AMERICA'S ESSENTIAL HOSPITALS

February 10, 2021

President Joseph Biden
White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Dear President Biden:

America's Essential Hospitals congratulates you and Vice President Kamala Harris for your historic inauguration. We greatly appreciate your swift efforts to address COVID-19, confront structural racism as an urgent public health threat, and reverse harmful immigration policies that have created a chilling effect in communities and threatened the health care workforce. We stand ready to work with your administration to strengthen the health care safety net and empower the communities we serve.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including vulnerable populations. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins a third that of other hospitals—2.5 percent on average compared with 7.6 percent for all hospitals nationwide.[1]

Essential hospitals are committed to serving all people, regardless of income or insurance status. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospitals' communities have limited access to healthy food, and nearly 24 million live below the poverty line.[2] Essential hospitals are uniquely situated to target these social determinants of health and are committed to serving these vulnerable patients. These circumstances, however, compound essential hospitals' challenges and strain their resources, requiring flexibility to ensure they are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

As you form your administration and define key health policy priorities, we ask that you consider the following issues to stabilize the nation's health care safety net and the communities

[1] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2018 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2020. https://essentialdata.info. Accessed January 22, 2021.
[2] Ibid.

AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004

t: 202 585 0100
f: 202 585 0101
e: contact@essentialhospitals.org

served by essential hospitals.

Structural Racism and Equity

THE BIDEN ADMINISTRATION SHOULD CONTINUE ITS PLANS TO CONFRONT STRUCTURAL RACISM IN HEALTH CARE AND PROMOTE POLICIES THAT SUPPORT THOSE WHO HISTORICALLY HAVE BEEN MARGINALIZED.

America's Essentials Hospitals is committed to confronting structural racism as a public health threat. This includes efforts to identify and foster the adoption of transformative health system approaches to combat inequities that lead to health disparities among underrepresented populations.

People of color constituted more than half essential hospitals' discharges in 2018. We acknowledge that structural racism—the normalization and legitimization of historical, cultural, institutional, and interpersonal dynamics that routinely advantage white people while producing cumulative and chronic adverse outcomes for people of color—is a barrier to health. As an association, we are dedicated to acknowledging and addressing the deeply entrenched historical racism that plays a critical role in determining the health and well-being of each member of our communities.

In your inaugural address, you spoke about the challenges we face as a nation, including "growing inequity" and "the sting of systemic racism." We stand ready to work with you and Vice President Harris to tackle long-standing policies and practices that have led to racial inequities. This work must take place across various federal agencies, not just within the Department of Health and Human Services. Your recent executive order on advancing racial equity and support for underserved communities was an unprecedented step toward advanced equity across federal programs and policies. We applaud this early action and stand eager to partner with your administration to identify opportunities for cross-sector, upstream collaborations to dismantle historic and current social barriers, including in housing and education.

a. <u>The administration should work across stakeholder groups to promote trust.</u>

We also encourage your administration to work with patient and community groups to gain trust among minority populations. Distrust in medical and public health institutions has a long history in the United States—from the failures of the Freedman's Bureau to the Tuskegee trials in the 1930s and other transgressions—and is felt today as the COVID-19 pandemic disproportionately impacts minority communities. **America's Essential Hospitals is ready to engage in dialogue that leads to meaningful change and promotion of strategies that improve the lives of the historically mistreated.**

COVID-19

THE BIDEN ADMINISTRATION SHOULD PRIORITIZE FUNDING FOR NECESSARY SERVICES AND INFRASTRUCTURE NEEDED DURING THE PUBLIC HEALTH EMERGENCY (PHE).

The COVID-19 pandemic hit the patients and communities served by essential hospitals particularly hard—especially racial and ethnic minorities. Sociodemographic factors greatly influence patient health status, making our member hospitals' patients most at risk, as COVID-

19 is detrimental for those with underlying health conditions. We applaud your swift action to release executive orders addressing issues critical to a national pandemic response, including your commitment to establishing a COVID-19 Health Equity Task Force. We are eager to partner with the administration to ensure that the task force is representative of the communities and essential hospitals hit hardest by the pandemic.

