beneficiaries from these harms by preventing disruptions in ongoing care, treatment delays, and unanticipated medical costs, and we urge CMS to finalize the following provisions as written:**

- Requiring a PA approval to remain valid for the duration of the course of treatment.
- Requiring MA plans to provide beneficiaries with at least a 90-day transition period where a PA would remain valid for any ongoing course of treatment when moving between plans,

transitioning from Traditional Medicare, or enrolling in Medicare for the first time. **This ensures continuity of care for beneficiaries, especially those with chronic disease or conditions and/or those living in underserved areas for whom frequent trips to and from their physician's office present logistical challenges.**
- Preventing retroactive coverage denials based on a lack of medical necessity, thus **protecting patients and physicians from costs and delays that may result from such unanticipated coverage denials.**

We also would like to highlight the synergy between the proposed 90-day transition period and a provision in the CMS Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule, which would require health plans to exchange patient data, including PA requests and decisions, when a patient changes plans. This proposed payer-to-payer data exchange would provide key technological support to the 90-day transition period and facilitate MA plans' implementation of this requirement.

The AMA also supports codification of current Part D plan policies that further strengthen protections for continuity of prescription drug therapy. **Specifically, we urge CMS to adopt the following proposals as written to prevent disruptions in ongoing drug treatment:**

- Part D plans must provide an appropriate transition for patients facing a new quantity limit on a formulary medication.
- Part D plans with access to a patient's prior drug claims must use a minimum 108-day lookback period to determine whether a pharmacy claim represents a chronic drug therapy requiring a transition fill; absent such claims history, the plan must treat the prescription as ongoing treatment entitled to a transition fill.
- Part D plans' Pharmacy & Therapeutics Committees must review and approve transition policies and procedures.
- Part D patients experiencing a level of care change, such as admission or discharge from a hospital, skilled nursing facility, long-term care facility, or hospice, must be provided with the plan's transition process for ongoing prescription drug therapy.

We believe that CMS could further improve continuity of care protections for patients on ongoing medication therapy by requiring that Part D plans' PA approvals remain valid for the duration of prescribed course of treatment. This would align Part D requirements for the duration of PA approvals with those proposed for MA plans in this rule and promote consistency between programs. Importantly, as stated above, this would prevent disruptions in treatment that can lead to loss of function, increased pain, hospitalization, and other negative health outcomes. Of note, CMS cited such consistency as desirable when proposing to use a 90-day transition policy for MA plans, as this mirrors current requirements for Part D plans.

Alternatives and exemptions

We appreciate CMS' acknowledgment of the enormous resource drain PA presents for physicians and their practices. As detailed above, AMA survey data quantify the time and resources that physicians and their staff spend on an ever-growing PA workload, with 88 percent of physicians describing their PA

burden as high or extremely high.[7] This burden translates into less clinical time with patients and contributes to an exhausted, burned-out, and overwhelmed workforce, making it imperative that stakeholders focus on reducing the volume of PAs. As such, and in alignment with Principle #20 of our PA Principles,[8] the AMA advocates that health plans should offer physicians at least one physician-driven, clinically based alternative to PA, such as but not limited to gold-carding or "preferred provider" programs or attestation of use of clinical decision support systems or clinical pathways.

For these reasons, we are pleased to see CMS encouraging MA plans to implement gold-carding programs to allow physicians to be exempt from PAs when they have a track record of high approval rates. The AMA stands ready to work with CMS to develop meaningful guidelines for gold-carding programs that would reduce the volume of PAs to the benefit of all stakeholders. Of note, health plan representatives agreed to selective application of PA requirements, such as is accomplished by gold-carding programs, in the 2018 Consensus Statement. **We believe that MA plans are particularly well suited to implement gold-carding programs, especially given the consistency in coverage criteria in this proposed rule, and we encourage CMS to establish a requirement on plans to develop such programs.**

Automation and efficiency

We continue to be concerned by the inefficiencies posed by the currently manual PA workflow. We stress that all tasks related to PA—from determining requirements and documentation needs to the actual submission of the PA request—**remain largely unautomated and extremely time consuming**. Of note, 65 percent of surveyed physicians report that it is difficult to determine whether a prescription medication requires PA.[9]

We therefore commend CMS for addressing the need for real-time, patient-specific prescription drug coverage information at the point of prescribing and proposing a requirement for Part D plans to implement the National Council for Prescription Drug Programs (NCPDP) Real Time Prescription Benefit (RTPB) standard, which would allow physicians to check PA requirements and drug formulary status at the point of prescribing in EHRs. Provision of accurate, current information about a patient's prescription benefit will enable physicians and patients to evaluate drug costs and consider possible alternative therapies when selecting a medication regimen. Additionally, and equally importantly, provision of these data within the e-prescribing workflow will ensure physician awareness and completion of PA and step therapy requirements before a patient arrives at the pharmacy to pick up a prescription. Transparency of coverage restrictions in EHRs can thus prevent medication nonadherence and treatment abandonment.

As discussed in the proposed rule, current CMS regulations only require Part D plans to support a single real-time benefit tool that is required to integrate with only one physician EHR/e-prescribing system, leading to suboptimal adoption and the patchwork of proprietary solutions available today. Adoption of the NCPDP RTPB standard should significantly increase access to formulary data, including PA

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[7] 2021 AMA Prior Authorization Physician Survey. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[8] Prior Authorization and Utilization Management Reform Principles. https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.
[9] 2021 update: Measuring progress in improving prior authorization. https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf.

requirements, at the point of care and in physicians' workflow. **We urge CMS to finalize this proposal to reduce administrative burdens and support informed patient-physician conversations regarding therapy selection.** Additional comments regarding specific RTPB implementation details can be found in the Health IT Standards portion of this letter.

Additional program enhancements

The AMA sincerely appreciates CMS' efforts to address the significant challenges that PA and other UM requirements pose for both Medicare beneficiaries and physician practices through the wide-ranging topics addressed in this proposed rule. We hope that CMS continues to evaluate the MA and Part D programs for additional opportunities to improve the PA process when finalizing this rule and in future rulemaking. Specifically, we request that CMS adopt the following changes to further improve UM programs in MA and Part D plans:

- As stated in previous AMA correspondence and sign-on letters with other physician organizations, **we urge CMS to reinstate the prohibition against use of step therapy for Part B drugs in MA plans.** Step therapy requirements for Part B drugs have proliferated in MA plans since CMS lifted this prohibition, and physicians are alarmed by the resulting care delays and negative clinical outcomes for patients with life-threatening, complex, chronic conditions, such as autoimmune diseases and cancer.
- **We urge CMS to extend the proposals related to clinical validity of PA criteria outlined in this rule to Part D plans.** For example, ensuring that Part D plans only use PA to confirm diagnoses (vs. delay or deny care) and increasing transparency surrounding the clinical criteria used for prescription drug PAs would significantly benefit patients and physicians.
- As detailed elsewhere in this letter, we believe that PA-related care delays can be especially devastating for patients with substance use disorders. **For this reason, we urge CMS to require MA and Part D plans to provide all forms of medications for opioid use disorders (MOUDs) without PA or other UM requirements that create care barriers and delays**.
- **Finally, to ensure realization of the full value of the proposed improvements to MA plans' PA programs, we urge CMS to create a formal oversight and audit process to ensure that these provisions, when finalized, are appropriately implemented.** To support effective PA program monitoring, we recommend that CMS establish documentation and reporting requirements for MA plans related to the proposed requirements, such as submission of PA clinical criteria with reference to the underlying Medicare statute, regulation, LCD, NCD, or treatment guidelines; records of UM Committee activities; and policies/procedures related to transition periods and duration of PA approvals. CMS can leverage these data to review/audit plans and appropriately enforce PA program requirements, from issuing corrective action plans through contract termination. We also urge CMS to annually issue an oversight report on MA plan conformance to PA-related regulations; this will provide the industry with insight into the impact of these new provisions and help identify potential gaps to address in future rulemaking.

