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Advancing Health in America

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Michael Chernew, Ph.D.
Chairman
Medicare Payment Advisory Commission
425 I Street, NW, Suite 701
Washington, D.C. 20001

Dear Dr. Chernew:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to share our comments as Medicare Payment Advisory Commission (MedPAC) begins its 2024-2025 cycle.

As the commission continues to consider topics related to the 340B Drug Pricing Program, inpatient rehabilitation facility (IRF) payments, the physician fee schedule (PFS) and telehealth in the new cycle, we urge MedPAC to:

- **Carefully consider the negative consequences for beneficiaries, providers and communities of any future efforts to cut Medicare payments to 340B hospitals.**
- **Reconsider its pursuit of an IRF-skilled-nursing facility (SNF) site-neutral payment policy and discourage it from recommending potential changes to the IRF payment system.**
- **Directionally support updates to physician reimbursement that more appropriately account for inflation.**
- **Recommend repealing the in-person visit requirements for tele-behavioral health services and to not pursue policy options that would remove telehealth “incident to” options, as these policies limit patient access.**

Our detailed comments on these issues follow.

340B DRUG PRICING PROGRAM

We have serious concerns about the direction that MedPAC has taken with regard to its analysis of the 340B program. Specifically, at its April 2024 meeting, MedPAC shared results of an analysis comparing Medicare fee-for-service payments for covered outpatient drugs purchased under the 340B program to 340B ceiling prices. While we appreciate that MedPAC did not offer any recommendations based on this analysis at this time, we think it is important for it to consider the facts we outline below should it continue this work in the 2024 – 2025 cycle.

For more than 30 years, the 340B Drug Pricing Program has provided financial help to hospitals (and other providers) serving highly marginalized communities to manage rising prescription drug costs.[1] The program works by permitting certain hospitals to purchase covered outpatient drugs at a discounted price, generate savings, and use those savings to stretch limited federal resources to address the unique health care needs of their patients and communities. For example, hospitals often use their 340B savings to establish behavioral health clinics and implement medication management and community health programs, as well as offer free or discounted medications.[2] These important patient benefits are put at risk when hospitals' 340B savings are cut.

The 340B program statute intentionally provides covered entities with additional funds by reducing the acquisition price on 340B drugs without changing hospitals' reimbursement under the Medicare program. It is precisely this delta between the hospital's acquisition price for the drug and the reimbursement received that allows 340B hospitals to meet the intent of the program and expand access to care for more patients. **Therefore, MedPAC's finding that Medicare payments exceeded 340B ceiling prices is consistent with the purpose and design of the 340B program.** If Medicare payments for 340B drugs were reduced, it would diminish the funding available to 340B hospitals to fulfill Congress' intent to allow these hospitals to use savings to expand the services they can provide. Thus, any Medicare cuts for 340B drugs undermine the congressional intent of the program by reducing the 340B savings available for covered entities to maintain, improve and expand access to health care services for patients.

We also encourage MedPAC's to analyze how 340B ceiling prices are set and the factors that influence those prices. 340B ceiling prices are based on two components: the average manufacturer price of the drug and a unit rebate amount. For brand-name drugs, which account for a majority of 340B volume, the unit rebate amount is statutorily set at 23.1%. However, the unit rebate amount is subject to an inflationary penalty where it can exceed 23.1% if a drug company decides to increase the price of their drug faster than the rate of general inflation. Drug companies routinely increase their prices faster and higher than the rate of inflation. A study by the Assistant Secretary for Planning and Evaluation found that from January 2022 through January 2023, approximately 2,000 drugs experienced price

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[1] https://www.healthaffairs.org/content/forefront/30-years-340b-preserving-health-care-safety-net
[2] https://www.aha.org/340b-case-studies

increases greater than inflation, with an average price increase of 15.2%.[3] As a result, for many 340B drugs, the ceiling price is well *below* what is statutorily required, which leads to a greater difference between the ceiling price and the Medicare payment rate. Put another way, any gaps between ceiling prices and Medicare payment rates are a direct result of decisions by drug companies to increase drug prices — not hospitals. As such, already-struggling 340B hospitals should not suffer rate cuts that mainly benefit drug companies. In fact, MedPAC itself has calculated that hospitals' Medicare margins are nearly *negative* 12%.[4] Payment cuts for 340B drugs would make these margins worse, further jeopardizing hospitals' ability to furnish programs and services that are supported by 340B savings.