As outbreaks continue, essential hospitals that serve vulnerable populations find themselves in an increasingly precarious position with tight operating margins and low cash on hand. The response efforts associated with COVID-19—including increasing capacity through alternative care sites, competing with other providers for personal protective equipment and other supplies, and ensuring staff capacity—have significantly increased costs incurred by essential hospitals. As essential hospitals continue to lose revenue and incur expenses related to unprecedented levels of COVID-19 cases and hospitalizations, along with ongoing surge in some areas, it is imperative that they receive adequate funding to support their efforts. **We support the new administration's work with Congress to ensure continued funding for essential hospitals on the front lines and appropriate targeting to providers and communities most in need.**

a. The administration should be transparent and predictable when distributing vaccines.

On the vaccination front, essential hospitals lack transparency on the quantity and availability of doses. **The country's most immediate need is more vaccine doses, distributed in a transparent, predictable manner that allows providers to plan ahead and communicate with patients about vaccinations**.

Mass administration of vaccines requires significant staff resources and logistics. Essential hospitals are working hard on vaccine rollout, building infrastructure and partnering with their communities to ensure access for disadvantaged people. However, lack of patient trust and vaccine hesitancy are significant hurdles to widespread vaccination; more tailored communication and outreach about the vaccines is needed for the general public and at-risk populations. Federal government contracting, such as indefinite delivery/indefinite quantity contracts**,** could be leveraged to promote broad vaccination and mitigate patient hesitancy to receive vaccines. For example, America's Essential Hospitals is one of 58 institutions included in the Centers for Medicare & Medicaid Services' (CMS) Network of Quality Improvement and Innovation Contractors. **We encourage the new administration to employ the expertise of this network in a COVID-19 vaccine education campaign or similar public health effort related to the pandemic.**

America's Essential Hospitals understands the evolving nature of COVID-19 and the need for flexibility in our nation's response. However, our members face great variation in guidance across states at a time when our communities are looking for a single voice, aligned across federal and state governments. **We urge the new administration to provide consistency in what is expected of essential hospitals now and moving forward in the fight against COVID-19.**

Medicaid

HHS SHOULD CREATE AND PROMOTE POLICIES THAT SUPPORT THE MEDICAID PROGRAM AND ITS BENEFICIARIES.

Essential hospitals have a unique position in the Medicaid delivery system. Given their largely low-income, high-need patient populations, they are distinctly positioned to make a real and lasting impact on the lives and well-being of their patients. Essential hospitals find increasingly innovative and efficient strategies for providing high-quality, complex care, all while facing high costs and limited resources. Given their patient mix and margins, our members utterly depend on Medicaid funding to carry out their missions and remain viable.

a. The administration must ensure adequate base rates for Medicaid services.

While Medicaid provides high-quality coverage to millions, it often pays hospitals substantially less than the cost of care. In the aggregate, Medicaid payments fell below costs in 2018, resulting in a $19.7 billion shortfall. This translated to hospitals receiving payment of only 89 cents for every dollar spent caring for Medicaid patients.[3] The history of low Medicaid base rates is part of the fabric of structural racism in our county—discriminating against the most vulnerable and undervaluing the provision of care to patients served by this program.

In the absence of adequate Medicaid base payment rates, states increasingly rely on various types of supplemental payments to support providers and ensure Medicaid beneficiaries have access to needed care. Although the Medicaid statute requires states to pay rates that will ensure equal access for Medicaid patients, courts have indicated it is CMS' responsibility to enforce that requirement. To date, the agency has not done so, particularly with regard to hospital payment rates. As a result, supplemental payments are a critical means of ensuring patients who rely on Medicaid—a population disproportionately comprising racial and ethnic minorities—have equal access to care through providers who are not themselves disadvantaged due to below-cost rates. **We ask the Biden administration to ensure states abide by the statutory requirement to pay adequate rates.**

b. The Biden administration must advance policies that promote a robust Medicaid program, ensuring access to the program.