We again applaud CMS for the comprehensive UM reforms outlined in the proposed rule. The AMA welcomes the opportunity to discuss additional changes CMS could consider to further improve PA programs to ensure beneficiary access to timely care.

II. Formulary Changes

CMS proposes to allow Part D plans to immediately substitute an interchangeable biological product for its corresponding reference product, expanding on current policy that allows plans to immediately remove a brand drug from their formularies and substitute a newly released generic equivalent. Part D plans would be permitted to provide notice of the substitution of an interchangeable biological product for the reference drug after the change takes place and without a transition supply. Importantly, CMS does not propose to allow such immediate substitution for biological products that have not been deemed interchangeable; this distinction is crucial to protect patients from adverse events and/or loss of efficacy associated with inappropriate substitution of noninterchangeable products for patients stabilized on ongoing therapy.

We appreciate CMS' efforts to promote cost savings for Part D beneficiaries as soon as possible after interchangeable biological products become available. However, we are concerned that the communication requirements for immediate substitution of these products (advance general notice, followed by written notice to impacted patients as soon as possible but by no later than the end of the month following any month in which a change takes effect) is insufficient for interchangeable biologics. As noted by CMS, substitution of interchangeable biologics for reference products is subject to varying requirements regarding patient and prescriber notice, depending on state pharmacy practice laws; this suggests the need for more stringent communication requirements. **The AMA therefore recommends that Part D plans be required to immediately notify both impacted patients and prescribers when an "immediate substitution" takes effect for an interchangeable biological product, instead of permitting a communication delay of up to two months.**

We also harbor concerns regarding what appears to be a shortened notice requirement for maintenance and non-maintenance negative formulary changes for beneficiaries and other entities (i.e., CMS, authorized prescribers, network pharmacies, and pharmacists) from the 60 days currently listed in the Part D Benefits Manual Chapter 6[10] to 30 days in the proposed rule. **To ensure that Part D beneficiaries and their physicians receive adequate notice of formulary changes, and to protect against potential care disruptions, we urge CMS to revert to the current 60-day notice period for maintenance and non-maintenance negative formulary changes.**

B. Medicare Advantage Network Adequacy: Access to Services (§ 422.112)

It is accepted practice for MA plans to establish provider networks, but they still must ensure that all covered services are available and accessible to patients. If patients need services that are not available within the plan's network, CMS has required plans to arrange for patients to get the services outside of the plan's network at in-network cost-sharing. In the current rule, CMS proposes to codify certain requirements in regulation, including the requirement for in-network cost-sharing and for access to "appropriate providers, including credentialed specialists." **The AMA supports these proposals. However, we stress that such alternative arrangements should not substitute for compliance with network adequacy requirements and urge CMS to monitor the use of these alternative arrangements to ensure that MA plans are consistently providing access to in-network care.**

I. Enrollee Notification for Provider Contract Terminations (§§ 422.111 and 422.2267)

[10]Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.

CMS proposes to expand certain requirements for notifying beneficiaries when their physicians are terminated from an MA plan's network. All enrollees who have ever been patients of a primary care or behavioral health provider who is terminated from the plan's network, not just those who are current patients or seen on a regular basis, would be required to be notified at least 45 calendar days before the termination effective date. In addition, these notices would need to be telephonic as well as written, and the plan would need to make repeated calls if necessary to contact the enrollee. CMS also proposes to codify in regulation several of its current best practices for handling provider termination notices. The AMA supports these proposals as improvements over current Medicare requirements. **The AMA urges CMS to go a step further, however, and ban "no cause" terminations of MA network physicians during the initial term or any subsequent renewal term of a physician's participation contract with an MA plan.** The AMA also recommends that MA plans be required to provide physicians with at least a 90-day notice of any pending termination.

C. Protecting Beneficiaries: Marketing Requirements

The AMA strongly supports efforts to refine the existing requirements to protect MA enrollees from deceptive and aggressive marketing practices by MA organizations. Abundant evidence of this issue prompted Senate Finance Committee Chair Ron Wyden to investigate these practices that exploit seniors and people with disabilities in the MA Program.[11] Key findings in the report that followed this investigation revealed that between 2020 and 2021, CMS received more than twice the number of beneficiary complaints related to the marketing of MA plans, with recurring themes to include unsolicited mail advertisements, robocalls, and telemarketers, targeted television advertisements, promises inducing potential enrollees to believe they were entitled to meaningful savings which inevitably turned out to be false, and an overarching lack of clarity with the information around general benefits covered.[12] MA organizations were noted to have targeted beneficiaries with known cognitive impairments among other vulnerable groups.[13]

AMA policy states that we advocate for better enforcement of MA regulations to hold CMS accountable for presenting transparency of minimum standards and to determine if those standards are being met for physicians and their patients. Given the existing evidence supporting greater scrutiny of these marketing practices, the AMA supports the proposals that clarify tighter, more specific requirements on the part of MA organizations' marketing practices. Many of the proposals cited in this NPRM mitigate the risk that MA enrollees will unknowingly sign up for plans that are inappropriate for their medical needs and experience subsequent harms.

We commend CMS for identifying specific instances where MA enrollees could benefit from additional transparency and assistance. The Commonwealth Fund also speaks to the role of marketing in Medicare

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[11] Wyden Probes Deceptive Marketing Practices by Medicare Advantage Plans, (Aug 2022), https://www.finance.senate.gov/chairmans-news/wyden-probes-deceptive-marketing-practices-by-medicare-advantage-plans.

[12] See Deceptive Marketing Practices Flourish in Medicare Advantage, wherein the U.S. Senate Committee on Finance report also identified examples of beneficiary complaints, including insurance agents soliciting enrollment at grocery stores; mailers from Medicare Advantage MA plans that looked like official business from the federal government; high-pressure solicitations, including robocalls multiple times a day; and agents suggesting in phone calls that they were speaking on behalf of Medicare and the government.

[13] Id.

beneficiaries' coverage choices[14] and highlighted the fact that the high number of MA enrollees has led to a sharp increase in the marketing push and the risk of misleading and inaccurate marketing to those targeted enrollees. The Commonwealth Fund raises many similar findings regarding aggressive marketing practices and whether the plan marketing is useful to beneficiaries in making coverage decisions.[15] Complaints involved inaccurate or confusing information about reimbursements, benefits, premiums, and provider networks, as well as misleading print and TV ads.

AMA recommends that MA plan agents maintain a level of transparency such that the incidence of confusion among potential enrollees about covered and not covered services is unmistakably clear. In light of the abundance of inaccurate and confusing information about reimbursements, benefits, premiums, and provider networks, we support the proposals that require an additional layer of transparency, and appropriate guardrails on the amount of marketing that enrollees can be subject to in this context. We believe that the proposals in this NPRM satisfy this heightened level of concern that beneficiaries should only be receiving marketing materials or information that advertises benefits available to the beneficiary where the beneficiary resides, and that MA organizations and Part D sponsors may not engage in marketing that advertises benefits that are not available to beneficiaries in the service area where the marketing appears unless unavoidable in a local market. We believe this assurance will also lend itself to the proposed requirement that agents share pre-enrollment information and explain the effect of an enrollee's enrollment choice on their current coverage whenever the enrollee makes an enrollment decision.

