IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, MERCY HEALTH MUSKEGON, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER, and YORK HOSPITAL *Plaintiffs,* v. ALEX M. AZAR II, In his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES *Defendant.*	Civil Action No. 1:18-cv-2841

BRIEF OF AMICUS CURIAE AMERICA'S ESSENTIAL HOSPITALS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to the Local Rule 7(o)(5) of the United State District Court of the District of Columbia, incorporating Rule 29(a)(4) of the Federal Rules of Appellate Procedure, the undersigned counsel to America's Essential Hospitals certifies that America's Essential Hospitals has no parent companies, subsidiaries, or affiliates that have issued shares to the public.

Date: February 21, 2019

s/ Barbara D.A. Eyman
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I. IDENTITY AND STATEMENT OF INTEREST OF AMICUS CURIAE AMERICA'S ESSENTIAL HOSPITALS

Amicus Curiae America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to providing high-quality care for all, including underserved and low-income populations.[1] Filling a vital role in their communities, the association's more than 325 member hospitals provide a disproportionate share of the nation's uncompensated care. Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care, including a substantial amount of outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, specialty care services, and "wraparound" services such as transportation and translation that help ensure that patients can access the care being offered. They do so on a shoe-string budget, providing state-of-the-art, patient-centered care while operating on margins half that of other hospitals—4% on average compared with 7.8% for all hospitals nationwide. America's Essential Hospitals, *Annual Member Characteristics Survey FY 2016* (June 2018), www.essentialdata.info ("Characteristics Survey").

In 2016, members of America's Essential Hospitals provided non-emergency outpatient care to 79.6 million patients, serving communities where 25.3 million people lived below the federal poverty line, 10.1 million people had limited access to healthy food, 19.4 million were uninsured, and 350,000 were homeless. Essential hospitals devote nearly 70% of their outpatient care to uninsured patients and patients receiving insurance through public programs, and 41.5% of such care is delivered in clinics that are located off the main campus. *Characteristics Survey*. Essential hospitals' longstanding history of expanding services into the community through the

[1] No party's counsel authored this brief in whole or in part. No party, party's counsel, or person – other than the amicus curiae – contributed money intended to fund the preparation or submission of this brief.

establishment of off-campus hospital-based clinics has been mission-driven, not profit-driven. Essential hospitals offer comprehensive, coordinated care beyond the four walls of the hospital to bring vital services to the communities where patients live and work.

Through its relationship with members across the country, America's Essential Hospitals has gained expertise regarding the unique and important benefits associated with the provision of community-based outpatient care to underserved populations. For decades, association members have established extensive networks of neighborhood-based clinics intended to make care accessible to the low-income communities they serve, where individuals would otherwise have no other options for care—including no access to physician offices. The members of America's Essential Hospitals are deeply and disproportionately impacted by the payment cuts at issue in this litigation. As explained in a detailed comment letter submitted to the Centers for Medicare & Medicaid Services (CMS) before the payment cuts were finalized, CMS' policy, if upheld, will "drastically limit the ability of essential hospitals to provide comprehensive, coordinated care to disadvantaged populations," a key part of their missions. America's Essential Hospitals, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 24, 2018), https://bit.ly/2EgXD7e. America's Essential Hospitals thus offers the court a unique perspective on the real-world impact CMS' payment cuts will have on underserved populations across the country.

II. INTRODUCTION

Over the years, essential hospitals have developed expansive networks of off-campus community-based clinics to support their mission of increasing access to care to underserved populations. As of 2016, the typical essential hospital had 35 outpatient departments, a third of which were off-campus and thus will be directly impacted by the outcome of this litigation.

Characteristics Survey. Not only do essential hospitals' community-based clinics provide sophisticated and comprehensive care to high-risk, complex patient populations, they also offer medical, specialty, and social services and supports not typically offered in freestanding physician offices. These vast networks of accessible, community-based sources of care were developed in reliance on longstanding Medicare payment policies that treated those clinics as if they were located on the main campus of the hospital. Congress understood the serious consequences of upending that reliance. CMS chose to ignore them.

As explained in plaintiffs' Memorandum of Points and Authority in Support of Plaintiffs' Motion for Summary Judgment (Plaintiffs' Memorandum), in 2015, Congress enacted Section 603 of the Bipartisan Budget Act of 2015. *See* Pub. L. No 114-74 § 603, 129 Stat. 584, 598 (2015) (Section 603). In Section 603, Congress modified Medicare payment policies applicable to off-campus outpatient hospital clinics to equalize payments between off-campus hospital-based clinics and physician offices, but deliberately chose to apply the new policy only to those clinics that started billing Medicare *after* the date of enactment. Then-existing clinics, known as "excepted clinics," were grandfathered into the Medicare Outpatient Prospective Payment System (OPPS) (Pl. Mem. at 6-9).