In recent years, several policy changes have eroded Medicaid eligibility and threatened to undermine program financing. Regulations like the Medicaid Fiscal Accountability Regulation (MFAR), proposed by the Trump administration, would have threatened the stability of state budgets, significantly narrowed and weakened Medicaid, and inevitably denied access to care for millions of Americans. We are pleased the MFAR was formally withdrawn in the *Federal Register* on January 19, 2021, and hope this administration will honor the withdrawal of this harmful policy. As more Americans lose employer-sponsored insurance during the current economic downturn, it is critical a robust and stable Medicaid program stand ready to absorb newly eligible beneficiaries. This is especially critical during the COVID-19 PHE. We support the recent executive order on strengthening Medicaid and the Affordable Care Act (ACA), and **we urge the Biden administration to continue to promote policies that expand, rather than limit, Medicaid eligibility**.

[3] Medicare-Medicaid Underpayment Fact Sheet. American Hospital Association. January 2020. https://www.aha.org/system/files/media/file/2020/01/2020-Medicare-Medicaid-Underpayment-Fact-Sheet.pdf. Accessed January 22, 2021.

THE BIDEN ADMINISTRATION SHOULD PRESERVE THE 340B DRUG PRICING PROGRAM AND REVERSE HARMFUL TRUMP ADMINISTRATION POLICIES.

Regulatory actions taken by the Trump administration have undermined the 340B program and contravened Congress' intent in creating the program to bolster safety-net institutions. Congress established the 340B program in 1992 to enable covered entities, including essential hospitals, "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4] Our association played a formative role in the creation of 340B, and the program is intrinsically linked to the identity and mission of essential hospitals. The 340B program is structured to provide hospitals treating a disproportionate share of low-income patients discounts for covered outpatient drugs, regardless of the patient recipient's insurance status. The program reflects the unique role of essential hospitals in caring for vulnerable populations, as well as their inherent financial challenges, and thereby offers our members the flexibility to tailor services and programs to their community's needs at virtually no cost to taxpayers. The benefits of 340B are especially evident now, when essential hospitals' thin operating margins are further constrained by financial pressures related to the COVID-19 PHE. **By preserving the 340B program as it was intended to operate by Congress and taking the following steps to undo damage to the program, the administration will ensure essential hospitals have the resources needed to continue serving their diverse patients.**

a. The Health Resources and Services Administration (HRSA) should enforce the 340B statute by requiring manufacturers to provide discounted drugs to covered entities' contract pharmacies.

Since last summer, multiple drug manufacturers have taken unilateral actions that undermine the ability of safety-net providers to access affordable drugs and realize 340B savings. Many hospitals in the 340B program use contract pharmacy arrangements approved by HRSA to expand access as widely as possible so patients maintain access to prescriptions despite living in an underserved area. These patients include individuals in rural areas and those facing various social risk factors, such as lack of transportation or inflexible employment hours. Contract pharmacies enable these patients to more readily access medications to help manage their health while concurrently holding down health care costs. **We urge HRSA to enforce the Department of Health and Human Services (HHS) Office of General Counsel's (OGC's) December 30, 2020, advisory opinion to prevent these drug manufacturer actions from restricting access to lifesaving drugs.**

To date, Eli Lilly, AstraZeneca, and Novo Nordisk have ceased shipping 340B-priced drugs to covered entities' contract pharmacies, with limited exceptions. Four other manufacturers have taken a different approach. Merck, Sanofi, Novartis, and United Therapeutics imposed arbitrary and ill-timed reporting requirements on 340B hospitals, requesting data on all contract pharmacy claims—including Medicaid, Medicare Part D, and commercial claims—on a biweekly basis as essential hospitals focus on combatting the COVID-19 PHE. These manufacturers have threatened to take punitive measures if covered entities refuse to comply with these frivolous inquiries, including ceasing to ship 340B drugs to their contract pharmacies.

[4] H.R. REP. No. 102-384, pt. 2 (1992).

America's Essential Hospitals appreciates the clear statement of the law provided in OGC's advisory opinion, which noted "covered entities … are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients." This was a positive first step to holding manufacturers accountable, but HRSA now must use the tools at its disposal to follow through on this advisory opinion. This includes referring manufacturers to the HHS Office of Inspector General for the imposition of civil monetary penalties for charging more than the statutorily-mandated ceiling price. **We urge HRSA to act swiftly to put an end to these actions and to require manufacturers repay covered entities for the forgone 340B discounts.**

b. CMS should reverse the 2018 Medicare Part B cuts to 340B hospitals.