Furthermore, we recommend that CMS educate Medicare beneficiaries accessing assistance for enrolling in Medicare Part D and MA plans. As such, we support the proposal that educational events are limited strictly to providing general education on how Medicare works, not lead to generation of future marketing opportunities for agents to persuade beneficiaries to enroll in a plan. Moreover, we find the instances noted in this NPRM as they relate to the misleading, confusing, and potentially harmful misuse of the Medicare name, logo, and Medicare card to be sufficient in supporting the need for requirements that place discrete limits around its use.

The AMA will continue its efforts to educate physicians and the general public on the implications of participating in programs offered under MA and educate physicians and the public about the lack of secondary coverage (Medigap policies) with MA plans and how this may affect enrollees. We also firmly believe that Medicare beneficiaries should be aware that while Traditional Medicare requires minimal PA for services, MA plans frequently impose UM requirements on a variety of items and services, which can result in care delays and barriers to accessing medically necessary care. While we agree that these plans may deliver valued benefits and trusted coverage for millions of Medicare beneficiaries, tighter scrutiny and an oversight plan that monitors the activities of its agents and brokers should be instituted to ensure an optimal level of compliance to protect MA enrollees. CMS has broad authority to regulate the marketing and enrollment activities of MA and Part D plans, and we would encourage the agency to leverage that towards combating the fraudulent practices that are likely undermining the trust in the Medicare program as a result.

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[14] The Role of Marketing in Medicare Beneficiaries' Coverage Choices, The Commonwealth Fund, (Jan 2023), https://www.commonwealthfund.org/publications/explainer/2023/jan/role-marketing-medicare-beneficiaries-coverage-choices.

[15] See also at id. that notes CMS reported more than 41,000 complaints about Medicare private plan marketing, more than double the number in 2020 and up from up about 6,000 in 2017.

D. Strengthening Quality: Star Ratings the Program

CMS proposes to reduce the weight of the patient experience/complaints and access measures to align efforts with other CMS quality programs and better balance the contribution of the different types of measures in the Star Ratings program. **The AMA does not support this proposal, specifically reducing the weight of the access measures.** The four access measures are the only quality measures in the program that specifically address, and hold plans accountable for, a timely appeals process and adequate interpreter services. Given the importance of health equity to the Administration and the AMA, we must ensure that plans are providing sufficient interpreter services to beneficiaries whose primary language may not be English and that they can appropriately navigate their interaction with health plans. The complaints and access measures are also the few measures that truly measure interaction and beneficiary experience with health plans.

The AMA has repeatedly highlighted to CMS the need for the Star Ratings program to focus more on compliance, communication, and access, as opposed to the current focus that relies on physician action. For health plans to increase their Healthcare Effectiveness Data and Information Set (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 and tests, and the plans state it is due to the Star Ratings HEDIS requirements. 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. In addition, the patient experience ratings are heavily based on Health-Plan, Consumer Assessment of Healthcare Providers & Systems (CAHPS) that emphasizes physician communication and behavior. While communication between a physician and patient is important, asking the questions in a de-identified survey does not lead to quality improvement or address potential challenges patients experience when seeking care. Similar questions are also in the hospital and clinician-group CAHPS survey and the more appropriate avenues for addressing provider communication in the context of patient experience. Without a better focus, the MA ratings program is just one more burden on physicians and does not provide beneficiaries with the information they need to determine the most appropriate and high-quality MA or drug plan. **Therefore, to further improve the information CMS receives about patients' experience with their plans, we encourage CMS to work with AHRQ to update the Health Plan CAHPS survey.** The last update to the health plan survey was May 2012, and the private insurance market has significantly changed.

Increasingly common in private insurance markets, including MA, is the utilization of narrow networks. Narrow physician networks create challenges for patients seeking care and pose potential patient protection issues. Specifically, a narrow network might have shortages of specific specialties, and plans may purposefully understaff specialties to avoid attracting enrollees with expensive pre-existing conditions, like cancer and mental illness. Generally, such plans offer enrollees a narrow set of physicians and hospitals in a geographic area in exchange for lower premiums. Although the traditional Medicare program allows seniors to visit any physician or hospital that accepts Medicare patients, access for MA beneficiaries is limited to physicians and hospitals within plan networks. More than one in three MA enrollees are in a narrow physician network, which is defined as participation of less than 30 percent of physicians in the corresponding county. Another 43 percent of enrollees are in medium networks, defined as participation of 30 to 69 percent of physicians within the corresponding county. On average, MA networks include less than half of all physicians in a given county.

Out of the 39 questions included in health plan-CAHPS, only four ask about access and in a very broad context:

In the last 6 months, when you needed care right away, how often did you get care as soon as you needed?

1. Never
2. Sometimes
3. Usually
4. Always

In the last 6 months, how often did you get an appointment for a check-up or routine care at a doctor's office or clinic as soon as you needed?

1. Never
2. Sometimes
3. Usually
4. Always

In the last 6 months, how often was it easy to get the care, tests, or treatment you needed?

1. Never
2. Sometimes
3. Usually
4. Always

In the last 6 months, how often did you get an appointment to see a specialist as soon as you needed?

1. Never
2. Sometimes
3. Usually
4. Always

The current survey also does not assess the extent to which physicians in the network are willing and able to see new patients or the extent to which patients want to use the physicians in the network. If most plan members are receiving services only from a subset of physicians in the network, that subset may not represent the "true" network that is available to patients. Therefore, we encourage CMS to work with AHRQ and consider expanding the "Your Health Care in the Last 6 Months" and "Getting Health Care From Specialists" sections of the survey. Preferably, this should include questions assessing whether patients are able to find physicians who accept new patients, including specialists within their insurance network, maintain utilization of physicians who have longitudinally provided them treatment, distance needed to travel to obtain care, the average time required to make an appointment when actively seeking care, and ability to obtain care at an in-network hospital and at an in-network hospital where the patient's physician has staffing privileges.

<u>Stability of Networks</u>

There is a need to evaluate patients' experience with the stability of insurance network plans. There is currently no way to determine if MA plans tend to have the same physicians in-network each year or their networks change significantly from year-to-year. Patients need to know whether they are likely to need to keep changing physicians if they choose a particular plan.

Accuracy of Provider Directories

We recommend AHRQ and CMS consider expanding the content of the survey to include questions about accuracy of provider directories and ease of accessing the information. Since CMS has begun conducting triennial reviews of directories, it has found significant inaccuracies, which impacts a patient's experience with a health plan and obtaining care.[16]

H. Measure Updates

CMS proposes to remove the Part C *Diabetes Care— Kidney Disease Monitoring* measure and replace/add the Part C *Kidney Health Evaluation for Patients with Diabetes* measure. As highlighted by the National Quality Forum (NQF) Measure Application Partnership (MAP) during the 2022 measure under consideration cycle, there is concern with the use of race-neutral estimated glomerular filtration rate (eGFR) when monitoring kidney health, and we recommend that CMS wait to implement the measure until universal adoption of race-neutral eGFR calculation is incorporated into the measure specifications. At the time of discussion, the developer specifically shared that work to incorporate race-neutral codes is ongoing and by moving forward with the measure prematurely, it will do more harm than good to implement a measure that relies on biases and further contributes to health inequities.

