AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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

December 21, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Regulatory Relief to Support Economic Recovery; Request for Information

Dear Secretary Azar:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to offer our comments on the Regulatory Relief to Support Economic Recovery; Request for Information (RFI). The AMA appreciates the regulatory changes that have been made by the U.S. Department of Health and Human Services (HHS) in response to the COVID–19 public health emergency (PHE) and the pandemic. There are several temporary actions we would like to be made permanent. However, given the very tight timeline for submission of public comments, we have identified a select list of key actions that we believe should be addressed, and we offer detailed comments below. Should HHS need any additional information regarding other actions proposed in the RFI, the AMA is happy to discuss further.

42 CFR Part 2 Statement (RFI Action #1)

As the Substance Abuse and Mental Health Services Administration (SAMHSA) COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance[1] document itself notes, Part 2 has always included an exception for a bona fide medical emergency. The guidance issued by SAMHSA was helpful in that it served as an additional way to educate clinicians in Part 2 facilities about that exception, but it was not necessary for those who already understood the rule and it was not (as some have suggested) "new guidance" from SAMHSA. Instead, the information was repackaged and disseminated within the context of COVID-19. Accordingly, even if this guidance is discontinued/removed from SAMHSA's website after the PHE ends, its underlying message will still apply to every other bona fide medical emergency. **The AMA asks that SAMHSA continue its policy—in effect before the PHE—of allowing clinicians to determine when a bona fide emergency exists.**

Take Home Medication (RFI Action #2)

During the COVID-19 PHE, SAMHSA provided a blanket exception for opioid treatment programs (OTPs) to permit take-home medication for patients receiving medication-assisted treatment (MAT). These changes include giving states discretion to allow OTPs to provide a 28-day take-home supply of

[1] https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf.

methadone to stable patients and a 14-day supply to those who are less stable but still able to safely handle take-home doses, subject to the treating physician's clinical determination.

Early evaluations[2] suggest that the policies have helped to maintain or even expand access to treatment without significant negative effects. For example, Rhode Island and Massachusetts have determined that increased take-home dosing has not resulted in higher rates of adverse events such as diversion and opioid-related deaths.[3,4] Early reviews[5] suggest that the easing of access restrictions on MAT and greater use of telehealth have helped mitigate some of the impact of COVID-19 on treatment for substance use disorder (SUD). These telehealth innovations have helped support many patients with a SUD.[6] **The AMA, therefore, recommends that these expanded-access provisions be extended permanently, or for at least the duration of the national opioid epidemic PHE.**

Notification of Enforcement Discretion for Telehealth Remote Communications (RFI Action #4)

To help clinicians quickly adopt telehealth, the Office for Civil Rights (OCR) announced early in the pandemic that it would use discretion in enforcing Health Insurance Portability and Accountability Act (HIPAA) violations for physicians and hospitals who, in good faith, utilized telemedicine platforms and applications to connect with their patients. The AMA supported this policy as it helped clinicians quickly adopt telemedicine without needing to first implement contracts and security reviews that are often complicated and time-consuming. However, while HIPAA compliance may seem onerous and burdensome, it is a necessary ingredient to the long-term, continued use and success of telemedicine technology. HIPAA's requirements are intended to ensure that both clinicians and their business associates are accountable for the privacy and security of patient information, thereby fortifying the trust that is central to the patient-physician relationship. Accordingly, **when the PHE declaration ends, the AMA urges OCR to not continue its enforcement discretion policy, but rather establish a glide path to compliance with HIPAA obligations.** For example, if the PHE ends on September 30, rather than requiring clinicians to be fully in compliance on October 1, OCR should instead provide the opportunity for clinicians to begin taking steps toward compliance (e.g., engage their vendors in discussions about business associate agreements and initiate or implement their security risk analysis of the new telehealth platform). The agency should also call on telehealth vendors to assist clinicians with coming into compliance.