CMS should reverse an arbitrary Trump administration Medicare policy, in place since 2018, that drastically reduced Medicare Part B payments to 340B hospitals. These cuts, instituted through the Outpatient Prospective Payment System rules, cut payments to 340B hospitals by nearly 30 percent, while increasing payments for outpatient services across all Medicare hospitals. This inequitable policy boosts payments for hospitals outside the program at the expense of 340B hospitals and their patients, all while saving the Medicare program no money. This policy is on tenuous legal grounds and violates the intent of the 340B program, which was designed for hospitals to realize savings through discounted drugs. In essence, the Medicare Part B payment cuts have redirected payment for 340B drugs to hospitals excluded from the program. Hospitals treating fewer low-income patients benefit at the expense of hospitals serving the most vulnerable patients, contrary to the spirit of the 340B program. **We call on the Biden administration to promptly reverse these cuts to preserve the benefit of the 340B program for the hospitals most in need—those treating high levels of vulnerable, low-income patients.**

c. CMS should withdraw the procedurally and substantively flawed Most Favored Nation (MFN) model interim final rule.

In late November 2020, the Trump administration issued the MFN model interim final rule, bypassing a notice of proposed rulemaking and the required 60-day delay in effective date. We are concerned CMS has not provided the opportunity for public comment and has rushed the implementation of the MFN rule, providing a mere 30 days from the date of the rule's publication before it took effect. This mandatory seven-year payment model, under the authority of the Center for Medicare and Medicaid Innovation, constitutes a sweeping overhaul of the current drug reimbursement system for Medicare providers. The final rule drastically reduces payment rates to providers for 50 of the highest-volume drugs, from 106 percent of average sales price (ASP) to an estimated 45 percent of ASP.

The rule will further burden hospitals in the 340B program. As CMS itself acknowledges in the rule, the MFN model could further burden 340B hospitals and restrict patient access to lifesaving drugs. Through the MFN model, CMS will tie the prices of 50 drugs to the lowest international price from a group of 22 Organisation for Economic Co-operation and Development (OECD) countries. The lower prices will be phased in over four years, with the fully phased-in MFN prices in effect in years four through seven of the model. Prices in these OECD countries are substantially lower than in the United States due to entirely different

market forces, drug negotiation practices in these countries, more aggressive government intervention in setting drug prices, and drug manufacturer pricing decisions. By tying U.S. reimbursement to international levels without putting pressure on drug manufacturers to reduce prices in the United States, CMS places providers at real risk of becoming financially insolvent.

CMS should not have proceeded with implementation of a rule with such far-reaching consequences without first issuing a proposed rule for public comment. The agency's omission of a critical step in the rulemaking process is a violation of the Administrative Procedure Act (APA) and several lawsuits are challenging the decision. In temporarily barring implementation of the rule nationwide, two courts have ruled that the plaintiffs are "virtually certain" to succeed on their claim that CMS violated the APA's notice-and-comment requirements.[5] **We urge CMS to consider the consequences of the MFN model on providers treating the nation's vulnerable patients, as well as the beneficiaries they serve, and withdraw the rule.**

Site-Neutral Payments

THE BIDEN ADMINISTRATION MUST ACKNOWLEDGE THE HARM THAT SITE-NEUTRAL PAYMENT POLICIES HAVE CAUSED TO UNDERSERVED COMMUNITIES.

Essential hospitals deliver comprehensive, coordinated care across large ambulatory networks to bring services where their patients live and work. Our average member operates a network of more than 20 ambulatory care sites. Their networks of hospital-based clinics include onsite features—radiology, laboratory, and pharmacy services, for example—that freestanding physician offices typically do not offer. These ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs. The COVID-19 pandemic underscored the need for providers to deliver care where patients live and work and to reduce unnecessary visits to the emergency department. However, recent outpatient payment changes have threatened access to care for the nation's most underserved communities.