The AMA also harbors concerns that the new Concurrent Use of Opioids and Benzodiazepines, Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults, and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measures will lead to increased administrative burdens for physicians without meaningful improvements in care quality. From experience with similar Star Ratings measures (for example, measures targeting medications on the Beers List), we know that plans often use such measures to bluntly apply PA or other UM requirements to specific medications, without regard to individual patients' specific clinical situation. AMA Policy H-185.940, "Beers or Similar Criteria and Third-Party Payer Compliances Activities," discourages "health insurers, benefit managers, and other payers from using the Beers Criteria and other similar lists to definitively determine coverage and/or reimbursement" and urges "health insurers, benefit managers, and other payers not to inappropriately apply the Beers or similar criteria to quality ratings programs in a way that may financially penalize physicians." **The AMA therefore urges caution in adoption of these new quality measures and requests that CMS ensure, if the measures are adopted, that plans cannot impose PA or other administrative burdens or financially penalize physicians to enforce measure compliance.**

II. Health Equity Index Reward

CMS proposes to add to the Part C and D Star Ratings programs a health equity index (HEI) that would reward contracts for obtaining high measure-level scores for the subset of enrollees with specified social risk factors (SRFs) to improve health equity and incentivize MA, cost plan and PDP contracts to perform well among enrollees with specified SRFs. CMS intends to use the original reason for entitlement to the Medicare program to identify enrollees with a disability for purposes of the HEI. However, as CMS highlights beneficiaries' disability status changes over time, and therefore there is a need to expand the definition to include enrollees who develop a disability after aging into the Medicare program. To address the issue, we recommend CMS (a) only allow the physician who is treating the patient to make the determination that the patient has become disabled after Medicare enrollment, and (b) that only a physician treating the patient make such a determination. The change in disability status would be

[16] For more detailed information on the accuracy of provider directories, please see Medicare Advantage (MA) Provider Directories (§ 422.111) on page 17

documented on the claim with an ICD-10 SDOH Z-code, and CMS would have to put out guidance on what would be considered eligible and the types of physicians or encounters that are required for the code to be used for this purpose. For example, Z73.6 is "limitation of activities due to disability," Z74.01 is "bed confinement status," and Z74.1 is "need for assistance with personal care."

E. Advancing Health Equity

I. Strengthening Translation and Accessible Format Requirements

CMS is proposing to specify that MA organizations, cost plans, and Part D sponsors must provide materials to enrollees on a standing basis in any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package service area or accessible format using auxiliary aids and services upon receiving a request for the materials or otherwise learning of the enrollee's preferred language and/or need for an accessible format using auxiliary aids and services. CMS is also proposing to extend this requirement to individualized plans of care for special needs plans and to require that fully integrated dual eligible special needs plans (FIDE SNPs), highly integrated dual eligible special needs plans (HIDE SNPs), and applicable integrated plans (AIPs) translate required materials into any languages required by the Medicare translation standard at § 422.2267(a) plus any additional languages required by the Medicaid translation standard as specified through their Medicaid capitated contracts. This means that once a plan learns of an enrollee's preferred language and/or need for auxiliary aids and services—whether through an enrollee requesting a material in a preferred language or using auxiliary aids and services, during a health risk assessment, or another touch point—the plan must provide required materials in that language and/or accessible format using auxiliary aids and services as long as the enrollee remains enrolled in the plan or until the enrollee requests that the plan provide required materials in a different manner.[17]

The AMA applauds CMS for working to increase access to health care for all patients regardless of language or communication style. "According to the U.S. Census Bureau, 67.3 million U.S. residents spoke a language other than English at home in 2018." "Language access services are designed to promote effective communication between LEP persons and non-LEP persons. LEP persons do not speak English as their primary language and have a limited ability to read, write, speak, [sign,] or understand English. Language access services can include oral interpretation and written translation."[18]

Effective communication can have a profound impact on how patients and families perceive their medical care.[19] Research demonstrates that patient engagement in health care leads to measurable improvements in safety and quality.[20] Moreover, open communication between the medical team and patients and families can broaden perspectives and reduce patient avoidance of physician, facilities, and medical care in general.[21] As such, language services are an essential part of providing holistic health care in a patient-

[17] https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.
[18] https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf.
[19] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.
[20] Agency for Healthcare Research and Quality. Guide to Patient and Family Engagement in Hospital Quality and Safety. Content last reviewed December 2017. https://www.ahrq.gov/patient-safety/patientsfamilies/engagingfamilies/guide.html.
[21] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.

centered, language, and culturally appropriate way.[22] Therefore, **the AMA recognizes the importance of using medical interpreters as a means of improving the quality of care provided to patients with LEP including patients with sensory impairments.**

Access to language services has been shown to improve communication, adherence to treatment regimen, diagnosis and treatment, and result in fewer complaints.[23] However, one of the top deterrents to providing language services is cost and the fact that "[l]imited reimbursement is available for language access services. [Moreover,] Medicare does not reimburse providers for language access services."[24] Due to the price associated with language services, physicians cannot be expected to provide and fund these translation services for their patients. When trained medical interpreters are needed, the costs of their services should be paid directly to the interpreters by health plans and physicians should not be required to participate in payment arrangements. The economies of scale are present for health plans to make language and auxiliary service resources available to subscribers of their health plan, whereas a physician may have a very limited number of individuals who present to the practice and require such services. For example, a physician-owned small practice cannot prepare for the full range of language assistance and auxiliary services; doing so would be an incredible financial strain. However, MA organizations, cost plans, and Part D sponsors can inform providers, health programs, and activities of the individual's language and auxiliary service needs and can best leverage assistive technologies across the patient's various providers. **Therefore, MA organizations and cost plans should cover the full cost of language services and directly pay interpreters for such services to ensure that proper and effective care can be provided.**

Furthermore, it is important that MA organizations, cost plans, and Part D sponsors adequately inform their members of the ability to be provided with interpreters and/or with written materials in their preferred language or an accessible format. In doing so, patients will be made aware of the available language services and aids across the full spectrum of their care, and not just by one particular provider.

Moreover, "[t]he Department of Health and Human Services (HHS) establishes competencies required of a 'qualified interpreter.' These competencies include the knowledge of specialized terminology and interpreter ethics and the skills to interpret accurately, effectively, and impartially. HHS requires that hospitals conduct an assessment of individuals claiming to have competencies prior to designating an individual as a qualified interpreter."[25] Especially in a medical setting, it is important that the information being translated is correct and conveyed in a culturally competent manner. Language services should include translators who have some health background or knowledge because it is easy for miscommunications to occur when the translator does not know what a provider is referring to. As such, it is crucial that as CMS works to implement this new language access standard, that they also ensure that proper safeguards are in place concerning the competency and ethics of interpreters.

Likewise, health plans should provide training to improve interpreter-use skills and increase education through publicly available resources such as the American Association of Medical College's "Guidelines for Use of Medical Interpreter Services" to ensure optimal patient care.[26] Additionally, it is important to have an environment that is conducive to language services. Phone lines are often the only way that

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[22] https://healthlaw.org/resource/summary-of-state-law-requirements-addressing-language-needs-in-health-care-2/.
[23] https://oig.hhs.gov/oei/reports/oei-05-10-00050.pdf.
[24] https://oig.hhs.gov/oei/reports/oei-05-10-00050.pdf.
[25] https://journalofethics.ama-assn.org/article/clinicians-obligations-use-qualified-medical-interpreters-when-caring-patients-limited-english/2017-03.
[26] https://www.aamc.org/system/files/c/2/70338-interpreter-guidelines.pdf.

hospitals have language services available but, in a busy and loud environment such as the emergency department, they are very ineffective and all parties—physician, patient, and translator—have difficulty understanding what any given person is saying. This could be improved by working with health plans to provide appropriately staffed in-person translation services or designated areas that are quiet and conducive for conversation.

Overall, language services are a vital part of patient care and should be covered by MA organizations, cost plans, and Part D sponsors so that these services, both written and verbal, can be provided to every LEP patient and optimal health outcomes can be achieved.