In its final rule adopting Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818 (Nov. 21, 2018) (Final Rule), CMS reversed Congress' carefully-considered policy choice to maintain OPPS reimbursement for "excepted" off-campus clinics. Specifically, CMS implemented a policy to reduce payments for clinic visit services (as described by Healthcare Common Procedure Coding System (HCPCS) code G0463) provided in excepted clinics to the equivalent of the amount paid to non-excepted clinics (the Clinic Visit Policy). The Clinic Visit

Policy will be phased in over two years, resulting in a 30% reduction in payments in 2019 and a 60% reduction in payments in 2020 and subsequent years.

III. ARGUMENT

A. CMS' Clinic Visit Policy Ignores the Unique Role Played by Hospital-Based Off-Campus Clinics, Which Serve Vulnerable Patient Populations, Offer Expanded and Integrated Services, and Provide Critical Access to Low-Income Individuals.

To assess what is at stake in CMS' unilateral decision to overturn the will of Congress, the court must first understand the critical role that off-campus clinics have played to date in providing low-income populations with access to primary and specialty care and enabling hospitals to transform their delivery systems to promote quality, value, and efficiency. In CMS' view, the growth in off-campus clinics is solely due to provider "payment incentives, rather than patient acuity or medical necessity." Final Rule at 59,005. The experience of essential hospitals demonstrates otherwise.[2]

Physicians in private practice often have limited to capacity to serve low-income patients. Hospitals, through their hospital-based clinics, have managed to fill in the gaps. Essential hospitals have established off-campus clinics to serve a different population than typical freestanding physician offices, serving predominantly low-income, publicly-insured, and other vulnerable populations, including racial and ethnic minorities.[3] Less than a third of essential

[2] This brief focuses on the impact of the Clinic Visit Policy on the essential hospitals that make up amicus' membership in order to demonstrate the complexity of the policy decisions that Congress carefully balanced and CMS upended. This discussion secondarily illustrates some of the harm that the policy will cause America's Essential Hospitals' members (the vast majority of whom are also members of one or both plaintiff associations), as supplementary to the harm amply demonstrated in plaintiffs' brief and accompanying declarations.

[3] For example, minority children and minority adults who are covered by Medicaid or are uninsured are twice as reliant on a hospital-based clinic as their usual source of care than their white counterparts. Lillie-Blanton et al., *Site of Medical Care: Do Racial and Ethnic Differences Persist?* YALE J. OF HEALTH POL'Y, L., & ETHICS 15, 17 (2013).

hospital outpatient care is provided to commercially insured patients. *Characteristics Survey*. As compared to physician offices, hospital-based outpatient clinics serve considerably higher proportions of low-income Medicare beneficiaries—those who are dually eligible for Medicare and Medicaid ("dual eligibles"). *See* KNG Health Consulting LLC, *Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices* (2018), https://bit.ly/2Ed4Iaf (Pl. Mem. note 1). Over 37% of beneficiaries treated at essential hospital outpatient clinics are dual eligibles. America's Essential Hospitals*, Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 24, 2018), https://bit.ly/2EgXD7e.

The patients treated in essential hospitals' clinics tend to be sicker and have more complex health and social needs than typical patients. Dual eligibles, for example, tend to be in poorer health status, and are more likely to have multiple co-morbidities and complex chronic conditions. Indeed, more than half of dual eligible patients have at least one chronic condition, such as diabetes or hypertension, and 30% live with a diagnosed mental illness. CBO, *Dual Eligible Beneficiaries of Medicare and Medicaid* (June 2013), https://bit.ly/2V6nOmQ. The majority of dual eligible patients also suffer from a disability or other functional limitation. MedPAC, *Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid* (Jan. 2018), https://bit.ly/2T24BFp. Likewise, low-income adults have higher rates of heart disease, diabetes, and other chronic conditions than wealthier Americans. Steven H. Woolf et al., *How are Income and Wealth Linked to Health and Longevity?* Urban Institute (April 2015), https://urbn.is/2qFOSw1. Similarly, minority patients such as African Americans are more likely to have asthma, diabetes, and heart disease compared to white patients. Samantha Artiga et al.,

Key Facts on Health and Health Care by Race and Ethnicity, Kaiser Family Foundation (June 2016), https://bit.ly/2U9AxFw.

Low-income and minority patients also face significant socioeconomic barriers to good health, including language barriers, limited literacy, housing and food insecurity, and insufficient social support. Approximately 20% of the U.S. population has limited English proficiency, with greater language barriers for beneficiaries in urban areas, where many essential hospitals are located, and for immigrants. Sara Heath, *Addressing Language Barriers in Patient-Provider Communication*, Patient Engagement HIT (Sept. 2017), https://bit.ly/2SdcTFU. Likewise, food insecurity disproportionately affects ethnic minorities and low-income populations, often resulting in obesity and chronic disease. Essential Hospitals Institute, *Food Insecurity, Health Equity, and Essential Hospitals* (June 2016), https://bit.ly/2EgY4hS. Additionally, many low-income populations either do not have access to transportation or lack adequate public transit to obtain health care services. Woolf, *How are Income and Wealth Linked to Health and Longevity?*