The Bipartisan Budget Act (BBA) of 2015 mandated a new payment system for off-campus provider-based departments (PBDs), resulting in a 60 percent cut to clinics that opened after November 2, 2015. The law allowed clinics operating before that date to continue to be paid under the Outpatient Prospective Payment System (OPPS). In recent years, the Trump administration took these cuts one step further by expanding the cuts to grandfathered clinics for common office visits. Site-neutral payment policies jeopardize access to care by making clinic expansion into our most underserved communities financially unsustainable. **We urge the Biden administration to reverse course on the Trump administration's expansion of site-neutral policies and acknowledge the unique role essential hospitals play in the health care delivery system.**

a. Communities served by essential hospitals face unique health and social challenges; CMS should account for these challenges and preserve adequate reimbursement rates for essential hospitals' PBDs.

[5] California Life Sciences Association, et al. v. Centers for Medicare & Medicaid Services, et al. Case. No. 20-cv-0863-VC. N.D. Cal. December 28, 2020; Association of Community Cancer Centers, et al. v. Alex M. Azar II, et al. Civil Action No. CCB-20-3531. D. Md. December 23, 2020.

As mandated by Section 603 of the BBA, CMS on January 1, 2017, discontinued paying nongrandfathered off-campus PBDs under the OPPS. The BBA instructed CMS to pay these nongrandfathered PBDs under a Part B "applicable payment system" other than the OPPS; CMS determined the Physician Fee Schedule (PFS) to be such a system. CMS' application of Section 603 played an undeniable role in limiting health care access for the country's most disadvantaged patients. Patients seeking care at essential hospitals' off-campus PBDs typically are low-income and racial and ethnic minorities. Essential hospital clinics often fill a void by providing the only source of primary and specialty care to these patients in their communities. Because of their integrated health systems, essential hospitals can help drive down overall health care costs, including for the Medicare program, by efficiently providing coordinated care through ambulatory networks.

In the aggregate, members of America's Essential Hospitals operate on margins one-third that of other hospitals nationally. For hospitals serving a safety-net role, operating on these narrow (often negative) margins, this payment rate reduction is unsustainable and has the potential to disproportionally impact low-income and vulnerable communities. Essential hospitals often are the only providers willing to take the financial risk of opening a clinic in a community with many clinically complex and low-income patients. Inadequate payment rates affect patient access by limiting the ability of essential hospitals to bring health care into these communities of need. CMS' implementation of Section 603—especially the inadequate payment rate—already has caused essential hospitals to re-evaluate plans to expand their provider networks into underserved areas. **America's Essential Hospitals urges CMS to reimburse nongrandfathered PBDs of essential hospitals—those subject to Section 603—at no lower than 75 percent of the OPPS payment rate.** Doing so would ensure essential hospital PBDs are adequately reimbursed for the cost of providing comprehensive, coordinated care to complex patient populations in underserved areas.

b. CMS must reverse course on the Trump administration's expansion of site-neutral payments to grandfathered facilities.

Since calendar year 2019, CMS has cut payment for outpatient clinic visits to grandfathered PBDs, which are clearly outside the reach of the reduced payment amount under Section 603. These services (assigned Healthcare Common Procedure Coding System [HCPCS] code G0463) are the most frequently performed in the outpatient setting and encompass visits from the most basic patients to those with multiple chronic conditions seeking care from specialists. Outpatient clinic visits are necessary to coordinate care, reduce readmissions, and keep patients out of the emergency department.

This harmful policy will continue to undermine the ability of essential hospitals to serve vulnerable populations in underserved areas. Many essential hospitals have off-campus clinics in federally designated areas with shortages of providers, including health professional shortage areas and medically underserved areas. Further, these clinics are more likely to serve patients dually eligible for Medicare and Medicaid, as well as uninsured patients and those on Medicaid, compared with freestanding physician offices. These clinics face severe cuts due to CMS' policy, and their closure would restrict access to care for communities in which access to health care already is limited and cannot be provided by freestanding physician offices. **We urge the administration to swiftly revert to the full OPPS payment rate for grandfathered clinics.**

Immigration Policy

THE ADMINISTRATION SHOULD REVERSE HARMFUL IMMIGRATION POLICIES THAT UNDERMINE PUBLIC HEALTH AND THE HEALTH CARE WORKFORCE.

Trump administration policies have created a chilling effect that discourages lawfully present immigrants from enrolling in public programs, such as Medicaid, for which they are legally eligible. These policies have deterred immigrants from engaging with the health care system, leading to restricted access and broader public health consequences. These detrimental policies have been compounded by visa restrictions and the rescission of the Deferred Action for Childhood Arrivals (DACA) program, which have undermined the ability of essential hospitals to maintain a competitive health care workforce.

