James L. Madara, MD





iamos madara@ama asen ora

August 30, 2021

The Honorable Nancy Pelosi Speaker U.S. House of Representatives Washington, DC 20515

The Honorable Kevin McCarthy Minority Leader U.S. House of Representatives Washington, DC 20515 The Honorable Charles Schumer Majority Leader U.S. Senate Washington, DC 20510

The Honorable Mitch McConnell Minority Leader U.S. Senate Washington, DC 20510

Dear Speaker Pelosi, Majority Leader Schumer, Leader McConnell, and Leader McCarthy:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to convey our ongoing commitment to reform and improve our nation's health care system, as well as provide our perspective on health care issues related to the budget reconciliation proposal. The nation faces many health care challenges and the policies included and omitted in the reconciliation legislation will indicate Congress' priorities.

As Congress begins the process of formulating the next reconciliation package, the AMA appreciates the opportunity to highlight a multitude of policy concepts that deserve inclusion in the final legislation, specifically:

- Enhanced Access to Health Care Coverage and lower health care costs by building upon improvements in the American Rescue Plan Act.
- **Medicare Program Sustainability** and postponement of impending physician payment cuts set to take effect on January 1, 2022.
- **Streamlined Prior Authorization,** which is currently overused, costly, inefficient, opaque, and has proven responsible for patient care delays, especially in Medicare Advantage.
- Continued Access to Telehealth in order to ensure effective, efficient, and equitable delivery of virtual health care services continues beyond the conclusion of the COVID-19 public health emergency.
- **Increasing the Health Care Workforce** to provide vital care to the nation, including enhancing the Conrad 30 program and supporting International Medical Graduates.
- Improvements in Health Equity, health outcomes and social determinants of health to decrease health disparities.
- Combating Maternal Mortality, which disproportionately affects Black and Native American/Alaska Native women.
- Medicaid Assistance for Eligible Incarcerated Individuals, to provide for critically needed health care services, care coordination activities, and linkages to care for incarcerated individuals.
- Lower Prescription Drug Prices.

• **Improving our Cybersecurity Infrastructure** and including physician input, where applicable, in cybersecurity infrastructure discussions.

The AMA is confident that efforts by federal lawmakers to enact meaningful changes to the United States health care system will be significantly enhanced by incorporating these key policy concepts and corresponding bipartisan pieces of legislation that are highlighted in more detail below.

Enhanced Access to Health Care Coverage

The AMA is strongly committed to seeking solutions that improve access to health insurance coverage and lower health care costs. Covering the uninsured and improving health insurance affordability have been long-standing goals of the AMA. The American Rescue Plan Act (ARPA) included the largest coverage expansion since the Affordable Care Act (ACA) and showed how much more we can accomplish under the ACA, without turning to proposals that have a real potential to cause significant health system disruptions. The nation has witnessed record enrollment in ACA coverage, via coverage offered on ACA marketplaces and under the Medicaid expansion, as well as through the Special Open Enrollment Period that recently ended.

The AMA supports the improvements to the ACA included in the ARPA that made premium tax credits more generous and eliminated ACA's "subsidy cliff," and we urge Congress to take steps to make these changes permanent to ensure our patients have access to affordable health insurance coverage. Beyond these improvements, it will be essential for Congress to target future policy proposals on the populations that remain uninsured despite the ARPA improvements. For example, millions of uninsured individuals in the U.S. are now eligible for zero-premium marketplace coverage or Medicaid. As such, the AMA believes that Congress should explore pathways to auto-enroll these individuals in health insurance coverage at no cost to them, which would have a significant impact on the number of uninsured in the U.S.

However, more affordable premiums that are now available thanks to the ARPA are only one piece of the puzzle. A segment of the uninsured still cannot receive the premium help they need, including some families of workers offered unaffordable employer coverage, which is why the AMA supports a legislative fix to the ACA's "family glitch." Also, uninsured young adults may need more of a financial incentive to get covered. In addition, some of the uninsured may not see the benefit in getting covered if they cannot afford their deductibles, copayments, and other cost-sharing responsibilities. Individuals need more help in affording their cost-sharing responsibilities, which is why the AMA urges Congress to make ACA's cost-sharing reductions more generous and available to more people. We also believe that solutions must be found for individuals who fall in the "coverage gap" in states that have not expanded Medicaid.

Before the COVID-19 pandemic, in 2018, 2.3 million of the nonelderly uninsured found themselves in the coverage gap—not eligible for Medicaid, and not eligible for tax credits because they reside in states that did not expand Medicaid. Without access to Medicaid, these individuals do not have a pathway to affordable coverage. The AMA is continuing to encourage all states to expand Medicaid eligibility to 133 percent federal poverty level (FPL). Additionally, the AMA encourages policymakers at all levels to work together to explore realistic coverage options for uninsured individuals who fall into the coverage gap.

Medicare Program Sustainability

The AMA is deeply alarmed about the growing financial instability of the Medicare physician payment system, due to the confluence of fiscal uncertainties confronting physician practices at the end of this year and legislative proposals to extend the current Medicare sequester that, in effect, will require physicians and health systems to pay for the costs of enhancing the nation's hard infrastructure. Medicare payments have been under pressure from the Centers for Medicare & Medicaid Services' (CMS) anti-inflationary payment policies for more than 20 years. While physician and non-physician provider services represent a very modest portion of the overall growth in health care costs, they are perennial targets for cuts when policymakers seek to limit spending. Medicare physician payments have remained stifled by a budget-neutral financing system.

On January 1, 2022, physician practices face the following Medicare financial impacts:

- Expiration of the current reprieve from the 2 percent sequester stemming from the Budget Control Act of 2011, which now is expected to continue into 2031, despite being originally slated for sunset in 2021.
- Imposition of a 4 percent Statutory PAYGO sequester resulting from passage of ARPA.
- Expiration of the Congressionally-enacted 3.75 percent temporary increase in the Medicare physician fee schedule (PFS) conversion factor to avoid payment cuts associated with budget neutrality adjustments tied to PFS policy changes.
- A continuing statutory freeze in annual Medicare PFS updates under the Medicare Access and CHIP Reauthorization Act (MACRA) that is scheduled to last until 2026, when updates resume at a rate of 0.25 percent a year indefinitely, well below the rate of medical or consumer price index inflation.

Combined, physician practices face a 9.75 percent cut on January 1. Additionally, potential penalties under the Merit-Based Incentive Payment System (MIPS), which apply to Medicare PFS services, will increase to **9 percent in 2022**. In a <u>study</u> published this year in the *JAMA Health Forum*, physician practice leaders reported that the mean per-physician cost of participating in MIPS was over \$12,000 per year, consuming more than 200 hours of physician and administrator time each year.

All this financial uncertainty comes at a time when physician practices are still recovering from the financial impact of the COVID-19 public health emergency, including continued infection control protocols that, while necessary, have increased the costs of providing care. The combination of all these policies would be challenging to endure in normal times. Yet, physician practices continue to be stretched to their limits clinically, emotionally, and financially as the pandemic persists well beyond 15 months. The enactment of further Medicare payment cuts will undoubtedly threaten patient access to care, especially considering the stark reality that, adjusted for inflation in practice costs, Medicare physician payment actually declined 22 percent from 2001 to 2020, or by 1.3 percent per year on average.

Furthermore, the promise of a robust and patient-centered alternative payment model (APM) pathway for physicians under MACRA has yet to be realized, leaving the majority of practices stuck in the MIPS portion of the MACRA program, with legacy and siloed cost and quality measurement programs that impose steep administrative burdens while lacking clinical relevance. We cannot achieve the promise of

high-quality, coordinated care that helps patients achieve optimal health if the barriers to success in the MACRA program are not examined and addressed. The state of the program is increasingly dysfunctional and, ultimately, it will be patients who suffer.

One recommendation to address the issues surrounding Medicare Program Stability and the movement to value-based care is for Congress to include H.R. 4587, the "Value in Health Care Act of 2021" within any forthcoming reconciliation package. This bipartisan legislation makes a number of important reforms to strengthen Medicare's value-based care models and Accountable Care Organizations (ACOs) to ensure that these models continue to produce high quality care for the Medicare program and its beneficiaries, as well as generate savings for taxpayers. The Value in Health Care Act, among other things, removes barriers to ACO participation, provides appropriate shared savings rates, modifies risk adjustment methodologies, improves the fairness and accuracy of benchmarks, corrects thresholds for participation in an APM and offers educational and technical support for ACOs. Most importantly, the legislation extends the 5 percent annual lump sum bonus for qualifying Advanced APM participants for an additional six years, until performance year 2028. One recent <u>analysis</u> estimates that the enactment of H.R. 4587 would save the Medicare Trust Fund \$280 million over 10 years.