For all these reasons, the patients treated in essential hospitals' clinics require high levels of services, coordination, and support, to an extent that is simply not feasible to provide in many physician office settings. Essential hospitals have met that challenge, tailoring the services furnished in off-campus clinics to provide underserved patients access to a broader range of primary care and specialty services than would otherwise be available in their communities. Essential hospitals' off-campus clinics often provide services on-site that typical physicians' offices do not, including radiology, laboratory, and pharmacy services. Essential hospitals also have established off-campus locations in a strategic effort to extend highly-complex, specialized services, such as oncology, cardiology, and neurology, into the community to address gaps in

patient care. For example, University of New Mexico Hospitals operates New Mexico's only National Cancer Institute designated Comprehensive Cancer Center, which provides access to cancer care, cancer clinical trials, and cancer prevention and screening studies through its hub in Albuquerque and a statewide network of community-based health systems and providers, touching over 85% of cancer patients in the state. University of New Mexico, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 24, 2018), https://bit.ly/2E4Kopd.

Beyond specialty services, there also are important differences in the primary care furnished in off-campus clinics. Even if both hospital-based and freestanding clinics are clinically capable of providing a particular clinic service, hospital-based clinics are required by law to meet more stringent regulatory requirements applicable to hospitals and to be integrated into the clinical and financial operations of the hospitals of which they are a part. 42 C.F.R. §§ 413.65(d)-(e); 42 C.F.R. Part 482 (Medicare's hospital conditions for participation). There are no equivalent conditions of coverage or participation for physicians. *See* CMS, *Conditions for Coverage (CfCs) & Conditions of Participations (CoPs)*, https://go.cms.gov/2EkD0r0 (listing organizations subject to CfCs and CoPs, which do not include physician practices). These enhanced requirements for hospital-based clinics recognize the broader context in which they are providing care, leading to more effective care coordination. Hospitals and their off-campus clinics share an integrated electronic health record, resulting in more effective information sharing and communication among providers across care settings, as well as more complete data collection to inform both treatment of patients in real-time and long-term hospital-wide efforts to improve quality and value. In addition, hospital-based clinics often can be staffed with professionals not traditionally found in clinic settings—including nurse care coordinators,

clinical social workers, community health workers, and patient navigators—who offer services that are not always reimbursed but are critical to care coordination.

To address social determinants of health, essential hospitals' off-campus clinics also offer a wide variety of wraparound services to better manage the social and environmental factors that impact the health of their patients. For example, since 2011, Eskenazi Health, a member of America's Essential Hospitals, has been "employing various providers of wraparound services that include[] behavioral health, social work, dietetics, respiratory therapy (for asthma education), patient navigation, pharmacist education, financial counseling, and a medical-legal partnership. These services [are] co-located at outpatient clinic sites, and patients [can] get referrals to these services through multiple pathways." J. Vest et al., *Indianapolis Provider's Use Of Wraparound Services Associated With Reduced Hospitalizations And Emergency Department Visits,* Health Affairs (Oct. 2018), https://bit.ly/2DS4pPE. Given the substantial language barriers faced by many living in communities served by essential hospitals, association members typically offer a wide range of translation services for patients who do not speak English as a primary language, a service that is much more difficult to provide in physician office settings. *See* L. Ku and G. Flores, *Pay Now Or Pay Later: Providing Interpreter Services In Health Care,* Health Affairs (Mar./Apr. 2005), https://bit.ly/2TWqval (citing the logistical challenges of providing adequate language services in physician offices as compared to a hospital setting).

Essential hospitals also dedicate resources to programs aimed at alleviating food insecurity in their communities. In the Minneapolis area, Hennepin County Medical Center supports approximately 3,000 households and 7,600 people every month through its food shelf program. It provides food to more than 25 hospital-based clinics and 7 community clinics for distribution to various patient groups. The outpatient setting allows Hennepin to offer patients

tailored meals and health education in the neighborhoods where they live and work. Similarly, Eskenazi Health in Indianapolis addresses food insecurity in one of its most vulnerable neighborhoods through its Crooked Creek Food Pantry. Essential Hospital Institute, *Food Insecurity, Health Equity, and Essential Hospitals* (June 2016), https://bit.ly/2EgY4hS; Crooked Creek Food Pantry, *About,* https://www.ccfpindy.org/our-team. The hospital partners with a local church to run a food pantry through its hospital-based clinic, located in the heart of a food desert. The clinic also serves as a community resource for connecting patients and residents with educational opportunities and additional programs and supports. These off-campus programs and countless others like them illustrate the expansive role played by essential hospital clinics in meeting critical community needs and eliminating barriers to good health.