Beyond their vital role in providing access to lifesaving care, essential hospitals also are economic pillars in their communities. They drive economic activity and are some of the largest employers in their communities. Nationally, essential hospitals contribute to more than 1.5 million jobs and add nearly $125 billion to their state economies.[6] By undermining essential hospitals, which are key drivers of economic activity in their communities, these policies have also undermined state and local economies.

a. DHS should halt enforcement of the revised public charge definition and reverse the 2019 final rules.

The Trump administration's 2019 Department of Homeland Security (DHS) and Department of State (DOS) final rules related to inadmissibility on public charge grounds caused fear and confusion among immigrants, including those lawfully present in the country. Changes to public charge determinations and their chilling effect on access to Medicaid and other public programs have put individuals and families at risk and have hampered the public health response to COVID-19. By expanding the types of public benefits considered in making public charge determinations to include Medicaid and housing benefits, the public charge rule discourages immigrants from applying for benefits for which they otherwise are eligible. Patients forgoing public insurance programs and seeking care without insurance strains the tight budgets of essential hospitals. The rules have been detrimental to the health care system at large, resulting in increased health care costs systemwide and worse health outcomes among the most vulnerable.

America's Essential Hospitals appreciates the February 2 executive order directing relevant federal agencies to review the public charge rule and its effect on public health and lawful immigration. However, the executive order stops short of ordering an immediate reversal of the public charge rule, which continues to sow confusion and fear in immigration communities about eligibility for public benefits. Lack of access to critical public benefit programs, such as Medicaid, will have even more pronounced implications during an ongoing pandemic. **Therefore, DHS and DOS immediately should halt enforcement of the 2019 public charge definition and rescind the rules.**

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[6] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2018 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2020. https://essentialdata.info. Accessed January 22, 2021.

b. The administration should ensure a robust health care workforce by rolling back detrimental policies undermining recruitment and training of health care workers.

President Barack Obama's creation of the DACA program in 2012 was critical to allowing hundreds of thousands of immigrants to remain in the country, seek employment, and contribute to the U.S. economy. Unfortunately, Trump administration policies restricting access to visas and undermining the DACA program have hampered the ability of health care providers to maintain a competitive workforce. The Trump administration repeatedly undercut the DACA program, rescinding it in 2017. Although the Supreme Court found this rescission to be unlawful, the administration continued to narrow the scope of the program. An estimated 27,000 health care professionals can seek employment and remain in the country due to the protections afforded by DACA. These health care professionals include medical students and medical residents. Their presence in the United States is indispensable to the larger health care system. **We are encouraged that President Biden issued a memorandum on preserving and fortifying DACA, and we look forward to actions from DHS implementing this memorandum.**

Trump administration executive actions also severely restricted the ability of hospitals to recruit and retain highly qualified international medical graduates for their residency programs. The travel ban on immigration from 13 countries resulted in a decline in visas, including for health professionals. **America's Essential Hospitals is pleased that President Biden issued a proclamation on ending these discriminatory bans on entry to the United States.**

Separately, the Trump administration proposed new restrictions on duration of status for exchange visitor visas, which will create uncertainty for teaching hospitals and trainees, potentially forcing residents and fellows to return to their country before the completion of their training. **We urge DHS to withdraw this proposed rule, which is unnecessary given the rigorous protocols in effect to vet and review the status of international medical graduates training in the United States.**

Social Determinants of Health

THE ADMINISTRATION SHOULD PRIORITIZE UNDERSTANDING SOCIAL DETERMINANTS OF HEALTH (SDOH) AND ADOPTING POLICIES THAT ENSURE FAIRNESS AND EQUITY ACROSS PROGRAMS LIKE MEDICAID AND MEDICARE.

