



JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

January 26, 2016

The Honorable Orrin G. Hatch
Chairman
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Johnny Isakson
Co-Chair
Senate Committee on Finance
Chronic Care Working Group
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mark Warner
Co-Chair
Senate Committee on Finance
Chronic Care Working Group
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Senators Wyden, Isakson, and Warner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to comment on the December 2015 “Bipartisan Chronic Care Working Group Policy Options Document” of the Senate Committee on Finance. The AMA commends the Committee and the Working Group for their dedication to improving care for Medicare patients with chronic conditions, and for undertaking this work in an open and transparent manner.

We particularly applaud the inclusion of initiatives to expand access to prediabetes education. The AMA has identified the prevention of type 2 diabetes as a crucial priority, particularly with the growing incidence of diabetes and the serious health complications that result from this disease. We are actively engaged in efforts to identify those at risk of type 2 diabetes as part of the AMA’s “Improving Health Outcomes” (IHO) strategic focus area, including working to fully implement the Centers for Disease Control and Prevention (CDC) National Diabetes Prevention Program (NDPP).

Also, as a general matter, the AMA urges the Working Group to implement proposed reforms with respect to all accountable care organizations (ACOs), whether or not they are in a track that requires them to make refunds to Medicare if spending exceeds target levels. As the Centers for Medicare & Medicaid Services (CMS) has recently indicated, as of 2016 only 13 percent of the 477 ACOs participating in all Medicare ACO programs are in a track that places them at risk for these repayments. All Medicare ACOs face risk of financial losses due to: start-up costs to get the ACO off the ground such as data analysis and establishing procedures for coordinating care and sharing information; ongoing costs for new employees such as care managers; and foregone revenue from billable services that are reduced by ACOs due to use of appropriateness guidelines and efforts to reduce exacerbations of patients’ conditions requiring emergency department visits and hospitalizations.

We offer the following comments on specific issues and proposals in the Options Document.

Receiving High Quality Care in the Home

Expanding the Independence at Home Model of Care

The AMA strongly supports the Working Group's proposal to expand the Independence at Home (IAH) demonstration to a nationwide program. The IAH demonstration has provided valuable cost savings thus far, and is likely to continue to do so at a national level. Likewise, expanding the IAH would allow a greater number of physicians to choose this option for their complex chronic care patients who wish to remain at home, with the inherent advantages of staying within their community, in a familiar environment, and closer to their loved ones.

However, we would urge the Working Group to consider making assessment of functional status the primary criterion for determining whether a patient is appropriate for the IAH program, rather than relying solely on the hierarchical condition categories (HCC) risk scores. We have heard from a number of physicians that level of function is often a more accurate indicator of the need for more comprehensive services than HCC risk scores.

Enhancing Ability of ACOs to Provide Home Health Care

For ACOs, the AMA recommends waiving the "homebound" or the "confined to the home" requirement. This waiver would allow Medicare to pay for non-homebound ACO patients to receive home health services. The homebound requirement should be waived for all Medicare ACOs, as all of them are incentivized to wisely use medical resources. Requiring ACO patients' health to deteriorate to the extent that they are homebound before eligibility for home-based services is indefensible.

Expanding Access to Home Hemodialysis Therapy

The AMA supports the Working Group's proposal to increase access to telemedicine services for patients receiving renal dialysis services. The AMA strongly supports efforts to remove the geographic restrictions across the board on telemedicine services as many patients that are outside of the geographically-covered areas of the nation will benefit equally from improved access to care. We also support the proposal to include free-standing renal dialysis facilities as originating sites. There are appropriate safeguards in such settings for patients and this proposal will remove barriers to access that have a negative impact on optimal patient health outcomes. The AMA, consistent with the American Society of Nephrology, supports establishing the home as an originating site for this service given the clinical evidence base to support such services and the significant barriers patients receiving such services face on a regular basis.

Advancing Team-Based Care

The AMA commends the Working Group for recognizing the value of team-based care.