Additionally, the agency should ensure that clinicians are held harmless for actions taken in good faith during the PHE and consider the pandemic's influence on actions taken during the PHE. **Any subsequent OCR investigations, settlement, and enforcement activities should not include violations related to action or inaction by clinicians related to activities that OCR was not enforcing during the PHE.** For example, if a practice is investigated in future months or years for failure to enter into a business associate agreement (BAA) with a vendor, its failure to enter into a BAA with its telehealth vendor during the PHE (as permitted by OCR's notice of enforcement discretion) should not be held against the physician or included in any settlement/enforcement activity. Similarly, physicians should not be held accountable for relying on inaccurate statements made by their vendors during the PHE. For example, the

[2] http://www.aatod.org/wp-content/uploads/2020/10/Full-Report.pdf.
[3] www.nga.org/wp-content/uploads/2020/07/NGA-Issue-Brief-SUD-Treatment-Access-COVID-19.pdf.
[4] www.bostonglobe.com/2020/05/24/opinion/post-coronavirus-pandemic-keep-methadone-easy-obtain/.
[5] https://www.aaap.org/wp-content/uploads/2020/10/COVID-29-Survey-Results-First-Glance_EW-10.15.pdf.
[6] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2767300.

Federal Trade Commission (FTC) recently settled[7] with Zoom Video Communications after the company deceived users about the level of security for its meeting platform.[8] As the FTC notes, "Zoom's misleading claims gave users a false sense of security…especially for those who used the company's platform to discuss sensitive topics such as health and financial information. In numerous blog posts, Zoom specifically touted its level of encryption as a reason for customers and potential customers to use Zoom's videoconferencing services." Physicians should not be held accountable by OCR now or in the future for reasonably relying on a company's stated claims of security and privacy protections during the PHE. **The AMA supports clinicians' efforts to come into compliance with HIPAA and be held harmless for actions during PHE.**

Audio-only Telephone E/M, Counseling, and Educational services (RFI Action #189)

Pursuant to authority granted under the CARES Act, the Centers for Medicare & Medicaid Services (CMS) waived the requirements of section 1834(m)(1) of the Act and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology for certain services. This has allowed the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services. The **AMA believes that audio-only services are an important part of a fully integrated care plan and that physicians should permanently be able to deliver E/M (evaluation and management) services by telephone to patients who need a telecommunications-based service in the home but who do not have access to a video connection or cannot successfully use one.** Without access to an audio-only option, limitations in internet and/or technology access as well as lack of experience with its use will increase inequities in access to medical care and widen disparities in health outcomes.

Telehealth (RFI Action #281)

During the COVID-19 PHE, pursuant to authority granted in the CARES Act, CMS has waived the geographic and site of service originating site restrictions for Medicare telehealth services, allowing Medicare patients across the country to receive care from their homes. Telehealth services have been critical during the PHE to ensure access to medical care while allowing for social distancing to avoid exposure and transmission of COVID-19, but the ability to use these services widely has also demonstrated a number of promising use cases, particularly for patients in need of chronic care management. Telehealth provides ready access to care for patients with mobility or functional impairments or other problems that make travel difficult and facilitate care for patients who do not live near their physician or have unreliable access to transportation. It allows physicians to see patients with sporadic symptoms at the time these symptoms occur and improves care for conditions where seeing the patient's living environment can inform treatment plans. Telehealth also facilitates team-based care by allowing other physicians, caregivers, and family members to join patient visits from their own location.

Consequently, CMS should continue to allow physicians to be paid for delivering face-to-face E/M services using telecommunications technology after the PHE to the extent allowable by law. Moreover, where face-to-face services delivered using telecommunications are equivalent to a

[7] https://www.ftc.gov/news-events/press-releases/2020/11/ftc-requires-zoom-enhance-its-security-practices-part-settlement.

[8] https://www.ftc.gov/news-events/press-releases/2020/11/ftc-requires-zoom-enhance-its-security-practices-part-settlement.

service delivered in person, the payment amount should continue to be equivalent to the payment for a standard office visit; otherwise the physician practice would lose money by delivering services through telehealth. Prior to the new policies put in place for COVID-19, telehealth services were paid about 30 percent less than comparable in-person services. We have heard from many physician practices that this payment differential does not make medical practices' provision of telehealth services in addition to in-person services financially sustainable. Indeed, the practice's costs may increase due to the need to install and maintain the necessary equipment and software to deliver secure video communications. CMS has recognized the need to pay the same amounts for telecommunication-based services and in-person services during the pandemic, and this should continue after the national emergency ends.