Given the important role that the 340B program plays in allowing hospitals to expand access to care for the patients and communities they serve, we urge MedPAC to carefully consider the negative consequences for patients and providers in any future efforts to cut Medicare payments to 340B hospitals.

IRF PAYMENTS

MedPAC has considered potential approaches to lowering Medicare payments for select conditions in IRFs but we **continue to discourage it from recommending such changes.** Specifically, at the April 2024 meeting, the commissioners specifically considered whether conditions that fall outside the 13 that must account for 60% of IRF beneficiaries (the "60% rule") should be paid at a lower rate than the one currently provided under the IRF prospective payment system (PPS). As the AHA detailed in response to the first session held on this topic (see AHA's October 2023 letter), such an approach not only would be far less precise and patient-centric than the current IRF PPS but also would have the potential to curtail access to needed rehabilitation services. **To that end, the AHA is pleased that staff and commissioners seemed to acknowledge even more shortcomings of this approach.**

In AHA's October 2023 letter, we explained why use of the 60% rule for payment determinations is misplaced. This letter will not recount those points in their entirety, but we would reiterate that the 60% rule was never intended as and has never been used as a tool to determine coverage or payment for IRF services. Instead, this rule has served *solely* as a tool to distinguish IRFs from other hospitals at the very highest level. Therefore, applying this broad classification tool to patient-specific determinations regarding payment or coverage is misguided. Further, and as MedPAC acknowledged, Medicare coverage regulations require that 100% of all Medicare beneficiaries treated in IRFs meet specific, detailed medical necessity requirements.[5] As such, we urge the commission's to refrain from using terms "compliant" and "noncompliant" to describe IRF patient groups that fall into

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[3] https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs
[4] https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch3_MedPAC_Report_To_Congress_SEC.pdf
[5] These medical necessity requirements include requiring at least 15 hours of therapy per week, a multiple disciplinary approach to care, close physician supervision, rehabilitation nursing and several others.

and out of the 60% rule, respectively, despite the explanations that MedPAC staff provided regarding these terms.

To this point, the AHA appreciated discussion from MedPAC commissioners and staff during this session acknowledging the difficulty involved in determining the appropriateness of IRF admissions for individual patients. Indeed, medical necessity determinations do not rely on the primary condition of the patient but instead involve a thorough assessment of the patient's medical and functional status and prognosis.[6] Therefore, the AHA endorses the view that this decision is a judgement call best made by the expert clinicians treating the patient. Thus, while it may appear based on the data alone that there is significant overlap in patient types treated in IRF and SNFs, experienced clinicians have utilized their expertise to screen patients and distinguish those that are best suited for IRFs based on characteristics that may not be readily apparent in the data MedPAC has available to them. **Thus, we are concerned MedPAC's premise for leveling payment for supposedly overlapping patient types is misguided, as those placed in IRFs have been properly screened and distinguished from other patients.**

The IRF PPS is a sophisticated payment system that takes numerous factors into account to provide a targeted payment amount. Through the IRF PPS, CMS analyzes the relative resource use of each diagnosis group (referred to as case-mix groups) and assigns a relative weight. Through this mechanism, the agency is already accounting for differences in resource use among patients and adjusts payments accordingly. **However, despite the use of this refined payment system, MedPAC is considering imposing a blunt and imprecise instrument — one that would group a third or more of the current patient population into a single noncompliant category — to summarily reduce payment. It would be both inconsistent with MedPAC's overarching goal of improving payment accuracy, as well as harmful to patients, to modify the current payment system in this way.** The AHA appreciates the need to explore avenues to improve the accuracy of payments but does not believe such a broad instrument is appropriate to do so.