II. Medicare Advantage Provider Directories (§ 422.111)

CMS has proposed to codify best practices to mirror the Medicaid provider directory requirements at § 438.10(h)(1)(vii) by adding the phrase "each provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office" to paragraph (b)(3)(i). This would change these two best practices to require data elements that all organizations must include in their provider directories. Currently, the Medicaid managed care regulation at § 438.10(h)(1)(vii) requires that provider directories for Medicaid managed care plans include information on the provider's cultural and linguistic capabilities, including languages (including American Sign Language (ASL)) offered by the provider or a skilled medical interpreter at the provider's office as well as other information identifying the providers location, contact information, specialty, and other information important for beneficiaries in selecting a health care provider. This proposal will help move CMS closer to its goal of aligning the various CMS program requirements.[27]

The AMA strongly supports the changes that CMS is proposing for the MA provider directory requirements. Ensuring that a patient knows in advance if a provider can deliver care that will meet their cultural and linguistic needs will aid in increasing positive health outcomes and will help to ensure that patients pick the provider that is best for them. However, "information, such as languages spoken and special skills and experience, which help patients identify physicians and practices that are a good fit for their specific needs is sparsely populated in health plan provider directories."[28] **In order for the requirement that linguistic and cultural care information be included in provider directories to be truly beneficial for providers and patients, MA provider directories must be accurate and complete.**

"Health plan provider directories allow members to search and view information about in-network providers, including the practice location, phone number, specialty, hospital affiliations, whether they are accepting new patients and other details. Some directories also provide information on health equity and accessibility issues, such as public transportation options, languages spoken, experience with specific patient populations and the ability to provide specific services."[29] According to two 2020 surveys more than half of patients use health plan provider directories to select a physician.[30]

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[27] https://www.federalregister.gov/documents/2022/12/27/2022-26956/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.
[28] https://www.caqh.org/sites/default/files/other/CAQH-AMA_Improving%20Health%20Plan%20Provider%20Directories%20Whitepaper.pdf.
[29] https://www.caqh.org/sites/default/files/other/CAQH-AMA_Improving%20Health%20Plan%20Provider%20Directories%20Whitepaper.pdf.
[30] https://cms.doctor.com/wp-content/uploads/2020/03/cxtrends2020-report-final.pdf; https://www.yext.com/wp-content/uploads/2020/07/ModernPatientJourney_Yext_July2020.pdf.

However, according to a 2018 CMS audit of MA online provider directories more than 50 percent of entries had at least one inaccuracy.[31] Furthermore, a July 2019 report from the U.S. Government Accountability Office (GAO) highlighted the need to improve the accuracy of MA plans' network directories and the way this information is communicated to patients.[32] The report reviewed research, including a CMS-sponsored study, that identified access to particular physicians as a key consideration for Medicare beneficiaries when selecting their Medicare coverage. The GAO also conducted a survey in which respondents stated that the Medicare Plan Finder (MPF) provides incomplete information on MA plan networks.

Moreover, MA plans are required to maintain accurate directories of in-network physicians on a real-time basis. However, currently they are only required to submit network directories to CMS when the plan first begins operations in an area, and then every three years unless CMS requests a review based on significant terminations of contracts or complaints. The triennial reviews of network directories by CMS have found significant inaccuracies. For example, a 2019 review found errors in half of all network directories reviewed, including physicians not practicing at the listed location, incorrect phone numbers, or physicians who were not accepting new patients when the directory indicated they were.[33] The persistently high error rates justify more frequent reviews and more significant penalties for noncompliance. MA plans could reduce the administrative burden on themselves and on physicians if they would develop and use a common system for updating provider directory information.

Therefore, the AMA urges CMS to boost its efforts to ensure directory accuracy by:

- **Requiring MA plans to submit accurate network directories to CMS every year prior to the Medicare open enrollment period and whenever there is a significant change to the status of the physicians included in the network;**
- **Auditing directory accuracy more frequently for plans that have had deficiencies;**
- **Publicly reporting accuracy scores on the MPF;**
- **Taking enforcement action against plans that fail to either maintain complete and accurate directories or have a sufficient number of in-network physician practices open and accepting new patients;**
- **Encouraging stakeholders to develop a common system to update physician information in their directories;**
- **Requiring MA plans to immediately remove from network directories physicians who no longer participate in their network; and**
- **Ensuring that beneficiaries can access network directories from the MPF.**

Moreover, the AMA encourages CMS to create a plan to effectively communicate with patients about network access and any changes to the network that may directly or indirectly impact patients. This is necessary for many reasons including due to information from a 2020 study in the Journal of General Internal Medicine that found that of patients receiving unexpected bills, 30 percent noted errors in their

[31] https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Round_3_11-28-2018.pdf.
[32] https://www.gao.gov/assets/gao-19-627.pdf.
[33] https://www.commonwealthfund.org/publications/journal-article/2019/jun/improving-accuracy-health-plan-provider-directories.

health plan's provider directory.[34] "If information is incorrect, then the patient may find him or herself with unanticipated medical expenses and hours or days of administrative follow-up."[35]

Furthermore, as CMS contemplates integration of MA network information including each provider's cultural and linguistic capabilities the AMA urges CMS to ensure the MPF website is user-centered. User-centered design is an iterative process in which architects of the technology or platform focus on the users and their needs in each phase of the design process. User-centered design requires the involvement of applicable users throughout this process via a variety of research and design techniques in order to create highly usable and accessible products (e.g., responsive design that adjusts to different screen sizes, font size and contrast adjustments, alternative text and text-to-speech functionality, full translation of all text including buttons and menus to other languages). The need for user-centered design has become increasingly important, as more health care professionals and patients are exposed to, rely on, and operate within electronic platforms for information related to treatment and diagnosis, disease management, prescription drug coverage, health insurance, and general health care delivery. Improved and intuitive user-centered design application can enable and empower patients to successfully shop for Medicare plans that meet both clinical need and financial reality. Providing one-click access to updated and accurate directories through the MPF can allow patients to quickly discern if their physician(s) is part of an MA plan's network.

As such, as CMS works to make this positive change that will require directories to indicate the linguistic and cultural care that a patient can receive from a provider, CMS should also ensure that this new provider information, along with the information that has already been provided in the directories, is easily accessible for patients and physicians and is accurate and complete.

III. Provider Directories and Treatment for Opioid Use Disorder

The AMA strongly supports the CMS proposal to require that MA provider directories assist beneficiaries in identifying which network physicians prescribe medications for opioid use disorder (MOUD). To achieve this, CMS proposes to add a new required data element to provider directories indicating that certain physicians in the plan's network offer MOUD, using the term "MOUD-Waivered Providers." As the requirement for physicians who prescribe buprenorphine for MOUD to obtain a waiver from the Drug Enforcement Administration (DEA) has recently been eliminated—a policy change that the AMA strongly supported—it would no longer be possible to designate physicians in this way in MA directories. Alternatively, the AMA recommends that CMS adopt four requirements for MA plans:

1. Plan directories should indicate network adequacy for patients with substance use disorders by detailing the types of MOUD offered by in-network physicians as well as whether the physicians who offer MOUD are accepting new patients with this condition.

2. All MA and Part D plans should be required to provide all forms of MOUD without any PA requirements or other access barriers and delays.

3. MA and Part D plans should ensure that all network pharmacies stock MOUD as well as naloxone to help prevent deaths from drug overdoses.

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[34] https://doi.org/10.1007/s11606-020-06024-5.
[35] https://www.caqh.org/sites/default/files/other/CAQH-AMA_Improving%20Health%20Plan%20Provider%20Directories%20Whitepaper.pdf.