Essential hospitals also have been leaders in coordinating and integrating physical and behavioral health in the outpatient setting, co-locating mental health and substance use disorder services within primary care clinics. Essential Hospitals Institute, *Behavioral Health and Primary Care Integration at Essential Hospitals* (Oct. 2015), https://bit.ly/2IpyBqR. Boston Medical Center (BMC), for instance, has been a national leader in developing an innovative, clinic-based program to improve treatment for patients with opioid addiction. Essential Hospital Institute, *The Opioid Crisis: Hospital Prevention and Response* (June 2017), https://bit.ly/2V5TCIo. After observing that many community-based physicians lacked adequate resources and support to obtain authorization to administer buprenorphine, an important tool for combating opioid addiction, BMC adopted its multidisciplinary Office-Based Opioid Treatment Program, deploying addiction-trained nurses to partner with physicians in primary care clinics to extend evidence-based treatment into the community. The program has resulted in an increase in the number of prescribing physicians by 530 percent in 10 years and expanded access to

buprenorphine treatment, particularly among traditionally underserved populations. American Hospital Association, *Boston Medical Center – STATE OBOT-B,* https://bit.ly/2SbAcA3. BMC was able to leverage its system-wide resources to invest in this program in a way that would be difficult to impossible for most freestanding physician offices.

Additionally, many hospitals are deploying "transitions of care," clinics co-located with hospital-based off-campus primary care clinics, to help reduce hospital readmission rates. These clinics provide follow up care, monitoring, and education, integrated with the inpatient setting from which the patient was discharged, and have been shown to have a significant downward impact on readmission rates. Tamer Hudali et al., *Reducing 30-Day Rehospitalization Rates Using a Transition of Care Clinic Model in a Single Medical Center,* Advances in Medicine (August 2017), https://bit.ly/2DTwXby.

In sum, patient complexity, medical needs, and access <u>*are*</u> driving patients to hospital-based clinics for care. Many patients—particularly low-income patients—receive better, more comprehensive, and more affordable care in these clinics than would otherwise be available. Essential hospitals have relied on their clinic networks to improve the quality, efficiency, and value of care that is provided to underserved populations.

B. CMS' Clinic Visit Policy Will Have Spillover Effects on Access to a Wide Variety of Ambulatory Services, Particularly for Underserved Populations.

1. CMS' Clinic Visit Policy Threatens the Viability of Excepted Clinics.

Given the more complex patient populations that off-campus clinics serve, the broader scope of services they provide, and the more stringent regulatory requirements they must meet, it should come as no surprise that they have higher costs than physician offices, as described in Plaintiffs' Memorandum (Pl. Mem. at 6-7). Medicare reimbursement through the traditional OPPS system has been critical to keeping these clinics' doors open. CMS' Clinic Visit Policy

threatens the viability of many excepted clinics grandfathered by Congress given the magnitude of the payment cuts—a 60% reduction for the most frequently performed service in the outpatient setting. *See* Boston Medical Center, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 24, 2018), https://bit.ly/2IpFyYJ. ("[T]he proposed site-neutral rule change could lead to . . . a potentially devastating financial picture for BMC and our [community health centers] as safety-net health care providers."); Henry Ford Health System, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 21, 2018), https://bit.ly/2GRBKNA ("[C]uts in the amounts proposed by CMS . . . would have a severe impact on our ability to provide care to uninsured and under-insured patients who need it most."); Hennepin Healthcare System Inc., *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 18, 2018), https://bit.ly/2GVWHXB (calling the payment rate adopted by CMS in its Clinic Visit Policy "too low to assure that patients can receive comprehensive, coordinated, and specialized medical care in accessible community locations").

For essential hospitals, the cuts are particularly devastating. These hospitals already operate on razor thin margins as noted above, and do not have the capacity to subsidize the losses that excepted clinics will sustain under CMS' Clinic Visit Policy. Essential hospitals provide high levels of uncompensated and unreimbursed care as part of their mission to provide access to all. In 2016, essential hospitals provided more than $5.5 billion in uncompensated care—nearly 14.4% of all uncompensated care provided at hospitals nationwide. *Characteristics Survey*. And with nearly 70% of outpatient care devoted to patients who are uninsured or who are insured through public programs, essential hospitals receive limited commercial revenues to cross-subsidize those losses. Given the high levels of uncompensated care they provide, essential

hospitals must stretch their limited margins (half that of all hospitals nationwide) to make necessary capital and infrastructure investments, forcing difficult decisions and tradeoffs. As a result of CMS' Clinic Visit Policy, many essential hospitals will have no choice but to cut services in excepted clinics or close them altogether.

2. If Excepted Clinics Close, Access to Care Will Be Threatened.

In the Final Rule, CMS focuses only on the availability of the particular clinic visit service at issue (HCPCS code G0463), and implies that because patients can "safely" receive the clinic visit service in physician offices, the Clinic Visit Policy will not impede access for patients. Final Rule at 59,008-09. But whether the clinic visit service can be provided safely in a particular setting for the average patient is just the tip of the iceberg, particularly for low-income patients who face substantial practical barriers to accessing care. To assess whether patients of excepted clinics will continue to have access to services if those clinics close, numerous additional questions need to be asked. Do other providers in the community accept low-income patients? Do patients have access to transportation to reach other community-based providers? Are there barriers to receiving timely care in other settings? Will other care settings meet the full range of patients' clinical and social needs? In other contexts, including in connection with its recently launched Rural Health Strategy to promote access to care, CMS has recognized these and other factors that create substantial barriers to access. CMS, *CMS Announces Agency's First Rural Health Strategy* (May 8, 2018), https://go.cms.gov/2V5FDCr ("CMS recognizes the many obstacles that rural Americans face, including living in communities with disproportionally higher poverty rates, having more chronic conditions, being uninsured or underinsured, as well as experiencing a fragmented healthcare delivery system with an overworked and shrinking health workforce, and lacking access to specialty services."). CMS apparently ignores those access concerns here. The Clinic Visit Policy will undoubtedly have an impact far beyond the

singular clinic visit service, restricting access to a broad range of outpatient services, particularly for low-income patients.

a. Patients of Excepted Clinics Will Lose Access to Clinic Visit Services.