Notification of Enforcement Discretion for Community-Based Testing Sites (RFI Action #6)

The AMA understands that certain emergency situations warrant flexibility, and we appreciate OCR's recognition that sufficient testing is of the utmost importance to managing the COVID-19 pandemic. However, HIPAA was enacted to ensure important protections, and therefore any type of medical testing site should strive to maintain privacy and security of information. **The AMA believes that, in general, this type of enforcement discretion should only occur on an ad hoc basis.**

Requirements for Opioid Treatment Programs (RFI Action #121)

In light of the PHE for the COVID–19 pandemic, during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio-video communication technology may not be available to all beneficiaries, CMS revised 42 CFR § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met. The AMA and the physician community have embraced these flexibilities and deeply appreciate their rapid implementation by the agency, especially the increased flexibility to prescribe controlled substances, including medications to treat opioid use disorder (MOUD), based on audio-video and audio-only patient visits.

CMS correctly points out that self-isolation and social distancing have adversely affected many patients' ability to see a mental health professional in-person. Access to SUD care in jails and prisons remains a particular concern.[9] In addition, the challenges experienced by some OTPs to remain open and fully staffed during the PHE have demonstrated the benefits of using both audio-video and audio-only telephonic counseling to help patients initiate and continue treatment.[10] The AMA further notes that not all patients have access to audio-video capabilities due to income, lack of access to technology, and other reasons,[11] making increased access to telehealth innovations such as those discussed above even more important. Given that the nation continues to face an increasingly complicated and deadly drug overdose epidemic, there is an urgent need to ensure that patients with pain and patients with opioid use disorder receive evidence-based care, and this need will not cease with the end of the COVID-19 pandemic. **The AMA strongly recommends, therefore, that all the flexibilities that have been put in place by CMS during the COVID-19 PHE be made permanent, or at least kept in place until both the COVID-19 and the opioid public health emergencies come to an end.**

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[9] https://www.journalofsubstanceabusetreatment.com/article/S0740-5472(20)30404-9/fulltext.
[10] www.aaap.org/wp-content/uploads/2020/10/COVID-29-Survey-Results-First-Glance_EW-10.15.pdf.
[11] https://www.acpjournals.org/doi/10.7326/M20-1212.

Physician Self-Referral Regulations (RFI Action #187)

The Temporary Stark Law Blanket Waivers are explicitly linked to the PHE, and therefore when the PHE expires the waivers would no longer have any effect. At that point, any financial relationships must come back into line with existing Stark Law exceptions and the Anti-kickback Statute (AKS) safe harbors. CMS has stated that any revisions and termination of the Temporary Stark Law Blanket Waivers will be on a prospective basis.[12] However, the Stark Law and AKS rules were recently updated to create additional flexibility, particularly with respect to value-based care arrangements.[13] As a result, physicians may be able to modify arrangements that were permissible under a PHE waiver so thatthey may be protected by new Stark Law exceptions and AKS safe harbors. **The AMA urges HHS to make the temporary Stark Law Blanket Waivers related to the PHE permanent. Additionally, the AMA asks that CMS provide explanatory guidance to physicians, citing specific examples of how new arrangements created in accordance with the temporary waivers will remain protected under the changes to the Stark Law final rules.** However, should HHS choose an alternate path, the AMA recommends that the temporary Stark Law Blanket Waivers be extended until the end of 2021, at a minimum, to provide physicians with additional time to modify the agreements as needed so they are protected under the new Stark exceptions and AKS safe harbors recently published in the Federal Register.

Medicare Accelerated and Advance Payment Program (RFI Action #220)

The AMA appreciates CMS' expansion of the Accelerated and Advance Payment Program in response to the COVID-19 PHE, which was a lifeline in the early part of the pandemic, helping physician practices remain open to continue providing care to patients in-person and via telehealth. **The AMA strongly supports a permanent expansion of and improved repayment terms for the program.** CMS also made several important sub-regulatory improvements to the program, including streamlining the application form. We urge CMS to make these changes permanent to ensure relief is available to physician practices in the event of a future public health emergency or natural disaster.

Specifically, the AMA urges CMS to make permanent the following improvements to the program as authorized under the Continuing Appropriations Act, 2021 and Other Extensions Act and applicable to all advance payments made during the COVID-19 PHE:

- Extending the grace period prior to recoupment from 120 days to 12 months;
- Extending the repayment timeline from three months to 17 months;
- Reducing the claim offsets from 100 percent to 25 percent for the first 11 months of repayment and 50 percent in the next six months of repayment; and
- Capping the interest rate on remaining balances at four percent.