Improving Care Management Services for Individuals with Multiple Chronic Conditions

The AMA fully supports coverage of care management services for complex patients with multiple chronic conditions. However, there is no need to mandate the development of new codes in order for

Medicare to cover such services. The Current Procedural Terminology® (CPT®) Editorial Panel has already defined CPT codes for “complex chronic care management” (CCCM) services, which represent more comprehensive services for more complicated patients. These include CPT codes 99487, *Complex chronic care coordination services; first hour of clinical staff time directed by a physician or other qualified health care professional with no face-to-face visit, per calendar month*; and 99489, *Each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*. These codes were developed with substantial input from a multitude of specialty societies of physicians and non-physicians working in consultation with CMS staff. In addition, the AMA/Specialty Society RVS Update Committee (RUC) recommended valuation of those codes, based upon input from the relevant specialty societies. The RUC initially sent comments to CMS in October 2011 supporting Medicare coverage for these services. These services are designed to support collaboration among and between physicians, non-physician clinicians, and clinical staff, and to support team-based care. They also provide physicians and other providers with the general framework and tools necessary to ensure a high quality of care by focusing their efforts to support ongoing coordination with the patient and evaluation of their status, transitions of care, and streamlining services to avoid complications, costly admissions, and preventable or unnecessary services and procedures.

Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries

The AMA commends the Working Group for recognizing the role of behavioral health issues in the management of chronic conditions and seeking solutions to better integrate behavioral health care with primary care. We strongly support Medicare coverage of collaborative care models for patients with common behavioral health conditions. Randomized control trials have demonstrated success with a particular collaborative care model for patients with common behavioral health conditions, such as depression and anxiety, which is described at <http://aims.uw.edu>. Each primary care office (which includes a primary care physician and a designated care manager) collaborates with a psychiatric consultant to manage a population of patients, ensure effective patient treatment, and make necessary adjustments in a timely manner to reach individual patient treatment goals. Much of this collaboration is performed without face-to-face patient contact, in interactions between the psychiatrist and the designated care manager. Medicare does not currently cover such encounters, particularly since it ended coverage for “consultations” between physicians several years ago. The CPT Editorial Panel at its February 2016 meeting will consider a proposal for new codes to describe this service. We urge the Working Group to take this process into account as it crafts any proposals addressing this crucial issue.

Expanding Innovation and Technology

Increasing Convenience for Medicare Advantage Enrollees through Telehealth

Telemedicine is already transforming clinical practice. We strongly support efforts to ensure that the nearly one in three Medicare beneficiaries who are participating in Medicare Advantage plans (31 percent in 2015) have access to these services where there is a demonstrated evidence base and where the services are utilized to promote and support care coordination and communication among a patient’s providers. We generally support ensuring that such services, however, are not used as a replacement for in-person care. We strongly applaud and support the specification that telemedicine shall not be used as a substitute to network adequacy requirements. While there is tremendous value to patients and providers of certain telemedicine services delivered in a coordinated manner with the patient’s in-person care, there remains a

clear evidence base that in-person care is the standard of care for patients, except in select specialties or for certain services.

Providing ACOs the Ability to Expand Use of Telehealth

The AMA strongly supports providing all ACOs the maximum flexibility to utilize telehealth services given the important patient ACO safeguards in place including patient care coordination, shared electronic health records, and provider accountability. Telehealth services have the potential to provide ACOs and their patient's valuable services that improve patient health outcomes by driving earlier diagnosis and treatment, patient compliance, and satisfaction. In addition, ACOs will not be incentivized to reduce access to in-person care for less costly alternatives that do not benefit patients. Although the Working Group recommends limiting the telehealth waiver to ACOs participating in two-sided risk models to protect against unnecessary utilization, the AMA urges the working group to provide the waiver for all ACOs, while establishing other safeguards to minimize the likelihood of inappropriate utilization. As noted above, all Medicare ACOs face financial risk due to start-up and ongoing operating costs, so it would be foolish to allow overuse of telehealth services and miss their shared savings opportunity. To ensure further the appropriate use of telehealth services, an ACO should be required to: outline a plan for how it will use telehealth services, particularly to improve chronic care management; have a mechanism in place to electronically transmit a record of the telehealth encounter to the patient's primary care physician if the eligible telehealth provider is not the patient's primary care physician; and publicly post their use/approval of the waiver.