Vulnerable populations—those treated by our members—often experience poor health due to social hardships outside the hospital's control, including poverty, illiteracy, homelessness, a lack of family support, substance abuse, and other social risk factors. Essential hospitals work outside their walls to expand health care access to areas where none otherwise would exist. Essential hospitals serve as anchors within their communities, with deep economic and social ties to the residents; this leads to a clear understanding of the nonclinical influences on patients and population health. However, infrastructure, staff time, and community engagement require resources that are especially scarce for essential hospitals that serve the disadvantaged populations most in need of this assistance. In designing new incentives or payment systems, CMS should give special recognition and financial support to providers who disproportionately deliver care to disadvantaged populations facing health and health care disparities. Incentives across the health care delivery and payment system need to be aligned to promote equity of care and eliminate disparities.

We encourage the new administration to engage stakeholders in the development of new voluntary delivery models, within the Medicare and Medicaid programs, that seek to address SDOH while improving the overall health of the nation. We believe demonstrations should be used in a manner that drives improvement without placing undue burden on essential hospitals. **We look forward to working alongside the Biden administration in each step of model development.**

Risk Adjustment

THE ADMINISTRATION SHOULD WORK WITH STAKEHOLDERS TO IDENTIFY AND ADDRESS RISK FACTORS, OUTSIDE OF A PROVIDER'S CONTROL, THAT CAUSE INEQUITIES IN PUBLIC POLICIES.
Within the context of various Medicare value-based purchasing programs, outcomes measures often are relied on as a proxy for quality of care. Such measures, especially those focused on readmissions, do not accurately reflect quality of care if they do not account for SDOH that can complicate outcomes. A large and growing body of evidence shows that sociodemographic factors—age, race, ethnicity, and language, for example—and socioeconomic status, including income and education, can influence health outcomes. These factors can skew results on certain quality measures, such as those for readmissions. For example, it is well known that patients who lack reliable support systems after discharge are more likely to be readmitted to a hospital or other institutional setting. These readmissions result from factors beyond the control of providers and health systems and do not reflect the quality of care.

Without proper risk adjustment, an essential hospital serving a disproportionate share of low-income patients with compounding social risk factors might receive a lower star rating or incur penalties in Medicare's value-based purchasing programs for reasons outside its control. The current system financially penalizes essential hospitals that treat populations with significant social barriers without factoring in these barriers when assessing performance. Most essential hospitals operate on narrow or negative margins and cannot absorb additional funding cuts. This creates a vicious cycle that reduces their already scarce resources to treat vulnerable populations.

To advance meaningful policy changes, America's Essential Hospitals encourages the collection of patient demographic and SDOH data in a culturally sensitive and linguistically appropriate manner. Limited documentation of SDOH data hinders our capacity to understand and adequately address social barriers to positive health outcomes.

Additionally, quality reporting should streamline quality measures to focus on high-impact, high-value measures that are meaningful to patients and that promote improved outcomes while minimizing costs. A set of "core measures" should be identified using agreed-on principles for measure selection. CMS' Meaningful Measures Initiative introduced a set of priority areas with the potential to focus quality improvement efforts, but more work is needed to effectively apply this framework to all levels of quality measure development, reporting, and assessment.

The health care community has yet to reach consensus on the "right" number of measures—with the 2015 Institute of Medicine report setting forth 15 "vital signs" and, more recently, the Medicare Payment Advisory Commission's (MedPAC's) recommendation of five measures as the basis of its proposed Hospital Value Incentive Program. While we do not propose a specific

number of measures that should be included in a core set, we caution against MedPAC's recommended measures as too few and too inflexible. As health care delivery transforms, and performance on these measures improves, the five measures and topics chosen by MedPAC might no longer represent the best opportunities for quality improvement for hospitals. **We encourage the new administration to engage stakeholders in the identification of specific measures and measure topics and to ensure measures are adequately and appropriately adjusted for case mix, including sociodemographic factors**.

Telehealth

CMS SHOULD PERMANENTLY ADOPT TELEHEALTH FLEXIBILITY BY BROADENING THE SCOPE OF TELEHEALTH REIMBURSEMENT AND LIFTING BARRIERS TO MEDICARE REIMBURSEMENT FOR THESE SERVICES.

The key role technology can play in access to high-quality care has become increasingly evident during the COVID-19 pandemic. Telehealth expands the reach of specialists and other providers, allowing hospitals to efficiently connect patients to high-quality care, increase access, and improve population health. Essential hospitals, which are on the front lines of the PHE, have used technology to connect their providers with patients in a variety of settings. The use of telehealth has been critical not only in screening potential COVID-19 patients, but also in allowing other patients to maintain continuity of care with their primary and specialty care providers while respecting social distancing mandates.

a. CMS must take early and definitive steps to permanently expand telehealth flexibilities.