4. Once naloxone products move from prescription to over-the-counter availability, all MA and Part D plans should be required to continue covering purchases of naloxone.

5. CMS should encourage MA plans to offer their enrollees transportation and other assistance to obtain treatment for substance use disorders.

IV. Health Equity in Medicare Advantage (§§ 422.111 and 422.112)

Culturally Competent Services

Current regulations require MA organizations to ensure that services are provided in a culturally competent manner. At § 422.112(a)(8), CMS proposes to replace the phrase "those with limited English proficiency or reading skills, and diverse cultural and ethnic backgrounds" after the word "including" and to add in its place additional paragraphs listing more examples of marginalized or minoritized populations to whom an MA organization must ensure that services are provided in a culturally competent manner and promote equitable access to services in order to satisfy the existing requirement.[36] The proposed new list would be as follows: (i) people with a primary language other than English or reading skills; (ii) people of minoritized ethnic, cultural, racial, or religious identities; (iii) people with disabilities; (iv) people who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (v) people who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (vi) people who live in areas with high levels of deprivation; and (vii) people otherwise adversely affected by persistent poverty or inequality. CMS noted that MA organizations must provide all enrollees, without exception, accommodations to equitably access services according to applicable statutory, regulatory, and other guidance. CMS also stated that these provisions should not be construed to mean that accommodations are required only for enrollees who belong to the listed groups.

The AMA supports CMS in its expansion of providing care in a culturally competent manner. New data have shown that beneficiary enrollment among minoritized groups in MA is higher than ever before. Nearly 44 percent of Hispanic Medicare beneficiaries and over 31 percent of African American Medicare beneficiaries are enrolled in MA plans. Moreover, data shows an increasing trend in enrollment of minoritized groups in MA plans.[37]

The AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. To increase access to care for marginalized and minoritized populations, MA plans should change the way that they structure their payment plans. Dual eligible beneficiaries and residents of nonmetropolitan areas are less often enrolled in MA plans.[38] Black, Asian, and Hispanic enrollees sign up for MA at higher rates than White enrollees—but members of minoritized racial and ethnic groups tend to be in plans with lower quality ratings.[39] Despite these issues with access and quality, MA plans annually spend $321 more per

[36] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.112.
[37] https://bettermedicarealliance.org/blog-posts/advancing-health-equity-inmedicare/.
[38] https://www.commonwealthfund.org/publications/issue-briefs/2021/oct/medicare-advantage-vs-traditional-medicare-beneficiaries-differ.
[39] https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13977.

beneficiary or $7 billion overall.[40] In a study, when Black enrollees had access to the highest-rated plans they chose five-star plans more often than White enrollees by 3.2 percentage points.[41]

This structural barrier that Black Americans are experiencing is due to the way that the MA program is designed, according to recent research:

> [The current structure] de-incentivize[s] insurers from offering "plans in areas with a large number of racial and ethnic minority group residents. The current payment adjustment used by Medicare Advantage tends to overpay plans for healthier enrollees and underpay for complex enrollees, the researchers note. Decades of structural racism and social disadvantage often result in increased clinical complexity among racial and ethnic minority groups. Because payments to Medicare Advantage plans do not account for race or ethnicity as a social risk factor, this may lead to systematic underpayments for racial and ethnic minority enrollees, providing little incentive to offer health plans in communities where a large number of racial and ethnic minority group members reside. Having more enrollees with poorer health also affects Medicare Advantage performance scores, adding to insurers' reasons to restrict access in areas where residents might need more care. In fact, Medicare Advantage performance scores are known to decrease as the proportion of enrollees with complex health and social needs increases. Because performance is linked to payment bonuses, decreases in performance scores worsen finances for insurers."[42]

This payment structure must be changed in order to provide a meaningful increase in access to high-quality care. In order to increase access to high-quality MA plans, CMS should encourage insurers "to offer five-star plans in areas that do not currently have them with premium subsidies, rebates, and tax exemptions, and also by including more robust payment adjustments for members' health and social risks."[43] **As such, in order to increase access and truly provide culturally competent care commensurate with higher spending per beneficiary, MA programs need to change their incentive structure.**

Furthermore, marginalized and minoritized populations need to be assured that care is not only culturally competent but is accessible and improving. For example, between 2009 and 2018 within MA plans Hispanic beneficiaries consistently experienced poor scores in "Getting Needed Care" and Black beneficiaries consistently lacked good scores on "Follow-Up After Hospitalization for Mental Illness" among other issues.[44]

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[40] https://www.kff.org/medicare/issue-brief/higher-and-faster-growing-spending-per-medicare-advantage-enrollee-adds-to-medicares-solvency-and-affordability-challenges/.
[41] https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13977.
[42] https://ldi.upenn.edu/our-work/research-updates/why-are-there-disparities-in-enrollment-in-medicare-advantage/.
[43] https://ldi.upenn.edu/our-work/research-updates/why-are-there-disparities-in-enrollment-in-medicare-advantage/.
[44] https://www.cms.gov/files/document/trends-inequities-medicare-advantage-2009-2018.pdf.

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Follow-Up After Hospitalization for Mental Illness (within 30 days of discharge)										
API	62.8	59.6	59.7	62.6	63.3	64.6	57.4	60.0	56.9	59.6
Black	43.9	44.9	42.6	42.0	42.7	41.3	39.5	40.3	44.1	39.7
Hispanic	53.8	56.6	60.8	62.3	59.6	56.1	62.6	61.7	63.0	58.5
White	59.3	59.6	57.7	58.0	58.0	56.9	54.7	54.8	56.6	53.1
Engagement of Alcohol or Other Drug Treatment										
API	3.6	2.1	1.5	1.4	1.3	1.3	1.2	1.3	1.3	1.0
Black	5.4	2.4	1.7	1.8	1.7	1.8	1.7	1.2	1.6	2.3
Hispanic	3.7	2.3	1.9	1.7	1.8	1.5	1.6	1.9	1.8	1.7
White	6.1	3.0	2.7	2.6	2.2	2.4	2.2	1.9	2.1	2.8
Older Adults' Access to Preventive/Ambulatory Services										
API	93.6	94.0	94.7	95.0	95.0	95.4	95.2	94.8	95.1	95.1
Black	92.3	93.4	94.0	94.5	95.0	95.5	95.4	95.5	95.6	96.0
Hispanic	93.5	94.1	94.7	95.2	95.8	95.9	95.9	95.6	95.7	95.9
White	95.2	95.8	95.8	96.0	96.2	96.4	96.3	96.4	96.5	96.6

NOTE: API = Asian or Pacific Islander. The racial groups API, Black, and White are non-Hispanic. Hispanic ethnicity includes all races.

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Just listing the groups of individuals who should receive culturally competent care, even though all individuals are entitled to this in MA plans, is not enough. MA plans need to ensure that these regulatory language changes are leading to actual improvements in care. MA plans should advance health equity by "directly paying for performance on equity of outcomes, requiring the collection and public reporting of data by race/ethnicity, and requiring participating entities to create plans to reduce documented inequities. Further … [CMS should] revisit its risk-adjustment methodologies to ensure they are not disadvantaging entities serving populations of color, low-income patients, or people with complex health and social needs."[46]

The AMA greatly appreciates that CMS is looking to address inequities in health. However, just listing out some of the groups that should be considered when providing care in a culturally competent and equitably accessible manner is not enough. CMS should work to ensure that MA plans are making tangible changes to guarantee that all individuals have access to 5-star plans and receive the best care possible.