Maintaining ACO Flexibility to Provide Supplemental Services

The AMA supports allowing ACOs to provide supplemental services such as social and transportation services, which could assist ACOs in accomplishing their goal of improving health care quality and lowering costs. We also support allowing ACOs to use remote patient monitoring to enable better patient access to care and to ease burdens that may hinder patients' ability to receive adequate care to manage their health.

Expanding Use of Telehealth for Individuals with Stroke

The AMA very strongly supports removal of the geographic restriction on physician telemedicine services to promptly identify and diagnose strokes, also known as cerebrovascular accidents (CVAs). There is clear clinical evidence demonstrating that rapid diagnosis and treatment of strokes are directly correlated to a patient's health outcomes, and there is also a demonstrated clinical evidence base to support the use of tele-stroke services. There is no legitimate clinical, technology, cost, or other policy basis for not ensuring all Medicare beneficiaries have access to such services. The geographic limitations on Medicare beneficiary access to telemedicine services are antiquated and do not reflect the current state of technological advancement nor the demonstrated clinical benefit to patients of certain technology and service combinations. The Medicare program will greatly benefit from improved patient health outcomes and the associated cost with this appropriate reform.

Identifying the Chronically Ill Population and Ways to Improve Care

Ensuring Accurate Payment for Chronically Ill Individuals

We strongly support the Working Group's proposal to call for a study examining whether functional status, as measured by activities of daily living, etc., would improve the accuracy of risk-adjusted payments. As we discussed above, we believe that functional status is generally the best indicator of the need for more intensive services.

In addition, the HCC risk adjustment model is critical to ACOs' success, but the current methodology does not adequately capture the risk and cost associated with ACO beneficiaries because HCC scores are capped at the ACO's baseline risk. Increases in risk adjustment are only permitted due to demographic changes, not changes in the acuity of the population. On the other hand, CMS does permit decreases in risk adjustment due to both demographic factors and changes in HCC scores. The current policy decreases ACO risk adjustments for patients whose health status improves due to ACO care management strategies, but prevents ACOs from receiving credit for caring for patients whose acuity worsens, whether or not the patients' illnesses were preventable. The AMA urges the Working Group to change this policy.

Providing Flexibility for Beneficiaries to be Part of an Accountable Care Organization

The AMA supports allowing ACOs to select either retrospective or prospective beneficiary assignment, as well as providing beneficiaries with the opportunity to voluntarily align with an ACO. This ability to choose to be involved in an ACO would balance beneficiaries' freedom to choose their providers with ACOs' interest in reducing churn, which would help provide a more defined and stable ACO patient population. Knowing their patient population would allow ACOs to better target their efforts to manage and coordinate patients' care and help increase beneficiary engagement in their care.

Developing Quality Measures for Chronic Conditions

The Working Group is considering requiring CMS to include measures focusing on outcomes for individuals with chronic disease in the measure development plan required under the Medicare Access and CHIP Reauthorization Act (MACRA), and is also considering whether to recommend that the Government Accountability Office (GAO) study holding providers accountable/linking payment to community-level measures related to chronic care management. We agree that it is important to have valid and reliable quality measures for treating patients with chronic conditions. However, we have significant concerns with establishing new statutory requirements to create measures that target chronic conditions or holding providers accountable under new measures.

CMS has just begun implementing the MACRA provisions that established a detailed process for identifying new priorities for quality measure development, identifying measure gaps, and supporting the development of new quality measures, for use in the new Merit-based Incentive Payment System (MIPS). The MACRA explicitly allows for interested stakeholders to provide input into this process at virtually every stage, and it also spells out specific priorities for measure development. We believe it would be unwise and premature to add additional requirements for measure development until CMS has been given a chance to conduct a thorough review of what measures are needed. It takes substantial time and resources to develop new quality measures and appropriately test and evaluate them to ensure they are

valid and reliable. Funds are extremely limited for measure development, and the MIPS will apply to all physicians (and some non-physician practitioners). Moreover, not every area of care lends itself to accurate measurement of outcomes.