Beyond the PHE, **CMS should preserve the program expansion and use every administrative lever to maintain the flexible repayment terms outlined above.** At a minimum, if CMS believes it must revert to a 120-day grace period, we strongly urge the agency to set 120 days as the minimum, not the maximum, length of time before recoupment begins. While a 120-day grace period may be reasonable in

[12] https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf.
[13] Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, final rules, 85 Federal Register 77492 – 77682, December 2, 2020. https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf.

the event of certain natural disasters, such as hurricanes, it is unrealistic during a public health emergency or extended natural disasters, such as wildfires. We also strongly urge CMS to permanently cap the interest rate on advance payment balances at four percent. If a physician practice is unable to provide care to patients, bill Medicare, and repay the loan due to the significant disruption caused by an emergency that is outside the control of the practice, applying an excessive interest rate to any outstanding balance will only compound the hardship and postpone the financial recovery of that physician practice.

Finally, **we reiterate our recommendation that CMS reinstate the loan program to allow physician practices who are facing the worst of the pandemic in their communities to apply for capital to prevent them from closing their doors to selling their practices to hospitals or health care systems, reducing access to care and increasing costs to patient and taxpayers.** It is especially crucial that CMS authorize similar advance payments or retainer payments to allow state Medicaid programs to provide critically needed funds to Medicaid physicians, clinicians, and other providers and suppliers. We are concerned that without ongoing financial assistance, the safety net that these Medicaid practices provide may not survive and our nation will lose a vital and critical part of our health care infrastructure.

GME Affiliation Agreements (RFI Action # 188)

Due to the PHE, CMS is allowing hospitals to submit new and/or amended Medicare GME affiliation agreements to CMS and the MACs by October 1, 2020. The AMA applauds CMS for providing hospitals with additional time to determine affiliation agreements during the PHE. However, the AMA would like to ensure that during this time hospitals communicate, in a timely manner, with current and prospective medical students, residents, and fellows about the extended deadline and how this extended deadline will affect affiliations among health care organizations, health care delivery, and medical education and training opportunities at their respective institutions. **As such, the AMA supports allowing for extensions of affiliation agreements during the PHE as long as hospitals provide comprehensive and timely communications.**

Responsibilities of Physicians in Critical Access Hospitals (CAHs) (RFI Action # 192)

CMS is waiving the requirement for CAHs that physicians be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH. However, physicians must be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral." The AMA supports physician-led teams and believes every health care professional, including nurse practitioners and physician assistants, should use their specific strengths to work together for the benefit of the patient. Waiving the requirement significantly weakens physician-led care and puts CMS at odds with state scope of practice laws.

CMS acknowledges three levels of supervision: general, direct, and personal. General supervision requires the procedure to be furnished under the physician's overall direction and control. Direct supervision varies depending on location and the service being provided, but generally requires that a physician is present in the location the service is being performed and is available for immediate assistance and direction. Finally, personal supervision entails the physician being in the room during the procedure. Though the AMA understands that greater flexibility is needed during the PHE, there are still numerous complex procedures and services that non-physician practitioners are not trained to perform, and that require personal supervision and/or the physical presence of a physician. All patients, including those in rural areas, deserve access to a physician. As such, the AMA believes that at a minimum, a physician must be on site and that, for certain procedures, telecommunication with a physician is simply

not enough. **Therefore, these waivers should be curtailed and should not extend beyond the end of the PHE.**

Anesthesia Services (RFI Action #193)

These waivers allow certified registered nurse anesthetists (CRNAs) to function to the fullest extent of their licensure so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. A CRNA's education and training spans four to six years after high school and includes an average of about 2,000 hours of clinical training. An MD or DO anesthesiologist has education and training that spans at least 12 to 14 years after high school and includes 12,000 to 16,000 hours of clinical training. CRNAs are trained to work within a physician-led care team, under physician supervision. Moreover, research has shown that removing the physician supervision requirement has not resulted in increased access to anesthesia care, as CRNAs and anesthesiologists tend to practice in the same areas of the state irrespective of state scope of practice laws. Removing physician supervision of anesthesia services lowers the standard of care and jeopardizes patient safety. **The AMA therefore strongly opposes this waiver, even during the PHE, and believes that it should be rescinded immediately.**

Physician Supervision of NPs in Rural Health Clinics RHCs and Federally Qualified Health Centers FQHCs. (RFI Action #194)

CMS granted a waiver that modifies the requirement that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners and only to the extent permitted by state law. Physicians are specifically trained to oversee and manage a care team. Moreover, it is important that patients are provided with the best coordinated care, meaning that it is vital that there is a physician providing medical direction and supervision. **The AMA therefore strongly opposes this waiver, even during the PHE, and believes that it should be rescinded immediately.**