[45] https://www.cms.gov/files/document/trends-inequities-medicare-advantage-2009-2018.pdf.
[46] https://www.commonwealthfund.org/blog/2021/making-health-care-accountable.

Call Center Interpreter Qualifications

CMS has proposed to codify requirements for minimum qualifications for interpreters available to people who speak languages other than English and LEP individuals at MA and Part D call centers and Part D sponsor interpreters. The required qualifications would include adhering to generally accepted interpreter ethics principles, including confidentiality; demonstrating proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and interpreting effectively, accurately, and impartially, both receptively and expressively, to and from such language(s) and English, using any necessary specialized vocabulary, terminology, and phraseology.

The AMA supports the proposal to have minimum qualifications for MA and Part D call center interpreters and Part D sponsor interpreters. Interpreters must provide "the accurate and complete transmission of messages between a patient and provider who do not speak the same language in order to support the patient-provider therapeutic relationship."[47] As such, it is imperative that interpreters can provide language assistance that is culturally sensitive and competent. If MA and Part D call centers and Part D sponsors have appropriately trained interpreters it will improve communication (resulting in fewer errors), improve clinical outcomes, and increase satisfaction within care for patients with LED.[48]

Since CMS is trying to ensure that interpreters at MA and Part D call centers and Part D sponsor programs are qualified to help LEP patients, CMS should consider requiring their interpreters to have a national certification provided by the Certification Commission for Healthcare Interpreters,[49] the National Board of Certification for Medical Interpreters,[50] or the Registry of Interpreters for the Deaf.[51] Properly trained interpreters result in "clear interpretation with fewer errors…improved comprehension and significantly greater patient satisfaction, better care and compliance, and lower risk of adverse events, thus mitigating malpractice risk. The use of professional interpreters also reduces hospital stays and readmission rates."[52,53] As such, having minimum qualifications for interpreters is vital for the health and wellbeing of the patient.

Finally, it is important that MA and Part D plans inform individuals both verbally and in writing that language services are available. This is especially important since there is evidence that beneficiaries have difficulty accessing language services that plans provide through call centers. "For example, one study found that only 69 percent of LEP persons calling plans could reach someone who spoke their primary language and were often unable to access translated documents from the plans."[54] **Since it is vitally important to provide access to qualified language services to ensure that high-quality health care is provided, MA and Part D health plans must start providing verbal and written notifications, in multiple languages, that they have qualified interpreters at their call centers to help individuals.**[55]

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[47] https://www.ncihc.org/assets/documents/publications/NCIHC%20National%20Standards%20of%20Practice.pdf.
[48] https://pubmed.ncbi.nlm.nih.gov/17362215/.
[49] http://www.cchicertification.org.
[50] http://www.certifiedmedicalinterpreters.org.
[51] http://www.rid.org.
[52] https://www.aafp.org/pubs/afp/issues/2014/1001/p476.html#afp20141001p476-b4.
[53] https://pubmed.ncbi.nlm.nih.gov/22424655/.
[54] https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf; http://www.nsclc.org.
[55] https://oig.hhs.gov/oei/reports/oei-05-10-00051.pdf.

Access to language services has been shown to improve communication, adherence to treatment regimen, and diagnosis and treatment, and result in fewer complaints. As such, the AMA strongly supports CMS having minimum qualifications for MA and Part D call center interpreters and Part D sponsor interpreters.

V. Digital Health Education for Medicare Advantage Enrollees Using Telehealth (§ 422.112)

The AMA applauds CMS' initiative to bring forward the health equity implications as it extends to digital health literacy and the varying need for improvements in the MA beneficiaries' experience with understanding and being able to fully realize the telehealth benefits afforded in each plan. We support the proposals to add requirements for MA organizations to develop and maintain procedures to identify and offer digital health education to enrollees with low digital health literacy to assist them with accessing any medically necessary covered telehealth benefits. Additionally, we agree with the proposal to allow a degree of discretion be allotted to the MA organizations when it comes to the design of both the initial screen and the subsequent digital health education tools. We agree to this discretionary measure without necessarily creating strict conditional parameters around what must be included, so long as the intended outcome of identifying digital health literacy levels resulting from the screen is achieved, and appropriate education for the individual in need follows. Our recommendation would echo that of CMS' to encourage MA organizations to research current trends causing limited enrollee usage of telehealth and furthermore, gain an understanding of the prominently noted patient-level and infrastructure barriers such as telehealth readiness, device and broadband access, and skills, comfort level and familiarity with technological capabilities necessary to take part in a telehealth visit.

AMA policy supports advocacy that directs the federal government, including CMS and other agencies, state governments and state agencies, and the health insurance industry to adopt clear and uniform laws, rules, regulations, and policies relating to telehealth services that provide equitable coverage that allows patients to access telehealth services wherever they are located. The AMA recognizes that ownership of devices and access to internet are beneficial for telehealth only if patients know how to utilize the devices and if those solutions are designed for patients with varying digital literacy levels.

The continued use and expansion of telehealth rely on equitable design to meet the need for varying levels of patient digital literacy, and how the availability of telehealth services is communicated to patients. Barriers to telehealth access for patients come in many forms, and we applaud CMS' recognition of the many drivers to inequity in MA enrollees that come in the form of limited digital health literacy. We encourage CMS to enhance its focus on system solutions by a greater acknowledgement of organizational health literacy, as defined by the CDC: "the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others."[56] Examples where common limitations occur that MA organizations should consider, include but are not limited to: accessibility to your electronic health record, the ability to communicate electronically with your health care team, the ability to discern reliable online health information, and the utility of remote monitoring when appropriate. Even among patients with equitable access to devices and to the internet, there remain exclusionary and suboptimal design issues requiring patients to navigate email, fill out a form online or require the use of a patient portal for accessing telehealth services, which all can serve as another barrier. Lack of transparency and equity in the design of privacy and security policies and practices can also cause hesitancy amongst enrollees.

[56] https://www.cdc.gov/healthliteracy/learn/index.html.

Furthermore, the AMA continues to study the changing landscape as it relates to coverage, payment, and access to telehealth, and data suggests that telehealth has and will continue to play an important role in increasing access to quality care. Studies suggest that telehealth has the potential to be an important tool for addressing long-standing health inequities among historically marginalized and minoritized communities; however, barriers in the form of disparate access to technology infrastructure and gaps in digital literacy among patients prevent them from being able to fully realize the benefits already available to them by way of this modality. This NPRM points to the significant fact that CMS does not currently collect this data regarding digital health literacy among MA enrollees and therefore, has no way of knowing or estimating the extent of low digital health literacy specifically among MA organizations' enrollees. To that end, we agree that to monitor the impact of this new proposed requirement for digital health literacy screening and digital health education programs—on MA organizations, providers, enrollees, and the MA program as a whole—MA organizations should be required to make information about these programs available to CMS upon request. Overall, we believe this will facilitate the collection of very valuable data and furthermore help implement policy around how to support this important health equity aim going forward. We find the information CMS proposes MA organizations gather as guidance is purposeful and not overly burdensome and can ultimately be collected through a methodically designed screening process and the subsequently implemented digital health education tools.

F. Improving Drug Affordability and Access in Part D

I. Medication Therapy Management

The AMA has previously supported the medication therapy management (MTM) program standards which require all Part D sponsors to have a program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. AMA strongly supports efforts to provide beneficiaries with services that improve patient care coordination and enhance communication among a patient's physician(s) and other health care providers. To that end, the AMA supports MTM programs where pharmacists communicate with the prescriber (as well as the supervising or collaborating physician if the prescriber is not a physician). We commend CMS for monitoring the trends over the years of MTM programs and sponsors' compliance with the MTM requirements since the program's inception. This data provides valuable insight that indicates that now is an appropriate time to re-introduce proposed criteria aimed at expanding the program in order to address the inequitable access to the program that the current criteria create. We agree with the premise that requiring that plans include all 10 core chronic diseases identified by CMS including HIV/AIDS; modifying the criteria related to the number of covered Part D drugs a sponsor may require; and revising the methodology for calculating the cost threshold, all have the potential to increase eligibility rates, as desired, and attract more of the most in-need patients who may now not be fully able to realize the benefits of the program.

<u>Implementation of Certain Provisions of the Consolidated Appropriations Act, 2021 (CAA) and the Inflation Reduction Act (IRA) of 2022</u>

In this NPRM, CMS proposes to make the Limited Income Newly Eligible Transition (LI NET) Program a permanent part of Medicare Part D, as required by the CAA. **The AMA supports this change as a positive step towards targeted rulemaking to reduce hardship for those with low-incomes and those with catastrophic costs. In that same vein, we also support the proposal to implement section 11404 of the IRA, which expands eligibility under the low-income subsidy program in 2024 and has the**

potential to help an estimated 0.4 million beneficiaries, based on number of beneficiaries receiving partial LIS benefits in 2020.[57]

II. Validity of DEA Registration Numbers for Controlled Substances (§423.120(c))

The proposed rule notes that some physicians who prescribe controlled substances, such as hospital residents, do not have their own individual DEA registration number and prescribe controlled substances under the organizational health care provider's DEA registration number. The AMA is aware of situations in which Part D plans have rejected claims for these prescriptions and interfered with patient access to needed medications. Consistent with its current guidance, CMS proposes to make clear that if there is no individual prescriber DEA registration number found, a Part D plan does not need to take any further action when processing a claim for a controlled substance in terms of validating a DEA registration number. Plans only need to check the validity of the DEA registration numbers associated with individual prescribers, not those for organizational providers such as hospitals. CMS solicits comment on whether it should require Part D plans to reject all claims for controlled substances for which they cannot validate the DEA registration number and schedule, and what impact this adjustment in policy would have on beneficiary access to controlled substances covered by Part D.

When Part D plans have rejected prescription claims in the past due to use of an organizational DEA number instead of an individual DEA number by a resident physician, it has caused confusion for physicians and problems for patients. It is well known that transitions in care can lead to problems with patient safety and quality, with hospital discharges being a key transition. If Part D plans delay or deny prescriptions issued by resident physicians who are authorized to prescribe controlled substances for patients using their hospital's DEA number, it will lead to patients returning home from the hospital without being able to fill their prescriptions. Many patients are discharged before they have fully recovered from the illness or procedure that led to their hospitalization. Care should not be delayed or denied due to excessive and unnecessary checking of organizational DEA numbers. Residents are not expected to obtain an individual DEA number unless required by state law at a defined point during their training program. **The AMA supports the proposal to codify current CMS guidance that plans only need to check individual DEA numbers and not organizational numbers.**

III. Approval for Use of Buprenorphine in Treating Pain

The AMA recommends that Medicare facilitate access by patients with prescription drug coverage to the diversity of available buprenorphine products to help manage pain. The final report of the federal Pain Management Best Practices Interagency Task Force included the following recommendation: "Encourage CMS and private payers to provide coverage and reimbursement for buprenorphine treatment, both for OUD [opioid use disorder] and for chronic pain. Encourage primary use of buprenorphine rather than use only after failure of standard mu agonist opioids such as hydrocodone or fentanyl, if clinically indicated."

The report notes that buprenorphine is a partial agonist at the mu opioid receptor and has a reduced potential for respiratory depression when compared to full mu opioid receptor agonists such as morphine, hydrocodone, and oxycodone (notably buprenorphine is a Schedule III controlled substance whereas these other opioid analgesics are Schedule II). Buprenorphine also acts as an antagonist at the kappa receptor, an effect shown in experimental studies to reduce anxiety, depression, and the unpleasantness of opioid

[57] Explaining the Prescription Drug Provisions in the Inflation Reduction Act, KFF, https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/#bullet06 (January 2023).

withdrawal. Buprenorphine is widely used and encouraged for treating patients with OUD and is approved for the treatment of pain. The task force noted, however, that there are significant challenges for physicians to get authorization for prescribing buprenorphine for pain management.

Currently Medicare coverage for buprenorphine for pain is restricted to Butrans (a patch) and Belbuca (dissolving buccal tablets) because they are FDA approved for pain indications. In contrast, if Suboxone and Subutex are prescribed for pain, this is considered off label use since they are FDA approved only for the treatment of OUD. All these products are the same drug—buprenorphine. The only difference from a pharmacologic perspective is the dosing and delivery mechanism.

G. E-Prescribing and Health IT standards

I. Implementation of Updated E-Prescribing and New RTPB Standards

CMS proposes to require the NCPDP SCRIPT Standard Version 2022011 and retire the current NCPDP SCRIPT Standard Version 2017071 as the e-prescribing standard for transmitting prescriptions and related information, including electronic prescription drug PAs, effective January 1, 2025, following a transition period. The AMA supports this change, although we agree with NCPDP's recommendation that CMS should instead adopt SCRIPT Version 2023011, due to further enhancements available in this more recent version. As discussed in more detail earlier in this letter, the AMA also strongly supports adoption of the NCPDP RTPB standard for the increased transparency it will bring to both physicians and patients at the point of care regarding PA requirements, formulary design, and patient financial responsibility. Moving from today's limited, proprietary solutions to a standard are critical to ensuring the widespread availability of this information at the point of care. We agree with NCPDP's recommendation that CMS adopt NCPDP RTPB Version 13 (vs. Version 12, as proposed) due to enhancements offered in the newer version.

For both the updated version of NCPDP SCRIPT and the new NCPDP RTPB standard, the AMA supports CMS' proposed implementation deadline of January 1, 2025 (with a transition period for the SCRIPT standard update). The backwards compatibility of the SCRIPT versions should support this upgrade being accomplished within the suggested timeframe. Our physician members place high value on accessing current, accurate formulary data in their EHRs at the point of prescribing, so we concur with adoption of the NCPDP RTPB standard without delay on January 1, 2025. **However, we urge both the ONC and CMS to ensure that updated SCRIPT and RTPB standards are widely available in the EHR vendor market prior to placing any requirements on physicians for adoption (e.g., ONC EHR certification or CMS Promoting Interoperability measures).** We urge ONC and CMS to monitor the availability of these standards in physician-facing products to ensure the feasibility of any future physician-facing requirements.

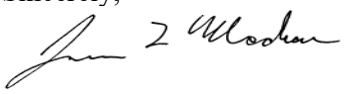
II. Aligned Approach to Standards Adoption

The proposed rule outlines a new approach to standards adoption through which the Secretary of HHS would adopt health IT standards under the authority of the Public Health Service Act. **The AMA supports this new approach to standards adoption and agrees that it will support greater alignment between ONC and CMS, improve the ability to synchronize timelines, reduce confusion, and minimize regulatory burdens.** We also note that this new approach allows standards to be "available for use by HHS," as stated in the rule. We encourage HHS to explore the opportunity to broaden the applicability of NCPDP standards to payers beyond Part D plans under this new model. Requiring drug

plans beyond the Part D program to support NCPDP SCRIPT ePA transactions, as well as the new NCPDP RTPB standard, will significantly increase the reach of these technologies and bring the associated benefits of reduced administrative burdens and increased transparency to a larger number of patients in a physicians' panel.

Thank you for the opportunity to provide input on this proposed rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



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