Imposing new requirements at this stage would disrupt the MIPS measure development process and could lead to unintended consequences and unforeseen distortions. For example, channeling resources solely to outcome measures related to chronic conditions could lead to fewer resources for developing quality measures for use by primary care providers who treat acute conditions. In the measure development process established under MACRA, CMS may find more efficient ways to support the development of measures that can apply to chronic as well as acute conditions. We are also concerned about unfairly holding physicians accountable for community-level measures that are beyond their control. Unlike hospitals, physicians receive no incentives to engage in community-level activities. Finally, we are not sure that the GAO has the appropriate expertise to perform the referenced study.

Empowering Individuals & Caregivers in Care Delivery

Encouraging Beneficiary Use of Chronic Care Management Services

The AMA encourages the Working Group to consider treating chronic care management services similar to preventive services, for which Medicare waives the beneficiary co-payment and pays 100 percent of the Fee Schedule amount.

Establishing a One-Time Visit Code Post Initial Diagnosis of Alzheimer's/Dementia or Other Serious or Life-Threatening Illness

The Working Group is considering requiring establishment of a specific payment code to recognize the additional time needed to have conversations with patients who have received a diagnosis of a serious or life-threatening illness, such as Alzheimer's or other dementia. At the February 2016 meeting, the CPT Editorial Panel will address some of the policy that the Working Group is considering in a CPT proposal regarding an Evaluation and Management code and guidelines for reporting comprehensive assessment and care plan services for patients with cognitive impairment. As proposed, the new CPT code would apply to an assessment provided to establish or confirm a diagnosis, its cause(s), and severity for patients exhibiting signs and/or symptoms of cognitive impairment. The proposed CPT code may address the Working Group's concerns, in that it describes the care of patients who have not yet received a diagnosis of cognitive impairment, and does include a care plan with medical decision making which includes current and likely progression of the disease; assessing the need for social or community-based services; legal and financial aid; and meal, transportation, and other personal assistance services.

Eliminating Barriers to Care Coordination under Accountable Care Organizations

The ability to waive copayment for primary care services could help Medicare ACOs improve care delivery and also encourage appropriate beneficiary health-seeking behavior. Allowing all ACOs the opportunity to waive these copays can encourage patients to get appropriate and time-sensitive care, preventive screenings, and help ACO physicians better manage patients' chronic conditions and prevent new conditions or exacerbations of existing conditions. In addition, it could help to address unstable beneficiary assignment, which is a well-recognized problem. Michael McWilliams and his colleagues

found in a 2014 *JAMA Internal Medicine* study that unstable assignment was as high as 33 percent and that “much of the outpatient specialty care for patients assigned to ACOs, particularly higher-cost patients with more office visits and chronic conditions, was provided by specialists outside of patients’ assigned organizations, even among more specialty-oriented ACOs.” CMS noted in its December 2014 proposed ACO rule that unstable assignment or “churn rate” is 24 percent on average. A copay waiver could reduce the instability that occurs when ACO-assigned patients’ office visits occur outside their ACO.

Expanding Access to Prediabetes Education

The AMA is very pleased that the Working Group is considering recommending that “Medicare Part B provide payment for evidence-based lifestyle interventions that help people with prediabetes reduce their risk of developing diabetes.” As mentioned earlier in this letter, through the AMA’s IHO initiative, we are engaged in efforts to reduce the incidence of Type 2 diabetes. As part of a multi-year initiative called [“Prevent Diabetes STAT: Screen, Test, Act - Today™,”](#) the AMA is partnering with the CDC to increase the number of physicians who screen and test patients for prediabetes and refer them to CDC-recognized diabetes prevention programs (DPPs), which include lifestyle interventions proven to prevent or delay progression to diabetes.¹ Prediabetes is a serious health condition that affects 86 million Americans (more than 1 in 3) and often leads to type 2 diabetes. People with prediabetes have higher than normal blood glucose levels, but not high enough yet to be diagnosed with type 2 diabetes. Nearly 90 percent of people with prediabetes do not know they have it and are not aware of the long-term risks to their health, including type 2 diabetes, heart attack, and stroke. Current trends suggest that, if not treated, 15 to 30 percent of people with prediabetes will develop type 2 diabetes within five years. However, prediabetes often can be reversed through weight loss, diet changes, and increased physical activity. Diagnosis is key: research shows that once people are aware of their condition, they are much more likely to make the necessary lifestyle changes.

According to CDC data, there are over 11 million adults with diabetes and another 26 million with prediabetes. Given that this translates to 77 percent of adults age 65 or older living with diabetes or prediabetes, the AMA strongly supports providing coverage of the NDPP under the Medicare program and allowing a diabetes prevention program to be delivered by entities that are not currently providers under the Medicare statute, as long as the CDC’s NDPP standards and criteria are followed. Extending coverage of the NDPP through Medicare will help to reduce the number of beneficiaries who develop type 2 diabetes and its costly and debilitating conditions, including stroke, cardiovascular disease, kidney disease, lower-limb amputation, and blindness. In line with its support for the Working Group’s proposal, the AMA supports the bipartisan, bicameral Medicare Diabetes Prevention Act, H.R. 2102/S. 1131, which would provide Medicare coverage for the NDPP for individuals with prediabetes.

The NDPP originated from the successful DPP clinical trial carried out by the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health. The clinical trial found individuals with prediabetes can reduce their risk for type 2 diabetes by 58 percent with lifestyle changes, including improved nutrition, increased physical activity, and weight loss of five to seven percent. The

¹ We would like to correct an inaccurate statement in the Working Group document on page 27, under the paragraph titled “Reason for Consideration.” Medically, Type 1 diabetes cannot be prevented; however, Type 2 diabetes can be delayed or prevented through medication and evidence-based lifestyle interventions that help people with prediabetes reduce their risk for developing type 2 diabetes.

results were even stronger for seniors. Participants over the age of 60 reduced their risk for type 2 diabetes by 71 percent. Further research translating the clinical trial to a community setting showed these results can be replicated in a group setting for a relatively low cost of about \$425-\$450 per participant.

While the Y-USA is currently the largest provider of the NDPP, with nearly 40,000 participants in 43 states, there are many other CDC-recognized providers of the DPP, offering in-person programs as well as virtual, or a combination of both. In light of its impressive results, both public and private insurance providers are covering the NDPP: 29 private payers and three Medicaid programs provide coverage, and eight additional states are covering the program for their state employees. Moreover, Omada Health and Weight Watchers International, Inc. are providing the NDPP virtually, rather than in person, and are following the CDC's curriculum and criteria. With regard to billing, Omada has worked with a payer and used an existing CPT code, 98969 (Online medical evaluation—non-physician) with modifiers to bill for their virtual program, Prevent. The modifiers reflect value-based outcomes, e.g., milestones such as enrollment, completion of four sessions, completion of nine-plus out of 16 sessions, five percent weight loss, and 10 percent weight loss.

A new Category III CPT code, code 0403T, has been established to report the services provided in a standardized diabetes prevention program, using a standardized curriculum recognized by the CDC, effective January 1, 2016. The Working Group has listed two reasons for consideration of new policy: 1) addressing patients that are at risk of developing diabetes; and 2) delivery of the program by entities not listed as providers under the Medicare statute, such as non-profit organizations and departments of health. CPT code 0403T addresses both of these issues by being specific to diabetes prevention services and not limited to certain providers.

The AMA recommends that entities delivering evidence-based lifestyle interventions like the NDPP should be required to meet the CDC's well-established standards in order to be recognized as an eligible provider under Medicare. The [CDC's Diabetes Prevention Recognition Program \(DPRP\)](#) standards are based on a defined curriculum, content and duration, program delivery standards, and data collection, as well as clearly articulated program performance criteria that organizations must meet to be recognized by the CDC as providing a high quality, effective diabetes prevention behavior change intervention. We agree with the Working Group that the NDPP is a well-established, evidence-based program and believe that the DPRP is an appropriate model to follow in order to certify new entities who wish to participate as providers in the NDPP.