As described above, essential hospitals' outpatient clinics predominantly serve the uninsured and patients with insurance from public programs, providing key points of access in communities with few other options. Many essential hospitals currently operate clinics in medically underserved areas (MUAs) and health professional shortage areas (HPSAs), where options for care are limited. MUAs are geographic areas or populations with "too few primary care providers, high infant mortality, high poverty, or a high elderly population." Health Resources & Services Administration, *MUA Find*, https://bit.ly/2SgP2VY; *see also* 42 U.S.C. §§ 254b(b)(3), 295p(6); 42 C.F.R. §§ 62.2, 62.22, 491.5. HPSAs are geographic areas or populations with shortages of primary care, dental, or mental health professional. 42 U.S.C. § 254e. In its comment letter to CMS on the proposed Clinic Visit Policy, essential hospital University of Illinois Hospital & Health Sciences System indicated that the policy will threaten its ability to serve patients in its outpatient Heart Clinic, which is located in a MUA and HPSA. University of Illinois Hospitals and Health Systems, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 24, 2018), https://bit.ly/2SQ2ZPW. Likewise, BMC's comment letter to CMS indicated that several clinics located in MUAs, including East Boston Neighborhood Health Center and Codman Square Health Center, will face severe payment cuts as a result of the Clinic Visit Policy. Boston Medical Center, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System*. The closure of clinics in MUAs and HPSAs would further restrict access to care in communities already facing access challenges.

Many physician offices will not be able to serve the low-income patients currently served in excepted clinics. Data from the Centers for Disease Control (CDC) shows that office-based physicians are far less likely to accept new Medicaid patients than privately insured patients, in part due to low reimbursement rates. M. Caffrey, *Physicians Far Less Likely to Take New Medicaid Patients, CDC Finds*, American Journal of Managed Care (July 20, 2017), https://bit.ly/2DP2fju. A newly released study commissioned by the Medicaid and CHIP Payment and Access Commission (MACPAC) confirmed the CDC data, finding that physicians are less likely to accept new patients with Medicaid coverage than patients with other forms of coverage. In particular, physicians in general and family practice are "markedly less likely to accept new Medicaid patients," accepting Medicaid patients at a rate of only 68.2%, compared to private insurance at 91%. The same is true of psychiatrists, who accept Medicaid patients at a rate of only 35.7%, compared to private insurance at 62.2%. MACPAC, *Physician Acceptance of New Medicaid Patients* (Jan. 2019), https://bit.ly/2TWGeX3; *see also* Institute of Medicine, *Transforming Health Care Scheduling and Access* at 29 (2015), https://www.nap.edu/download/20220 (IOM Access Report) ("Medicaid patients, both adults and children, are limited in their access to health care, by virtue of limited acceptance among physicians of Medicaid payments.").

Uninsured patients also are less likely to have access to services in freestanding physician offices. Essential hospitals have established financial assistance and charity care policies that extend to off-campus clinic locations, making care more affordable there. Indeed, all tax-exempt hospitals are required by law to have widely publicized financial assistance policies in place to provide discounts to low-income patients and to avoid excessive collection efforts until the hospital is able to determine the patient's eligibility for such financial assistance. I.R.C. § 501(r).

Many physician offices by contrast require an up-front down payment or payment in full at the time of service from uninsured patients, eliminating access for low-income patients who cannot afford to pay up to hundreds of dollars out-of-pocket at one time. Brendan Saloner, et al., *Most Primary Care Offices Do Not Offer Reduced Price Care to the Uninsured, Study Finds,* Health Affairs (Apr. 2018), https://bit.ly/2EECd0J. While office-based physicians sometimes provide charity care, "the amount … they provide on average is very small, varies considerably across specialties and practice types, and has been declining in recent years." Peter Cunningham et al., *Identifying Affordable Sources of Medical Care among Uninsured Persons*, 42 Health Serv. Research, 265, 266 (2007), https://bit.ly/2SNRB7c. One survey found that slightly over half of physicians provide an average of just three hours of charity care per week. T. Coughlin et al., *Uncompensated Care for the Uninsured in 2013: A Detailed Examination*, Kaiser Family Foundation (May 2014), https://bit.ly/2DScX9c (citing the 2009 American Medical Association's Physician Practice Information Survey).

Even where clinic visit services are technically available in another clinical setting that accepts low-income patients, the location may not be accessible. In many instances, without the transportation assistance that essential hospitals have provided to their patients, low-income and disabled patients would otherwise be unable to arrange transportation to community-based locations. *See* S.T. Syed et al., *Traveling Towards Disease: Transportation Barriers to Health Care Access*, J. Community Health (Oct. 2013), https://bit.ly/2uRtkOl. If excepted clinics close, these patients will either forego care altogether, or they will rely on the more expensive emergency department setting for services because ambulances provide a means of transportation to access care.

Beyond transportation, low-income patients often experience other barriers to receiving timely care outside the hospital setting. Many low-income patients report long waits for an appointment with a physician, particularly for specialty care. *See* IOM Access Report at 10 ("[C]hildren with coverage from Medicaid or the Children's Health Insurance Program are more likely than those with private insurance to be made to wait more than 1 month, even for serious medical problems."); MACPAC, *Medicaid Access in Brief: Adults' Experiences in Obtaining Medical Care* (2016), https://bit.ly/2IpAP9H (reporting that low-income adults with Medicaid coverage and adults with a disability covered by Medicaid were more likely to wait more than two weeks for an appointment than similarly situated individuals with private insurance).

Essential hospital clinics are better equipped to address these barriers, offering extended hours and scheduling flexibility because they are integrated with hospitals and have access to additional resources. *See* IOM Access Report at 47 (recommending that health care organizations move "from siloed, independent, and fragmented to integrated, aligned consultative, with shared accountability" in order to improve scheduling and access to health care); *see also* Commonwealth Fund, *Ensuring Equity: A Post-Reform Framework to Achieve High Performance Health Care for Vulnerable Populations* (Oct. 2011), https://bit.ly/2TXnEOy (identifying "[p]romoting greater clinical integration in safety-net health care systems" as a strategy to improve access to care for vulnerable populations). Hospital-based clinics have more opportunities to optimize staffing, as they can rely on care teams and non-physician practitioners to facilitate timely and effective care. Parkland Health and Hospital System (Parkland) in Texas, for instance, submitted comments on the Final Rule describing how it gives clinic patients 24-hour access to a nurse line for immediate concerns. Parkland's clinics also "routinely hold open spots in the schedule to assure that patients needing to see a caregiver on an urgent basis

can be seen as quickly as possible." Parkland Health and Hospital System, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 24, 2018), https://bit.ly/2GQ2Ch8. In addition, with integrated health records, hospital-based clinics can more easily use telemedicine and other technology-based strategies to connect patients to appropriate clinicians regardless of location and provide care outside of regular business hours. In short, even if clinic visit services are provided safely in physician offices, those offices may not be accessible for many patients currently served by excepted clinics.

b. Patients of Excepted Clinics Will Lose Access to Specialty and Support Services.

Many services offered in essential hospitals' excepted clinics simply are not available in other community-based settings or are not safely available in physician offices. *See* Laurie E. Felland et al., *Improving Access to Specialty Care for Medicaid Patients: Policy Issues and Options*, The Commonwealth Fund (June 2013), https://bit.ly/2EiHLB6 (safety net hospitals are partnering with Medicaid programs, Medicaid health plans and community health centers to improve access to specialty care); Ctr. For Studying Health System Change, *Suburban Poverty and the Health Care Safety Net* (July 2009) (examining access to specialty services in suburban communities surrounding five major cities and observing that the "suburbs examined typically have *at most one* [community health center] organization and small free clinics and/or hospital outpatient clinics") (emphasis added). Physician offices are not always an adequate substitute for hospital-based clinics, as CMS presumes. Freestanding physician offices often must refer patients to hospital-based sites for specialty care and other comprehensive services. *See* Florida Hospital Association*, Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 20, 2018), https://bit.ly/2V5TCIo. Likewise, a recent survey of non-hospital-based community health centers (CHCs) in the state of Washington reported that

"[t]wenty-five percent of patients who present to CHCs require specialty and diagnostic services that are not provided by the centers." Mabel C. Ezeonwu, *Specialty-Care Access for Community Health Clinic Patients: Processes and Barriers*, 11 J. Multidisciplinary Healthcare 109 (2018), https://bit.ly/2IpmQAN. If essential hospital clinics close their doors, many patients will be diverted not to physician offices or other non-hospital sites, but to emergency departments for less convenient, and often more costly, care. *See, e.g.*, Ctr. For Studying Health System Change, *Suburban Poverty and the Health Care Safety Net* (July 2009) (concluding that lack of access to specialty services in suburban areas leads to greater emergency department use).

Patients receiving care in non-hospital-based settings also will lose access to the comprehensive care coordination services that hospital-based clinics can provide. When community-based physicians are not an integrated part of the hospital, communication gaps and challenges often lead to delayed or duplicative services, ineffective documentation of services in patient records, and limited follow-up with patients, all of which result in poorer patient outcomes. Mabel C. Ezeonwu, *Specialty-Care Access for Community Health Clinic Patients*; IOM Access Report at 24, 62 (reporting that inefficiencies in care coordination cause prolonged wait times and delayed access to care). Coordinated care is particularly important given the complexity of the patients treated in hospital-based clinics, many of whom have multiple chronic conditions.

Finally, few physician offices have the staffing or financial capacity to provide the non-clinical supportive services that essential hospitals offer in excepted clinics, such as nutrition, language, transportation, health literacy education, and housing assistance. These often non-reimbursable services may be as important to patient health as the clinical services that patients receive. America's Essential Hospitals member Hennepin Health, for example, found that

patients who received access to housing through interventions deployed across its hospital-based sites experienced "appreciable improvements in health." Martha Hostetter et al., *Hennepin Health: A Care Delivery Paradigm for New Medicaid Beneficiaries*, The Commonwealth Fund (Oct. 7, 2016), https://bit.ly/2Sg0cul. More specifically, Hennepin's patients who received housing:

- Were admitted to a hospital 16% less often;
- Visited the emergency department 35% less often;
- Visited the psychiatric emergency department 18% less often; and
- Received outpatient clinic visits (including primary care) 21% more often. *Id.*

Physician offices cannot replicate the level of socially supportive, culturally sensitive care that essential hospitals provide in excepted clinics.

In sum, patients will have more difficulty accessing primary care, specialty care, and supportive services that are critical to health if excepted clinics do not remain open to serve them. CMS' Clinic Visit policy, if upheld by the court, will greatly diminish access to care, particularly for low-income populations.

c. Access Concerns Are Reflected in the Recommendations of the Medicare Payment Advisory Commission (MedPAC).

Essential hospitals are not the only party concerned about access. MedPAC, the non-partisan agency that advises Congress on Medicare payment policies, shares this concern and conveyed it to Congress prior to its adoption of the legislation shielding excepted clinics from the site-neutral payment policy. Although MedPAC has advocated for site neutral payments for certain outpatient services, it also has recognized the negative impact payment cuts will have on access to hospitals serving a large share of low-income patients. More specifically, in estimating the impact of site neutral policies, MedPAC has found that as a category, hospitals serving low-

income populations will bear a disproportionate share of payment cuts, with government hospitals losing 1.0% of *overall* Medicare revenues, compared to only 0.2% for for-profit hospitals. Thus, MedPAC has expressed "concern[] that some of the hospitals losing the most Medicare revenue provide ambulatory physician services to many low-income members of their communities. Large reductions in Medicare revenue for these hospitals may adversely affect access to ambulatory physician services in these low-income populations." MedPAC, *Report to the Congress: Medicare Payment Policy* 77 (Mar. 2012), https://bit.ly/2IkCk8P; MedPAC, *Comment Letter on Proposed Rule to Change the Hospital Outpatient Prospective Payment System* (Sept. 21, 2018), https://bit.ly/2NfheaX. Unlike CMS, MedPAC has recognized that a "prudent purchaser" of health services must consider not only whether a "service can be safely provided in different settings," but must also consider "the resources needed to treat patients in the most efficient setting, adjusting for differences in patient severity, to the extent that severity differences affect costs." MedPAC, *Report to the Congress* at 73. Again, focusing only on the safety of furnishing clinic service G0463 in physician offices, CMS summarily and unreasonably dismissed MedPAC's access concerns. Final Rule at 59,010.

C. Efficiency Gains Realized by Integrated Hospital-Based Clinic Systems Are Threatened Under the Clinic Visit Policy.

While CMS' Clinic Visit Policy may lower payments on a per-service basis in the short-term, over the long-term, the policy may increase costs on a per-capita basis, further straining the finances of essential hospitals. Essential hospitals have for many years relied on off-campus clinics to reach previously underserved patients, and the integration, coordination, and social support that hospital-based status has facilitated has been essential to effectively managing those patients' complex care needs while controlling costs. For example, Eskenazi Health found that its wraparound services described above resulted in cost savings of $1.4 million annually due to

potentially avoided hospitalizations. J. Vest et al., *Indianapolis Provider's Use Of Wraparound Services Associated With Reduced Hospitalizations And Emergency Department Visits,* Health Affairs (Oct. 2018), https://bit.ly/2DS4pPE. With the closure of excepted clinics, care will once again become more fragmented, threatening to reverse the gains essential hospitals have achieved in reducing readmissions, reducing emergency department visits, and eliminating duplicative services as described above.

A recent study indicates these concerns are well founded. A statistical analysis of Medicare payments published in the Journal of Healthcare Financial Management demonstrated that the hospitals most impacted by site neutral payment policies—those with extensive networks of hospital-based off-campus clinics—"produce much better value compared with hospitals receiving little payment for these services." J. James Rohack et al., *Why Medicare Should Recognize the Value of Provider-Based Clinics,* Healthcare Financial Management Association (July 2015). They achieve higher levels of efficiency on an important measure of resource use (the Dartmouth Atlas End-of-Life measure) and have lower rates of readmissions despite serving a higher than average caseload of indigent or underserved patients. *Id.*

The experiences of America's Essential Hospitals member Henry Ford Health System (HFHS), as reported to CMS in its comment letter on the Final Rule, also are instructive. HFHS is a large, integrated health care system, with five acute-care hospitals, an inpatient psychiatric facility, and a longstanding network of 40 outpatient medical facilities staffed by members of the Henry Ford Medical Group (HFMG). The majority of HFHS' outpatient encounters (350,000 of 517,000) occur in off-campus clinics, making HFHS one of the 200 hospitals that will bear almost 80% of the cuts under CMS' Clinic Visit Policy according to CMS data. Henry Ford Health System, *Comment Letter on Proposed Rule to Change the Hospital Outpatient*

Prospective Payment System. In part due to efficiencies gained through its use of provider-based clinics, HFMG has maintained costs that are substantially lower than other practices in the same geographic area. *See* WB Weeks et al., *Higher Health Care Quality and Bigger Savings Found at Large Multispecialty Medical Groups*, Health Affairs, 29(5), pp. 991-97 (2010), https://bit.ly/2GTGdzt (comparing costs of physician practices, including HFMG, in 22 markets and in an online appendix, available at https://bit.ly/2Xh8E07, graphically depicting practices with lower per capita costs than other physician groups in the same market). In other words, HFHS has been able to find efficiencies across episodes of care that offset the costs to CMS of higher OPPS payment rates for clinic visits. CMS' Clinic Visit Policy could unwind those efficiencies, leaving HFHS, which in 2017 reached an uncompensated care burden of $443 million, to bear the cost. Henry Ford Health System, *Comment Letter.*

D. CMS' Clinic Visit Policy Will Undermine Access in a Manner Congress Deliberately Sought to Avoid.

America's Essential Hospitals asks this court to consider the real-world impact of CMS' Clinic Visit Policy as outlined in this brief not in an attempt to ask the court to substitute its policy judgment for the agency's. To the contrary, a full appreciation of the consequences of the policy is integral to the court's understanding of the extent to which CMS substituted its policy judgment for that of Congress.

Congress enacted Section 603 at a time when MedPAC and the Government Accountability Office, among others, were calling for Congress to adopt site neutral policies applicable to all off-campus hospital-based clinics, then existing and in the future. MedPAC, *Report to Congress*; GAO, *Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform* (Dec. 2015), https://bit.ly/2Xenp3p. Congress rejected that approach in Section 603. While Congress desired for Section 603 to stem the tide of *future* hospital acquisitions of

physician practices, it carefully crafted a grandfathering provision to ensure that off-campus clinics that were billing under the OPPS prior to the law's enactment continued to receive higher OPPS payment rates. Pub. L. No 114-74 § 603, 129 Stat. 584, 598 (2015). Concerns about the unintended consequences of applying the policy to existing clinics clearly motivated the congressional choices made.

In letters to CMS in connection with rulemaking to implement Section 603, a majority of members of both the House and Senate made clear that they deliberately chose not to dismantle the extensive networks of off-campus clinics that hospitals had established prior to the law's enactment in order to preserve access for patients in that care setting. Letter from Senator Rob Portman et al. to Andrew M. Slavitt, Acting Administrator, CMS (May 19, 2016), https://bit.ly/2GQtm0Y ("[W]e write to underscore the importance of including flexibilities to enable hospitals to continue to serve patients in [off-campus outpatient] settings."). In a follow-up letter, a bipartisan group of Senators criticized much more modest regulatory proposals than those at issue in this case, stating "[t]he facilities impacted by this rule provide care to the most vulnerable patient populations in difficult to serve areas, and a number of changes in the rule are needed to ensure they can continue serving their communities. . . . If finalized, these regulations would cripple the ability of hospitals to provide community-based outpatient care to seniors." Letter from Senator Rob Portman et al. to Andrew M. Slavitt, Acting Administrator, CMS (Oct. 3, 2016), https://bit.ly/2tw3Juy. Yet the dismantling that Congress sought to avoid is exactly what will occur if CMS' Clinic Visit Policy is upheld. This is not an area where Congress left any ambiguity for the agency to interpret. The court should uphold the clearly expressed policy decisions adopted by Congress and strike down the Clinic Visit Policy.

IV. CONCLUSION

This court should not be misled by CMS' attempt to frame its Clinic Visit Policy as a reimbursement cut for a single service or a necessary step to prevent volume growth driven solely by payment incentives. On the contrary, this policy obliterates Congress' carefully designed compromise that recognizes and protects good faith efforts by essential hospitals and others to establish community-based points of access to care. The real-world impact of the policy on access and costs will be substantial, with implications not just for Medicare patients, but for all low-income and underserved patient populations. America's Essential Hospitals urges this court to grant the Plaintiffs' Motion for Summary Judgment and grant the relief requested.

CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system.

By: /s/ Barbara D.A. Eyman

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of the Local Civil Rule 7(o). This brief contains less than 25 pages, exclusive of the Table of Contents, Table of Authorities, Attorney identification, and Certificates of compliance.

Dated: February 21, 2019

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