In addition, we strongly urge you to consider that, as Congress debates expanding benefits under the Medicare program, the payment infrastructure for physician practices is unsustainable and must be addressed prior to the January 1, 2022, payment cliff. The AMA continues to request that Congress convene hearings on the alarming state of the Medicare physician payment system, not only from a financial perspective but also related to many fundamental operational aspects. Serious discernment through committee hearings and stakeholder input must be exercised to ensure that a critical and fundamental component of the Medicare program's infrastructure—physician practices—can be sustained under the current program and to determine what structural changes are needed to protect patient access to care. We urge you to include language in the reconciliation bill that provides the committees of jurisdiction with instructions to draft and mark up legislation that will provide a clear pathway to preventing these cuts from taking place prior to January 1, 2022.

Streamlined Prior Authorization

Prior authorization (PA) is a health plan cost-control process that requires physicians and other health care professionals to qualify for payment by obtaining approval before performing a service. The AMA believes that PA is overused, costly, inefficient, opaque, and responsible for patient care delays. According to the AMA's 2020 PA physician survey, more than nine in 10 physicians (94 percent) reported care delays while waiting for health insurers to authorize necessary care; nearly four in five physicians (79 percent) said patients abandon treatment due to authorization struggles with health insurers; and 85 percent of physicians describe the burden associated with PA as high or extremely high. Most alarmingly, nearly one-third (30 percent) of surveyed physicians reported that PA has led to a serious adverse event (e.g., hospitalization, disability, or even death) for a patient in their care. Patients—especially the vulnerable Medicare Advantage (MA) population—deserve PA reforms that will protect them from these harms associated with PA requirements.

The AMA supports H.R. 3173, the "Improving Seniors' Timely Access to Care Act of 2021." This important legislation, which currently has more than 190 bipartisan cosponsors, would require MA plans to implement a streamlined electronic prior authorization process in compliance with HHS technical

standards, require increased transparency for beneficiaries and providers, ensure that care and treatments that routinely receive pre-approval are not subjected to unnecessary delays, and require MA plans to meet certain beneficiary protection standards, such as ensuring continuity of care when patients change plans. Efforts to standardize, streamline, and simplify prior authorization within Medicare Advantage will improve the overarching timeliness of patient care and minimize physician burden while complementing efforts to strategically enhance health coverage offered through the ACA and Medicare.

Continued Access to Telehealth

The AMA has long supported efforts to ensure that Medicare beneficiaries continue to have access to telehealth services after the COVID emergency ends. Telehealth is a critical part of the future of effective, efficient, and equitable delivery of health care in the United States. Efforts must continue to build capacity and support access to care centered on where the patient is located to the greatest extent it is clinically efficacious, and to ensure physicians and other health care professionals have the tools to optimize care delivery. The AMA has been a leader in advocating for expanded access to telehealth services for Americans because it has the capacity to improve access to care for many underserved populations and improve outcomes for at-risk patients, particularly those with chronic diseases and/or functional impairments.

The **omission** of retaining telehealth services for Medicare beneficiaries in the budget resolution is glaring. The AMA strongly recommends that Congress act to prevent seniors from losing access to services expanded during the public health emergency (PHE).

While millions of Americans have benefited from access to telehealth services during the COVID-19 PHE, without further legislative action from Congress, Medicare beneficiaries who have come to rely on telehealth services will abruptly lose access to these services completely. Under section 1834(m) of the Social Security Act (SSA), Medicare is prohibited from covering and paying for telehealth services delivered via two-way audio-visual technology unless care is provided at an eligible site in a rural area. This means that, in order to access telehealth services, patients must live in an eligible rural location, and must also travel to an eligible "originating site"—a qualified health care facility—to receive telehealth services, except in the few cases where Congress has authorized provision of telehealth services in the home of an individual. As a result, the section 1834(m) restrictions bar the majority of Medicare beneficiaries from using widely available two-way audio-visual technologies to access covered telehealth services unless they live in a rural area, and with a few exceptions, even those in rural areas must travel to an eligible health care site.

It is critically important that Medicare beneficiaries continue to be able to access telehealth services from their physicians without arbitrary restrictions throughout the COVID-19 PHE and beyond. The AMA supports permanently fixing the originating site and geographic restriction on telehealth coverage for Medicare patients, thereby ensuring Medicare coverage of telehealth services regardless of where the patient is located. This includes:

• H.R. 1332/S. 368, the "Modernization Act of 2021," which would lift the rural-only restriction and add any site where a patient is located as a potential originating site and ensure all Medicare beneficiaries may receive covered Medicare telehealth benefits, including at home and via mobile technologies, as appropriate.

• H.R. 2903/S. 1512, the "CONNECT for Health Act," which would permanently eliminate the Medicare telehealth geographic restrictions, add the home as an originating site, and establish a process for the HHS Secretary to add additional originating sites. The legislation also provides HHS with the permanent authority to waive further 1834(m) restrictions, so long as they do not negatively impact quality of care, which is similar to the authority the agency has for the duration of the COVID-19 PHE.

Mental Health Telehealth Services

Congress enacted much needed reform last year to permanently waive origination and geographic restrictions for patients needing mental health services via telehealth at the end but required a patient to have an in-person evaluation within six months of the first telehealth visit with their provider, despite a lack of evidence demonstrating this had a clinical impact or the lack of a similar requirement on SUD or co-occurring SUD/MH conditions. That is why the AMA is strongly supporting H.R. 4058/S. 2061, the "Telemental Health Care Access Act," which would eliminate the newly enacted restriction on access to telemental health services. We urge Congress to eliminate this arbitrary restriction and allow specialty societies to determine when it is appropriate to treat a patient or establish a doctor-patient relationship.

Medicare Diabetes Prevention Expanded Model Flexibilities Should be Made Permanent

Through the rulemaking process for the 2021 Medicare physician payment schedule, CMS adopted important flexibilities that are effective for the duration of the COVID-19 PHE and in future 1135 waiver emergencies that could cause a disruption to in-person Medicare Diabetes Prevention Program (MDPP) services. These MDPP policies will only apply in emergency situations, however, and not on an ongoing basis. MDPP services are being significantly underutilized. If the MDPP flexibilities that have been adopted for COVID-19 and future emergencies were instead continued as regular, ongoing MDPP policies, it would significantly strengthen the effectiveness of diabetes prevention services for Medicare patients with prediabetes. The AMA strongly urges Congress to pass H.R. 2807/S. 2173, the "PREVENT Diabetes Act," or similar legislation to make these flexibilities permanent.

In addition, to furnish virtual services during an emergency period, MDPP suppliers must already have preliminary or full Centers for Disease Control and Prevention (CDC) Diabetes Prevention Program recognition for in-person services. CMS continues to bar virtual-only suppliers that have achieved CDC recognition from furnishing MDPP services, even during the PHE. Under its current regulations, CMS will require MDPP providers to resume in-person services at the conclusion of the COVID-19 PHE. Against AMA urging, CMS has declined to allow virtual providers to participate in MDPP to the fullest extent either during or after the PHE. CMS regulations also prohibit patients from participating in their MDPP sessions virtually when offered by suppliers who provide both in-person and virtual services except during an emergency period. Many patients with prediabetes are unable to effectively participate in in-person MDPP sessions, often because they live far from any supplier location or because the sessions are not offered at times that are convenient for them. Furthermore, CMS regulations also impose a once-per-lifetime limit on patients obtaining MDPP services. The MDPP should be modified to allow patients to obtain their session virtually at any time, plus the once-per-lifetime limitation should be eliminated.

<u>Increasing the Health Care Workforce</u>

Graduate Medical Education

The COVID-19 pandemic has exposed the critical need for additional federal investment in our health care infrastructure, and in particular the need for more physicians. Workforce experts predict that the United States will face a shortage of approximately 90,000 physicians by the year 2025. To protect patient access to care, the AMA urges Congress to invest in additional Medicare-funded Graduate Medical Education (GME) positions. Physicians are a vital part of our health care infrastructure, and it is critical that we train more in order to meet the needs of our diverse and growing nation, ensure patient access to care, and prepare for the next public health crisis.

Also, the AMA supports robust funding for programs under the Title VII of the Health Professions Education Assistance Act that supports educational experiences for medical students and resident physicians in underserved areas. The Health Resources and Services Administration Title VII health professions pipeline, education, and training programs are critical in helping shape and prepare our nation's health workforce to address new and emerging public health challenges in rural and other underserved communities across the U.S.

Further, we urge you to consider viable ways to improve GME, ensuring medical students have the opportunity to fulfill training requirements and become practicing doctors, including:

- H.R. 2256/S. 1024, the "Resident Physician Shortage Reduction Act." This <u>bill</u> would gradually raise the number of Medicare-supported GME positions by 2,000 per year for seven years, for a total of 14,000 new slots. A share of these positions would be given to hospitals with diverse needs including hospitals in rural areas, hospitals serving patients from health professional shortage areas, hospitals in states with new medical schools or branch campuses, and hospitals already training over their caps.
- S. 54, the "Strengthening America's Health Care Readiness Act." This <u>bill</u> would provide additional funding for the National Health Service Corps (NHSC), the Nurse Corps, and establish a National Health Service Corps Emergency Service demonstration project.
- H.R. 2130/S. 924, the "Rural America Health Corps Act." This <u>bill</u> would establish a demonstration program to provide payments on qualified loans for individuals eligible for, but not currently participating in, the NHSC Loan Repayment Program who agree to a five-year period of obligated full-time service in a rural health professional shortage area.
- H.R. 3441, the "Substance Use Disorder Workforce Act." This <u>bill</u> would provide 1,000 additional Medicare-supported GME positions in hospitals that have, or are in the process of establishing, accredited residency programs in addiction medicine, addiction psychiatry, or pain medicine.
- S. 1438, the "Opioid Workforce Act." This <u>bill</u> would provide 1,000 additional Medicare-supported GME positions in hospitals that have, or are in the process of establishing, accredited residency programs in addiction medicine, addiction psychiatry, or pain medicine.
- H.R. 3671/S. 1958, the "Doctors of Community Act or the "DOC Act." This bill would permanently authorize the Teaching Health Center Graduate Medical Education program. As

- such, this legislation is vitally important to ensure that patients in underserved areas continue to have access to the care that they need.
- H.R. 4014/S. 2094, the "Physician Shortage GME Cap Flex Act." This <u>bill</u> would help to address our national physician workforce shortage by providing teaching hospitals an additional five years to set their Medicare GME cap if they establish residency training programs in primary care or specialties that are facing shortages.

We also recognize that one of the major barriers to acquiring medical education is the cost of medical education. As such, significant efforts on student loans, beyond targeted loan relief programs, are required including, but not limited to:

- H.R. 2418, the "Student Loan Forgiveness for Frontline Health Workers Act." This <u>bill</u> which would provide physicians, residents, medical students, and other health care professions who perform work to combat, control, and recover from COVID-19 with student loan forgiveness.
- H.R. 2917/S. 1443, the "Retirement Parity for Student Loans Act." This <u>bill</u> would permit 401(k), 403(b), SIMPLE, and governmental 457(b) retirement plans to make voluntary matching contributions to workers as if their student loan payments were salary reduction contributions. The House legislation actually passed the House Ways and Means Committee as part of H.R. 2954, the "Securing a Strong Retirement Act of 2021."
- H.R. 4122, the "Resident Education Deferred Interest (REDI) Act." This bill would allow borrowers to qualify for interest-free deferment on their student loans while serving in a medical or dental internship or residency program.

Immigration and Conrad 30

The AMA has been a strong supporter of the Conrad 30 program, and H.R. 3541/S. 1810, the "Conrad State 30 and Physician Access Reauthorization Act," for more than a decade. In 2017, nearly 30 percent of medical residents in the U.S. were international medical graduates (IMGs), with about half working as physicians in the U.S. on non-immigrant visas, such as J-1. These non-U.S. citizen IMGs play a critical role in providing health care to many Americans, especially in areas of the country with higher rates of poverty and chronic disease. For example, over the past 10 years, more than 10,000 J-1 IMGs have worked in underserved communities. Moreover, nearly 21 million people live in areas of the U.S. where foreign-trained physicians account for at least half of all physicians. As such, it is important to support and create pathways for these physicians to be able to continue to remain in the U.S. and care for their patients.²

¹ The AMA has been a strong supporter of the Conrad 30 program in previous congressional sessions (2019, 2017, 2015, 2013, 2012).

² https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-5-27-Letter-to-Senate-re-Support-for-Conrad-State-30-and-Physician-Access-Reauth-Act.pdf.

International Medical Graduates

International Medical Graduates (IMGs) are an important part of our U.S. health care teams and serve on medical front lines across the country. Consequently, the ability to recapture 15,000 unused employment-based physician immigrant visas from prior fiscal years would help enable our U.S. physicians to have the support they need and our U.S. patients to access the care they deserve during this unprecedented public health crisis.^{3,4} As such, the AMA supports H.R. 225/S. 1024, the "Healthcare Workforce Resilience Act." This <u>legislation</u> would recapture 15,000 unused employment-based physician immigrant visas and 25,000 unused employment-based professional nurse immigrant visas from prior fiscal years would help enable our U.S. physicians to have the support they need and our U.S. patients to access the care they deserve during this unprecedented public health crisis.

Improvements in Health Equity

The AMA is <u>strongly committed</u> to improving health equity, health outcomes, and social determinants of health (SDOH) and decreasing health disparities. The COVID-19 pandemic has created a concurrent economic crisis that has exposed and exacerbated pervasive and severe health and social inequities. Not only has the pandemic disproportionally impacted minoritized and marginalized communities, but economic insecurity, housing insecurity, and food insecurity have disproportionately burdened communities of color and other underserved populations (e.g., rural areas) the hardest. There are many opportunities in the budget reconciliation package to increase investments to improve equity and SDOH, including through investments in housing, transportation, nutrition, and environmental programs. In addition, we believe that legislation on SDOH should be included in the package, such as H.R. 2503, the "Social Determinants Accelerator Act of 2021," and S. 509, the "Leveraging Integrated Networks in Communities (LINC) to Address Social Needs Act."

- We support building upon the initial investment in the Centers for Disease Control and Prevention's National Center for Chronic Disease Prevention and Health Promotion for its SDOH program to ensure that public health departments, academic institutions, and nonprofit organizations are properly supported to address the SDOH in their communities.
- The AMA also supports S. 509, the "Leveraging Integrated Networks in Communities (LINC) to Address Social Needs Act." This important, bipartisan legislation provides critical network infrastructure support allowing for enhanced communication capabilities among physicians, social services, and community resources to help patients overcome longstanding challenges associated with SDOH.

³ https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-7-Letter-to-House-re-Healthcare-Workforce-Resilence-Act-(1).pdf.

⁴ Much of our advocacy work related to H-1B visa holders has been with the Administration. On March 31, 2021, the AMA sent the U.S. Department of Homeland Security a <u>letter</u> identifying several regulations relating to immigration that we urged the Biden Administration to review and revoke, modify, or supersede.

Combating Maternal Mortality

The AMA is continuing its commitment to tackling the issues surrounding maternal mortality and morbidity, which disproportionately affects Black women and Native American/Alaska Native women. We understand that there are a multitude of considerations necessary to address this crisis, including, but not limited to:

- Lack of insurance or inadequate coverage prior to, during and after pregnancy.
- Closures of maternity units in many rural and urban communities.
- A lack of inter-professional teams trained in best practices.

There are concrete actions that should be taken to reduce and prevent rising rates of maternal mortality and serious or near-fatal maternal morbidity in the United States.

We urge Congress to:

- Permanently expand Medicaid and Children's Health Insurance Program (CHIP) coverage to 12 months postpartum.⁵
- Increase support for maternal mortality review committees.
- Implement equitable standardized data collection methods.
- Expand access to medical and mental health care and social services for postpartum women.
- Continue to develop a health care workforce that is diverse in background and experience.
- Address shortcomings in our institutions.
- Adopt standards to ensure respectful, safe, and quality care before, during and after delivery.

Many of these key policy priorities are included in H.R. 3407/S. 411, the "Momma's Act," bipartisan legislation strongly supported by the AMA. Of note, the AMA recently submitted a Statement for the Record to the House Committee on Oversight and Reform as part of the hearing entitled, "Birthing While Black: Examining America's Black Maternal Health Crisis." The AMA is committed to working with stakeholders to support efforts to reduce and prevent rising rates of maternal mortality and serious or near-fatal maternal morbidity, and specifically to address health inequities and SDOH.⁶

⁵ Note: The AMA supports, as recommended by Medicaid and CHIP Payment and Access Commission (MACPAC), an enhanced 100 percent federal matching rate for services provided during the extended postpartum coverage period. However, we are willing to support other impactful federal medical assistance percentage (FMAP) increases. Additionally, a mandatory Maintenance of Effort (MOE) is very important to ensure that coverage is expanded, and that eligibility is not changed to "cover the cost" of the mandatory extension. The AMA believes that if an FMAP bump and a Medicaid MOE requirement, both crucial elements, are left out of any proposal, then there would be no way to ensure that states maintain eligibility levels for all existing adult Medicaid beneficiaries, that other important optional services are not cut, that coverage is extended to additional pregnant and postpartum women, and that physician reimbursement levels for services provided to Medicaid beneficiaries are not reduced.

⁶ https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-5-6-Statement-of-the-Record_House-Oversight-Hearing_Maternal-Mortality.pdf.

Medicaid Assistance for Eligible Incarcerated Individuals

The AMA has voiced its support for the Medicaid Reentry Act.^{7, 8} This important bill would provide states with the flexibility to allow Medicaid payment for medical services furnished to an incarcerated individual during the 30-day period preceding the individual's release. Such coverage is critical to help start treatment for individuals with substance use disorders (SUDs) before they are released back to civilian life and will help to save lives from opioid and other drug overdose deaths once they are released. It is widely acknowledged that the incarcerated population has a higher rate of chronic diseases, mental health conditions, substance use disorders, and infectious diseases than the general population. Moreover, research demonstrates that individuals who are released back into the community post-incarceration are approximately eight times more likely to die of an opioid overdose in the first two weeks after being released compared to other times. The AMA believes that by allowing Medicaid assistance for eligible incarcerated individuals up to 30 days prior to their release, the Medicaid Reentry Act would help to provide for critically needed health care services, care coordination activities, and linkages to care for such individuals. This, in turn, could help establish coverage effective upon release, assist with transition to care in the community, help reduce recidivism, and help save lives.

Lower Prescription Drug Prices

Medicare Negotiation of Prescription Drug Prices

The AMA supports efforts to eliminate prohibitions on the negotiation of prescription drug prices within the Medicare program. However, it is critical that efforts to allow Medicare to negotiate the prices paid for prescription drugs also seek to maintain access to all necessary treatments for Medicare patients. Policies that allow for Medicare prescription drug price negotiation must ensure that they are not accompanied by overly restrictive drug formularies.

Additionally, the AMA believes that any proposal should include safeguards to ensure that if international index pricing strategies are used, they are utilized as a part of drug price negotiations in a way that upholds market-based principles and preserves patient access to necessary medications. Further, the burden of negotiation and index pricing must be borne by the Medicare program and cannot be placed on physicians, as was proposed by the International Pricing Index model policies created by the previous Administration.

Drug Price Arbitration/Value-Based Drug Pricing

In addition to supporting Medicare negotiation of prescription drug pricing, AMA policy supports the use of arbitration-like efforts to determine appropriate prices for prescription drugs. AMA policy suggests that where prescription drugs have insufficient competition, have high list prices, or have experienced

⁷ https://searchlf.amaassn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-7-16-Letter-to-Tonko-re-HR-955-Medicaid-Reentry-Act.pdf.

^{8 &}lt;a href="https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-7-16-Letter-to-Braun-and-Baldwin-re-S-285-Medicaid-Reentry-Act.pdf">https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-7-16-Letter-to-Braun-and-Baldwin-re-S-285-Medicaid-Reentry-Act.pdf.

unjustifiable price increases, use of an arbitration process to determine an appropriate drug price would be appropriate. Arbitration processes should be overseen by objective, independent entities and should take into account a number of factors to determine the true value-based price of a prescription drug product.

Drug Price Transparency

The AMA strongly supports efforts to increase transparency in all aspects of the drug pricing process, including information at the manufacturer, pharmacy benefit manager, and health plan level. Transparency into contractual purchase and rebate agreements involving pharmacy benefit managers is especially important, given the significant impact on drug list prices and out-of-pocket drug costs to patients, as well as the traditional opacity of these types of arrangements. Transparency is also critical in instances of drug price increases, especially those well outside the bounds of inflationary increases in price. Without transparency into the pricing and contracting of prescription drugs, making good policy to keep them affordable is exceptionally difficult.

Transparency is also important at the point of care to help physicians and patients make treatment decisions that consider not only the patient's clinical considerations, but financial considerations as well. Easy to access transparent information about a patient's pharmacy benefits and the out-of-pocket costs of prescription drugs under those benefits is a critical tool to help physicians and patients best manage prescription drug costs.

Inflationary Caps on Drug Prices

The AMA also supports measures to address increases in prescription drug prices that exceed the rate of inflation, including legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation (which has since become law). In addition, we support drug price transparency legislation that would require pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase. We also support policies that would prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.

Cap on Patient Out-of-Pocket Expenses

The AMA has long supported efforts to cap patient out-of-pocket prescription drug expenses. As drug prices continue to rise, in some cases to exorbitant levels, patients are increasingly asked to bear the burden of out-of-control drug list prices. As the price of new, branded therapies continue to rise, more and more prescription drug products are being shifted to the "specialty" tiers of health plans' drug formularies, which frequently require significant patient cost-sharing—sometimes up to 40 percent of the list price of the drug. With new, branded therapeutics frequently coming to market with list prices of at least \$50,000 (and sometimes well over \$100,000), few patients can reasonably afford the cost-sharing required. Therefore, the AMA strongly supports efforts to ensure patient out-of-pocket expenses are capped.

Ban on Pay-for-Delay Agreements and Patent Evergreening

AMA policy strongly supports efforts to permanently ban pay-for-delay agreements between brand and generic drug manufacturers. Pay-for-delay arrangements have long been detrimental to the availability of affordable generic medications for American patients. Patent evergreening—when pharmaceutical manufacturers make slight changes to the formulation of their product to increase its patent exclusivity period—likewise has the same impact. Pharmaceutical manufacturers must not be allowed to engage in patent gaming in ways specifically targeted at extending exclusivities or limiting competition in the market.

Limit Use of Drug Utilization Management Tools by Payers

In this era of rapidly rising drug prices, payers have turned to widespread use of draconian utilization management tools to help manage their prescription drug expenditures. While implementation of prior authorization programs and step therapy policies may ultimately reduce payor drug expenditures, it has little meaningful impact on the bigger issue of prices and can have severe negative implications to patients. Overly aggressive drug utilization management programs can result in patients losing access to necessary therapeutics or having lengthy delays in accessing critical treatments.

Improving our Cybersecurity Infrastructure

Cybersecurity is not just a technical issue; it is a patient safety issue. <u>AMA research</u> has revealed that 83 percent of physicians work in a practice that has experienced some kind of cyberattack. Unfortunately, practices are learning that cyberattacks not only threaten the privacy and security of patients' health and financial information, but also patient access to care. In response, the AMA has developed numerous resources to help improve physician awareness of cybersecurity risks and provide advice on protecting physician practices and patient health records and other data from cyberattacks. We would support additional funding to improve the cybersecurity infrastructure, including resources to provide physician practices, hospitals, and other health care entities sufficient to protect the security of the patients they serve.

In conclusion, we strongly urge Congress to address Medicare program sustainability, continued access to Telehealth services, and streamlining prior authorization, as well as the other needs identified in this letter. The AMA appreciates the opportunity to provide these comments and looks forward to working with you as you develop legislation to implement positive changes to our nation's health care system infrastructure.

Sincerely,

Moolin

James L. Madara, MD

cc: U.S. Senate Committee on Finance

U.S. Senate Committee on Health, Education, Labor & Pensions

U.S. Senate Committee on Homeland Security and Governmental Affairs

U.S. House Committee on Energy & Commerce

U.S. House Committee on Ways and Means

U.S. House Committee on Education and Labor

U.S. House Committee on Homeland Security