This program also increases care coordination (between physicians and care teams and community programs) and incentivizes the appropriate level of care, which benefits the Medicare population greatly. Providing Medicare coverage of this program would increase care coordination among individual providers across care settings by allowing Medicare beneficiaries to be referred by their respective physician to a community-based DPP that focuses on lifestyle change to prevent the progression to type 2 diabetes. Physicians receive feedback from these programs as to their patients' progress so they can support the patient in their efforts to make this important lifestyle change. In addition to coverage of the DPP, it is critically important that the physician services involved in managing these patients be covered. Physicians need to screen and test patients before making a decision to refer for counseling. As a first step, patients must complete screening or a risk test during check-in and body mass index (BMI) must be calculated in the exam room. Physicians use this data to diagnose a patient with prediabetes and in consultation with the patient determine his or her willingness to participate in a diabetes prevention

program. They also need to do follow-up to monitor the patient's progress in the DPP and reevaluate the risk for developing type 2 diabetes, as well as ongoing counseling of the patient.

Medicare beneficiaries enrolled in the program would be empowered to make changes in their lifestyle that will put them on the road to better health, especially since many seniors have multiple chronic conditions. Diabetes is one of the top health care cost drivers in the Medicare program: according to the American Diabetes Association (ADA), one in three Medicare dollars is spent on individuals with diabetes. The annual cost of diagnosed and undiagnosed diabetes, gestational diabetes, and prediabetes had skyrocketed to \$322 billion in 2012, a 48 percent increase in just five years, and according to the Institute for Alternative Futures, it is estimated that the total annual cost of diabetes in adults aged 65 and over could reach \$168 billion by 2025, which would represent an increase of nearly 60 percent from 2010. Studies have demonstrated that programs such as the NDPP are cost-effective, and the AMA believes that the Working Group's proposal could save the Medicare program significant resources. [A study done last year by the consulting firm Avalere Health LLC](#) shows that this policy could reduce federal spending by \$1.3 billion over 10 years. This amount reflects a combination of an estimated \$7.7 billion in new spending on the DPP, offset by an estimated \$9.1 billion in savings. Savings from preventing type 2 diabetes would likely continue to increase beyond 10 years, suggesting even greater impact on longer-term federal spending. [A more recent study published in the *Annals of Internal Medicine*](#) which reviewed studies assessing the incremental cost-effectiveness ratio of diet and physical activity promotion programs, concluded that such programs are cost-effective among persons at increased risk for diabetes.

Other Policies to Improve Care for the Chronically Ill

Increasing Transparency at the Center for Medicare & Medicaid Innovation (CMMI)

While we support the general concept of increasing the transparency of the CMMI's decisions of whether to implement alternative payment and delivery models, we believe it would be a serious mistake to require the CMMI to announce each decision—and particularly any adjustments in such models—in notice and comment rulemaking. There needs to be maximum flexibility for the CMMI to adopt, implement, and make necessary adjustments in such models, in a very timely manner. Tying such decisions to formal rulemaking would prevent the necessary level of flexibility. However, formal rulemaking would be entirely appropriate to announce standards for such models and the process for their consideration, approval, and implementation.

Study on Obesity Drugs

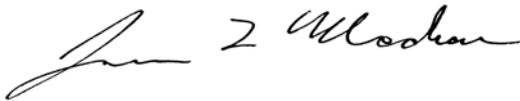
The Working Group is considering requiring a study to determine the use and impact of obesity drugs in the Medicare and non-Medicare populations. The AMA supports this proposal. The AMA has long supported heightened efforts to address the health problems associated with obesity and to offer patients the resources and the support they need to maintain a healthy weight. The AMA House of Delegates has adopted policy deeming obesity a "disease" to raise awareness of the problem within health care and to increase treatment opportunities and options. Obesity also contributes to the widespread problems of type 2 diabetes and hypertension, two chronic conditions that the AMA is addressing through its IHO initiative. The AMA also urges the Working Group to consider including in its proposal additional provisions from S. 1509, the "Treat and Reduce Obesity Act of 2015."

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Conclusion

The AMA appreciates the opportunity to provide comments on the Working Group's Options Document, and we look forward to working with the Committee and the Working Group on this important initiative to improve care for Medicare patients with chronic conditions. If you have any questions about this letter, please contact Thomas C. Roberge, Jr., Senior Assistant Director, Division of Congressional Affairs, at 202-789-7411 or tc.roberge@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and "M".

James L. Madara, MD