Beyond the use of the 60% rule, the AHA does not believe that attempting to align payments between IRFs and SNFs more generally is a worthwhile endeavor. This is due to the vastly different regulatory environments under which IRFs (hospitals) and SNFs (subacute facilities) operate. The difficulties in aligning payment incentives and other important factors between these and other sites of care became apparent during MedPAC's work on the Unified Post-Acute Care payment system. In addition, and as was noted during the commission's discussion, IRFs provide a vastly more intensive course of treatment than SNFs. Further, Medicare cost sharing, lifetime coverage and several other factors vary greatly between the two types of facilities. Therefore, to the extent MedPAC continues work

[6] The preadmission screening requirement at 42 C.F.R. § 412.622(a)(4)(i) must be conducted by a licensed clinician within 48 hours of admission, include a detailed review of the patient's condition, history, prior and expected level of function, expected level of improvement, expected duration of treatment, evaluation of patient's risk for complications, conditions causing the need for rehabilitation, the detailed therapies needed by the patient, and the discharged expectations for the patient. The rehabilitation physician at the IRF must review and concur with the findings of this screening.

on the IRF PPS, the AHA encourages it to examine payment accuracy within the IRF PPS, rather than attempt to analogize IRFs and SNFs.

When comparing IRFs and SNFs, MedPAC has expressed a reluctance to utilize functional data due to it being provider reported and tied to payment and therefore potentially prone to inaccuracies. The AHA urges MedPAC to reconsider this position. While no data are perfect, the functional data provided, especially on aggregate, should not be considered any more flawed than other Medicare data which require provider submitted information, including information that impacts payment. This includes cost reports, claims and other data on which MedPAC regularly relies, and all of which influences reimbursement for providers. Instead of dismissing this data, we respectfully request that it be considered as one of many points of insight into the experience of patients treated at IRFs.

PHYSICIAN FEE SCHEDULE UPDATES

We appreciate MedPAC's recognition that the current framework for physician payment is inadequate and that it is considering policy approaches to address these issues. The impacts of inflation and rising input costs continue to outpace the reimbursement for services covered by the PFS. There is a widening gap between physician payment and increases in the Medicare Economic Index (MEI), and we have previously commented on the need to right size payment with inflation. As detailed below, we have specific feedback on the three policy approaches MedPAC is considering.

We oppose updating physician practice expenses (PEs) based on the hospital market basket minus productivity, as this approach would add unnecessary complexity by creating two conversion factors (one for practice expenses and another for malpractice and work expenses) and would inappropriately penalize clinicians performing low practice expense services and those operating in facility settings. We directionally support updating physician payments by the MEI but do not think the discussed MEI minus one percentage point update is nearly sufficient to cover the existing shortcomings in physician reimbursement. Finally, we support extending Advanced-Alternative Payment Model (A-APM) incentive payments to support transition to value-based care.

However, we are concerned that MedPAC seems to be framing many of their discussions and approaches on physician payment updates with a goal of reducing site-of-service payment differentials. The AHA strongly opposes site-neutral payments, which reduce access to critical health care services, especially in rural and other underserved areas. Site-neutral policies ignore fundamental differences between hospital outpatient departments (HOPDs) and other outpatient care settings. Hospitals and health systems provide unique benefits to their community like 24/7 standby capacity for emergencies and special service capabilities such as burn, neonatal, psychiatric services, and more. HOPDs also are required to comply with more regulatory and safety codes and care for sicker, more complex patients than other care settings. Expanding site-neutral cuts would endanger the critical role hospitals and health systems play in their communities, including access to care for patients.

Approach 1: Update Physician PEs Based on Hospital Market Basket Minus Productivity.
We oppose MedPAC's approach to increase the PE portion of fee schedule payments by the hospital market basket minus productivity. First, this proposal would exacerbate disparities in reimbursement in certain specialty areas by effectively penalizing clinicians performing low PE services because their payments would be increased at a lower rate than clinicians performing high PE services. It also would penalize clinicians performing services in facility settings such as those in critical care, hospital medicine, emergency medicine and behavioral health. Decreasing reimbursement for certain physicians in order to augment reimbursement for others risks reducing patient access and exacerbating provider shortages.

In addition, this option would add unnecessary complexity by creating separate conversion factors for the PE versus the work and malpractice components of the physician reimbursement equation. Yet, physician work and malpractice insurance are also impacted by inflation that has not been adequately accounted for by payment updates. Indeed, a recent report from AMA found that increases in malpractice insurance premiums are accelerating. In 2018, 13.7% of malpractice premiums increased year-to-year, yet from 2020 through 2022, 30% of premiums increased annually.[7] All three factors contributing to physician reimbursement (practice expense, work and malpractice relative value units (RVUs)) require updates to account for inflation and rising input costs.

We also reiterate our previous concerns regarding site-neutral payments. Both Approach 1 and Approach 2 (listed below) are framed in the context of reducing site of service payment differentials. Proposals that attempt to treat HOPDs the same as independent physician offices and other ambulatory sites of care ignore the very different level of care provided by hospitals and the needs of the patients and communities cared for in that setting. These outpatient departments treat more patients from medically underserved populations who tend to be sicker and more complex to care for than Medicare patients treated in independent physician offices and ambulatory surgical centers. They also are held to more rigorous licensing, accreditation and regulatory requirements.

The cost of care delivered in hospitals and health systems, including HOPDs, is fundamentally different than other sites of care and thus needs to consider the unique benefits that only they provide to their communities. This includes maintaining standby capacity for natural and man-made disasters, public health emergencies, other unexpected traumatic events, and the delivery of 24/7 emergency care to all who come through their doors regardless of ability to pay or insurance status. Since the hospital safety-net and emergency standby roles are funded through the provision of all outpatient services, expanding site-neutral cuts to additional HOPDs and the outpatient services they provide would endanger the critical role that they play in their communities, including access to care for patients, especially the most medically complex**. The AHA strongly opposes further site-neutral payment cuts, which threaten access to care.**

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[7] https://www.ama-assn.org/practice-management/sustainability/medical-liability-premium-hikes-continue-4th-straight-year

Approach 2: Update Payment Rates by MEI Minus One Percentage Point. **While we directionally support updating rates consistent with the MEI, MEI minus 1% is insufficient to cover existing shortcomings in physician reimbursement.** Indeed, we echo the concerns expressed by many commissioners that this could result in a negative compounding effect over time. We encourage MedPAC to pursue annual updates to payment rates that are more in line with inflation and are made outside budget neutrality.

We also are encouraged that MedPAC is evaluating strategies to improve RVU calculations. We suggest that the commission revisit this issue once updated Physician Practice Information Survey (PPIS) data are available. The AMA PPIS provides critical data to support updates to the MEI and Resource Based Relative Value Scale. Indeed, integration of PPIS data was phased into CMS RVU calculations over the course of 2010-2014. Current rate setting is based on AMA PPIS data, supplemental data sources as required by Congress, and in certain circumstances, crosswalks in indirect PE allocation. PPIS surveys are still in the field through June 2024, with data available to CMS in early 2025. We believe it would be premature to discuss strategies to improve RVU calculations without the latest data. Additionally, the agency is still evaluating trends and impact on data from COVID-19.

We also caution that any updates to RVUs would cause a redistribution of payments based on physicians' geography and specialty. The same can be said for efforts to rebase and rescale MEI, as was suggested by the discussion. Historically, the MEI had been based on 2006 data representing only self-employed physicians. In the calendar year (CY) 2023 PFS final rule, CMS rebased and revised the MEI to use publicly available data sources for 2017 input costs that represent all types of physician practice ownership. However, the agency has delayed implementation of the rebased and revised MEI. This was because while it anticipated that revised weights would not impact overall spending for PFS services, they would impact distribution of payments based on geography and specialty. **We have echoed CMS' concerns about the redistributive effects of the new MEI and therefore support a further delay in its implementation as we commented in response to the CY 2024 PFS proposed rule.**[8] Updating the MEI would cause significant cuts for certain specialties like cardiac surgery, neurosurgery and emergency medicine. In addition to significant specialty redistribution, geographic redistribution also would occur. For example, a significant reduction in the weight of office rent would lead to reductions in payments for urban localities. These changes would, of course, come on top of the other substantial cuts physicians have seen in recent years, including the year over year decreases to the conversion factor. As such, careful evaluation is necessary particularly given current workforce shortage concerns.

Approach 3: Extend the A-APM Participation Bonus. **We support MedPAC's approach to extend A-APM incentive payments. Indeed, we have urged Congress to do the same to facilitate the transition to value-based payment.** Specifically, the Medicare Access and CHIP Reauthorization Act (MACRA) provided 5% incentive payments for clinicians

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[8] https://www.aha.org/system/files/media/file/2023/09/aha-comments-on-cms-physician-fee-schedule-proposed-rule-for-calendar-year-2024-letter-9-11-23.pdf

participating in A-APMs to support non-fee-for-service programs like meal delivery programs, transportation services, digital tools and care coordinators which promote population health, among other services. These incentive payments have been critical to support organizations in transitioning to value-based care. However, MACRA only provided the A-APM bonuses through the CY 2024 payment period. The Consolidated Appropriations Act (CAA) of 2023 extended these bonus payments through 2025 (albeit at 3.5% vs. 5%), and the most recent CAA of 2024 included an extension through 2026 at 1.88%.

In addition, we encourage MedPAC to recommend removal of CMS' problematic high- and low-revenue thresholds for APMs. CMS has used this label as a proxy measure to, for example, determine if an organization is supporting underserved populations. Yet, there is no valid reason to conclude that this delineation is an accurate or appropriate predictor of whether an organization treats an underserved population. In fact, analysis suggests that critical access hospitals, federally qualified health centers and rural health centers are predominantly classified as high revenue. Further, both low- and high-revenue organizations are working to address health equity as part of their care transformation work. Assistance investing in these efforts would help across the board.

TELEHEALTH STATUS REPORT

We appreciate MedPAC's continued discussion of telehealth utilization. Telehealth has always provided patients with increased access and convenience, but waivers implemented during the COVID-19 pandemic have allowed broader portions of the population to experience the benefits of virtual care.

Prior to the public health emergency (PHE), telehealth utilization was minimal due to limited fee-for-service coverage. Artificial barriers, such as requirements for patients to be located in specific settings (like clinics) or geographies (limited to rural areas), meant that relatively few patients could benefit from telehealth services. Telehealth waivers implemented as a result of the PHE have contributed to improved access for millions of Americans, especially those with transportation or mobility limitations. Continuing these flexibilities is necessary to ensure patients' continued access to high-quality care. Yet, there is currently a patchwork of temporary waivers for telehealth services that, barring further action, will expire at the end of 2024. If this occurs, we risk a telehealth "cliff" that would negatively impact patient access in all communities.

Recognizing both the immediate and potential long-term benefits of telehealth, we recommend permanent extension of certain telehealth waivers, as we have communicated to Congress.[9]

- Permanently eliminate originating- and geographic-site restrictions, thus allowing telehealth visits to occur at any site where the patient is located, including urban areas and the patient's home.

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[9] https://www.aha.org/2024-04-10-aha-house-statement-legislative-proposals-support-patient-access-telehealth-services

- Permanently eliminate in-person visit requirements for tele-behavioral health, which would ensure that patients do not need an in-person visit before initiating virtual treatment.
- Permanently remove distant site restrictions on federally qualified health centers and rural health clinics, which would ensure that they can continue to provide telehealth services.
- Permanently allow payment and coverage for audio-only telehealth services.
- Permanently expand eligible telehealth provider types to include physical therapists, occupational therapists, speech-language pathologists and audiologists.

We encourage MedPAC to also recommend permanent extension of these provisions to support continued access for patients.

We also have specific feedback regarding a few of the guardrail proposals the commission has discussed, per below.

In-person Visit Requirements. We appreciate the concerns identified by many of the commissioners regarding in-person visit requirements and the potential disruption these options would have on existing care patterns, particularly in clinical areas like behavioral health. While some patients may benefit from a periodic in-person evaluation, it should be left to clinical judgment when and how frequently these should occur, rather than an arbitrary general requirement. Indeed, adding a requirement for an in-person visit at specific cadences may unintentionally lead to scheduling of additional appointments that otherwise are not clinically necessary simply to “check the box” that the patient had an in-person visit to continue virtual services. **As such, we urge MedPAC to recommend repealing the in-person visit requirements for tele-behavioral health services.**

The CAA of 2021 required that a patient must receive an in-person evaluation six months before they can initiate tele-behavioral health treatment and also must have an in-person visit annually thereafter. This requirement has been waived since the start of the PHE; however, there are concerns about the impact that reinstatement of this policy or enactment of similar in-person visit policies for other specialty areas could have on patient access.

This requirement was derived as a cost savings measure rather than a policy to support clinical necessity. As such, we are very concerned about its potentially negative impacts on access to care. Specifically, particularly for behavioral health, there is a widening gap between provider capacity and patient demand. Over 30% of the U.S. adult population has reported symptoms of anxiety and depression since the start of the pandemic (compared to 11% prior), and provider shortages in areas like psychiatry are only expected to grow (estimates for 2024 indicate a shortfall of between 14,280-31,091 psychiatrists nationally).[10,11]

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[10] https://www.kff.org/statedata/mental-health-and-substance-use-state-fact-sheets/
[11] https://pubmed.ncbi.nlm.nih.gov/29540118/

We also know that the widening gap between patient demand and provider capacity is being felt even more acutely in rural and underserved communities. This may be part of the reason that the majority of patients utilizing tele-behavioral health services during the pandemic were in rural areas (55%).[12] These patients are not able to readily see an in-person provider given the shortages in their geographic area and in many cases would need to drive several hours to see the closest provider in person. Therefore, in-person visits may simply not be an option for many patients in rural and underserved communities.

Guardrail Policies. While we appreciate the commission's discussion of guardrail policy options to ensure appropriate utilization of telehealth, we point to recent publications issued by the Department of Health and Human Services Office of Inspector General (OIG) that found no widespread instances of fraud, waste and abuse attributed to telehealth during the PHE.[13] In its most recent telehealth report, the OIG did not make "recommendations because providers generally met Medicare requirements when billing for E/M services provided via telehealth and unallowable payments we identified resulted primarily from clerical errors or the inability to access records."[14] In addition, a previous OIG report found that only 0.2% of all telehealth providers were "potentially high-risk" for fraud, waste and abuse during the PHE.[15] Policies should support the 99.8% of providers safely and compliantly delivering services.

We recognize and appreciate the importance of identifying program integrity risks and establishing reasonable guardrails to prevent fraud, waste and abuse. However, the fact remains that virtually all providers who administered telehealth services during the PHE did so in a compliant manner; as such, concerns about propensity for widespread fraud, waste and abuse are not supported by the data. **Therefore, establishing additional guardrails above and beyond the existing policies for the general Medicare program are not warranted at this point.**

MedPAC also considered "outlier guardrail" policies that focus on providers who bill disproportionately more telehealth services. **We are concerned that such a focus also would do little to identify fraud and abuse.** For example, given physician shortages in areas like behavioral health, an increasing number of clinicians are solely providing virtual services. Doing so does not indicate a lack of compliance, but only an effort to provide access to as many patients as possible — something providers should not be penalized for through increased administrative burden and review.

Incident-to Services. We disagree with policy options to remove incident-to billing for telehealth. Doing so would limit the ability to leverage telehealth to support certain services, such as virtual supervision. As an example, prior to the PHE, CMS required that physicians serving in supervisory capacities be physically present in the same office suite when auxiliary personnel performed visits under their supervision and be available if assistance

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[12] https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/
[13] https://oig.hhs.gov/oas/reports/region1/12100501.asp
[14] https://oig.hhs.gov/oas/reports/region1/12100501.asp
[15] https://www.pandemicoversight.gov/media/file/telehealthfinal508nov30pdf

was needed. However, during the PHE, this supervision could be completed virtually using real-time audio-video technology, which supported improved access for geographically dispersed patients. Such flexibilities that leverage geographically dispersed providers are becoming more critical, especially as staffing shortages become more severe. This is also true for hospitals and health systems operating across multiple locations. **Therefore, we encourage MedPAC *not* to pursue policy options that would remove telehealth incident-to options, as this would limit patient access.**

We thank you for your consideration of our comments. Please contact me if you have questions or feel free to have a member of your team contact Shannon Wu, AHA's director of payment policy, at swu@aha.org or 202-626-2963.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

Cc: Paul Masi, M.P.P.
MedPAC Commissioners