In response to the COVID-19 PHE, CMS expanded flexibility by adding to the list of reimbursable telehealth services, waiving geographic and site-of-service restrictions on the originating site, and allowing hospitals to bill an originating-site fee. The permanent continuation of such flexibility will be indispensable as essential hospitals continue to respond to COVID-19 and prepare for future outbreaks. This pandemic demonstrated the effectiveness of telehealth in providing high-quality, cost-effective care while protecting health care personnel from unnecessary exposure to coronavirus. **We urge the agency to expand vulnerable populations' access to lifesaving services by broadening the scope of telehealth reimbursement and lifting barriers to Medicare reimbursement for these services.**

Specifically, CMS should:

- make permanent additions to the list of Medicare reimbursable telehealth services that were made for the duration of the COVID-19 PHE;
- allow reimbursement of certain services provided using audio-only technology, which are critical for vulnerable patients who do not have access to computers or phones with video capabilities, and those who have limited access to broadband that can support synchronous video visits;
- continue to offer parity between telehealth and in-person services by paying practitioners at the appropriate Physician Fee Schedule rate depending on the place of service;
- work with Congress to ensure hospitals receive an adequate facility fee to cover the hospital's costs of providing telehealth services;

- work with Congress to permanently eliminate the geographic and site-of-service restrictions on Medicare telehealth services, which is vital for patients with lack of transportation and other barriers to access; and
- work with state Medicaid agencies to facilitate the approval of state plan amendments and waivers related to telehealth.

This flexibility will serve an important role in hospitals' recovery efforts and patient' access to high-quality care, both during and after the COVID-19 pandemic.

Nondiscrimination

HHS SHOULD REVERSE THE TRUMP ADMINISTRATION'S CHANGES TO THE ACA NONDISCRIMINATION POLICIES.

Under the Trump administration, HHS finalized a rule that would overhaul parts of Section 1557 of the ACA, removing some nondiscrimination protections for transgender individuals and requirements for covered entities treating people with limited English proficiency (LEP).

Section 1557 protects against discrimination based on race, color, national origin, sex, age, or disability of individuals in federally funded health programs. These requirements apply to all hospitals and other entities participating in federal health programs. In 2016, the Obama administration finalized a rule providing additional definitions and clarity related to Section 1557. The 2016 rule faced legal challenges, which resulted in conflicting rulings on whether the 2016 definition of discrimination on the basis of sex exceeded statutory authority.

Days after the final Trump administration rule was released in 2020, the Supreme Court decided that sex discrimination under Title VII of the Civil Rights Act includes discrimination based on sexual orientation and gender identity.

Essential hospitals remain very concerned the rule finalized in 2020 fails to account for existing barriers certain patients face when seeking care, including members of the lesbian, gay, bisexual, transgender, and queer or questioning community and individuals with LEP. Essential hospitals are uniquely situated to address diverse patients and serve a disproportionate number of patients who face sociodemographic challenges to accessing health care. Given essential hospitals' commitment to providing high-quality, patient-centered care to all patients, we underscore the importance of protecting those with LEP and individuals based on sex, including gender identity. We applaud the recent executive order on preventing and combating discrimination on the basis of gender identity or sexual orientation; this is a critical step forward. However, **it is imperative federal agencies share this commitment and we urge HHS to revert back to the 2016 version of the Section 1557 rule.**

America's Essential Hospitals appreciates your time and consideration and once again extends our congratulations to the new administration. We look forward to future meetings and gatherings with the administration to further align our priorities and strengthen the health care safety net for all.

If you have any questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO

CC: Kamala Harris, Vice President
Norris Cochran, Acting Secretary, Department of Health and Human Services
Alejandro Mayorkas, Secretary, Department of Homeland Security
Liz Richter, Acting Administrator, Centers for Medicare & Medicaid Services
Susan Rice, Director, Domestic Policy Council
Marcella Nunez-Smith, Chair, COVID-19 Equity Task Force