Physician Visits (RFI Action #200)

CMS granted a waiver that modifies 42 CFR § 483.30(c)(3) by permitting physicians to delegate any required physician visit to a nurse practitioner (NPs), physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the state and performing within the state's scope of practice laws. The AMA understands that some physicians are currently overwhelmed due to COVID-19 therefore need additional flexibility. Moreover, this waiver requires that the NP, physician assistant, or clinical nurse specialist is working as part of a physician-led team in collaboration with and at the direction of the physician and within the state's scope of practice laws. **The AMA therefore supports this provision but only for the duration of the PHE.**

Practitioner Locations (RFI Action #201)

CMS granted a temporary waiver that removed the requirements that out-of-state physicians and other health care professionals be licensed in the state where they are providing services when they are licensed in another state. CMS waived the physician or non-physician practitioner licensing requirements when the following four conditions were met: (1) Must be enrolled as such in the Medicare program; (2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; (3) is furnishing services—whether in person or via telehealth—in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, (4) is not affirmatively

excluded from practice in the state or any other state that is part of the emergency area. The AMA understands that during the PHE additional flexibilities are needed. However, to protect patients, physicians and NPPs must be licensed or authorized to practice in the state where the patient is receiving care. This ensures state practice acts, informed consent, and scope of practice laws apply and that the state has jurisdiction and oversight over the health care professional. Alternatives raise serious enforcement issues, including ambiguity about who and how physicians and other health care professionals will be held accountable. The AMA also recognizes that scope of practice laws vary by state for non-physicians. As such, these waivers could allow NPPs to provide services or perform procedures for which they are not licensed. **The AMA therefore does not support this provision to be extended beyond the end of the PHE.**

Prior Authorization and Other Utilization Management Requirements

During the PHE, CMS took a number of actions to reduce prior authorization (PA) and other utilization management (UM) burdens for both patients and physicians, to include temporary suspension of Medicare FFS PA requirements and demonstration projects and extension of existing PA approvals. The AMA appreciates this flexibility. In addition, CMS encouraged Medicare Advantage (MA) and Part D plans to similarly relax their UM requirements. However, as detailed in the AMA's COVID-19 PA policy change tracker,[14] PA policy adjustments have varied widely across MA, Part D, and commercial plans, and offered inconsistent relief from care barriers and administrative burdens. Moreover, many plans reinstituted regular PA and UM protocols after only a few months of relaxation—meaning that patients and physicians currently face business-as-usual UM requirements during the current dire state of the pandemic. In April, the AMA urged all commercial plans[15] to temporarily suspend all PA requirements during the COVID-19 pandemic for medical services and prescription drugs to prevent confusion due to highly variable PA policy changes and ensure that these burden reduction measures continue throughout the PHE.

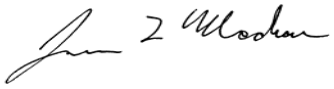
The 2019 AMA Prior Authorization Physician Survey[16] describes PA's significant negative impacts on both timely, quality patient care and practice efficiency. Based on these data, and the many powerful stories captured on our grassroots FixPriorAuth website,[17] **the AMA supports continued suspension of PA requirements in the Medicare FFS program at the end of the PHE to protect Medicare beneficiaries from care delays and align with the objectives of the Office of Burden Reduction and Health Informatics. Furthermore, we urge CMS to require MA and Part D plans to implement programs that will reduce the overall volume of PAs both now and after the PHE.** In early 2018—nearly three years ago—national health care professional organizations and insurer trade associations released the Consensus Statement on Improving the Prior Authorization Process,[18] in which health plans agreed to decrease PA volume through selective application of requirements and regular review and adjustment of PA lists, as well as to take action to protect continuity of patient care. The inconsistent relaxation of PA policies in MA and Part D plans during an unprecedented national public

[14] https://www.ama-assn.org/system/files/2020-12/prior-auth-policy-covid-19.pdf.
[15] https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-4-20-AHIP-COVID-admin-burden.pdf.
[16] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf.
[17] https://fixpriorauth.org/.
[18] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

health crisis illustrates the clear need for regulatory action that will mandate key PA and UM reforms and ensure care access for America's vulnerable senior population.

The AMA appreciates and shares the Administration's continued focus on reducing burdens for physicians across the U.S. If you have any questions, please feel free to contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD