



AMERICA'S ESSENTIAL HOSPITALS

October 5, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave. SW
Washington, DC 20201

Ref: CMS-1734-P: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates the Centers for Medicare & Medicaid Services' (CMS') proposals that recognize the importance of telehealth in expanding access and would encourage the continuation of flexibility that benefits vulnerable populations. We also support the agency's work to encourage improved care delivery across the health care industry but are concerned by the significant quality changes proposed in the Medicare Shared Savings Program (MSSP) and Quality Payment Program (QPP). We also are deeply troubled by the continued cuts to Medicare payments for off-campus provider-based departments (PBDs) under the Bipartisan Budget Act of 2015 (BBA). These changes come at a time when providers at essential hospitals are responding to the challenges and uncertainty caused by the COVID-19 public health emergency (PHE) and serving many of the communities hardest hit by the pandemic in the United States.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a

vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care (UC), 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 one-third that of other hospitals—2.5 percent on average compared with 7.6 percent for all hospitals nationwide.¹

Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. 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 hospital 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 essential hospitals are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

CMS should further examine the significance of the proposed quality changes in the MSSP and how they could adversely impact accountable care organizations (ACOs). These changes, including removal of the CMS Web Interface and required reporting of data via the newly proposed APM Performance Pathway (APP), come at a time when ACOs are continuing to respond to COVID-19. Further, many ACOs still are adapting to the agency's overhaul of the MSSP, which created new participation tracks in 2019.

We support CMS' work to identify measures and activities that appropriately assess performance, promote quality of care, and improve outcomes through the Merit-based Incentive Payment System (MIPS) and alternative payment models (APMs) under the QPP. We urge CMS to be thoughtful in its approach and timeframe for adoption of the new APP to ensure success across providers and settings. To ensure alignment across Medicare programs and allow all providers the flexibility needed to be efficient and successful under the QPP, CMS should consider our recommendations before finalizing calendar year (CY) 2021 updates to the program.

Improving care coordination and quality while staying true to a mission of helping those in need can be a delicate balance. To ensure our members have sufficient resources to advance their mission and are not unfairly disadvantaged for providing comprehensive care to complex patients, we urge CMS to consider the following recommendations when finalizing the abovementioned proposed rule.

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 September 14, 2020.

² Ibid.

1. 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’ excepted and non-excepted PBDs.

As mandated by Section 603 of the BBA, CMS on January 1, 2017, discontinued paying certain off-campus PBDs under the Outpatient Prospective Payment System (OPPS). The BBA instructed CMS to pay these non-excepted PBDs under a Part B “applicable payment system” other than the OPPS; CMS determined the Physician Fee Schedule (PFS) to be such a system. America’s Essential Hospitals urges CMS to reimburse non-excepted PBDs of essential hospitals 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.

Since 2018, CMS has established an interim payment rate under the PFS for non-excepted items and services provided at non-excepted off-campus PBDs that is equivalent to 40 percent of the OPPS payment rate. To public knowledge, CMS has not analyzed how reduced reimbursement would affect patient access to care in PBDs or the differences between the patients treated at PBDs and physician-owned offices. Reduced payments to off-campus PBDs already impede the ability of essential hospitals to provide care to vulnerable patients in their off-campus PBDs. We therefore urge CMS to ensure essential hospitals are adequately reimbursed for complex services provided in their PBDs.

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 disproportionately 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.

CMS’ application of Section 603 has 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. A significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for Medicare and Medicaid, which is a key indicator of patient complexity. Dual-eligible beneficiaries tend to have poorer health status and are more likely to be disabled and costlier to treat compared with other Medicare beneficiaries.³ In fact, CMS uses a hospital’s proportion of dual-eligible beneficiaries as a proxy for adjusting the

³ Medicare Payment Advisory Commission. *Data Book: Health Care Spending and The Medicare Program*. June 2018. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf. Accessed September 15, 2020.

hospital readmission measures to recognize differences in sociodemographic factors. 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.

It is worth noting that PBDs must comply with provider-based regulations, which include requirements pertaining to billing, medical records, and staffing. For example, an outpatient department must be clinically and financially integrated with the main provider and have full access to services at the main hospital to qualify as a provider-based facility and receive Medicare reimbursement. The department also must integrate its medical records into the main provider's system. These and other requirements impose additional compliance costs on hospitals that freestanding physician offices do not bear.

CMS has acknowledged it cannot directly compare payment to hospital PBDs and freestanding clinics because payment under the OPSS accounts for the cost of packaging ancillary services to a greater extent than payment under the PFS. For many services paid under the OPSS, including comprehensive ambulatory payment classifications, CMS makes a single payment for the main service and related packaged services. Comparing payment under the OPSS and PFS without accounting for the higher level of packaging that occurs under the OPSS understates the costs of services in hospital PBDs.

The Medicare Payment Advisory Commission (MedPAC) in a June 2013 report discussed equalizing payment across settings. MedPAC noted that any adjustment in payment rates to hospital PBDs should account for the higher level of packaging in the hospital setting by paying the hospital department at a higher rate than the physician freestanding office.⁴ To adjust for the higher level of packaging in the OPSS, as well as higher costs incurred by essential hospital PBDs compared with freestanding offices, CMS should revise its payment rate for non-excepted items and services of essential hospital PBDs to at least 75 percent of the OPSS payment rate.

By paying non-excepted PBDs at 40 percent of the OPSS rate, CMS is grossly undercompensating hospitals for the services they provide to complex patients. We urge CMS to increase the payment rate for non-excepted PBDs of essential hospitals to adequately account for the higher acuity of patients they treat compared with physician offices and promote access to care in the nation's most vulnerable communities. Payment rates also should reflect the requisite resources, staff, and capabilities necessary for PBDs to both comply with other CMS regulations and provide high-quality care to all patients. Essential hospital PBDs offer culturally and linguistically competent care tailored to the disadvantaged patients in their communities. Whether due to the clinical complexity of their patients or the additional resources needed to provide translators and wraparound

⁴ Medicare Payment Advisory Commission. *Report to the Congress: Medicare and the Health Care Delivery System*. June 2013. http://www.medpac.gov/docs/default-source/reports/jun13_entirereport.pdf. Accessed September 15, 2020.

services, essential hospitals incur higher costs in treating their patients than other facilities. By considering the recommendations above, CMS can lessen the negative effect of Section 603 on disadvantaged patients' access to care.

2. CMS should expand vulnerable populations' access to lifesaving services by broadening the scope of telehealth reimbursement and lifting barriers to Medicare reimbursement for these services.

During the COVID-19 PHE, CMS has 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 continuation of such flexibility will be indispensable as essential hospitals continue to respond to COVID-19 and prepare for future outbreaks. This pandemic has demonstrated the effectiveness of telehealth in providing high-quality, cost-effective care while protecting patients and health care personnel from unnecessary exposure to coronavirus.

The key role technology can play in linking patients to access and high-quality care has become increasingly evident amid COVID-19. 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 responding to the COVID-19 pandemic, use 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. At essential hospitals, no-show rates among low-income patients have been significantly lower for telehealth visits compared with in-person visits. The ability to virtually access care helps overcome some of the usual barriers to care that low-income populations face. While the pandemic has demonstrated the usefulness of telehealth, the importance of telehealth will expand well past COVID-19, to include responding to future outbreaks, as well as ensuring the continuity of care for patients with acute and chronic conditions.

In the rule, CMS proposes changes to Medicare reimbursement for telehealth, including the addition of reimbursable services on a temporary and permanent basis, as well as seeking comment on payment for certain audio-only codes. We are encouraged that the agency is evaluating ways to extend flexibility on telehealth services, but as we note below, the agency should assess additional ways it can ensure beneficiary access through telehealth.

- a. CMS should permanently add a broad range of services to the list of Medicare reimbursable telehealth services.

Through previous rulemaking, CMS added more than 130 new services to the list of reimbursable Medicare telehealth services but only for the duration of the COVID-19 PHE. The services added during the PHE include physical and occupational therapy, behavioral health, audio-only evaluation and management (E/M), emergency department (ED), and critical care services. The addition of these services has been

crucial to essential hospitals responding to this pandemic—it enables them not only to assess potential COVID-19 patients, but also to monitor and treat patients with acute and chronic conditions unrelated to COVID-19.

CMS seeks comment on further adding to the list of reimbursable telehealth services either permanently or on a category-three temporary basis. Specifically, CMS proposes to add nine Healthcare Common Procedure Coding System (HCPCS) codes to the list on a category-one basis, meaning they will be permanent. Additionally, CMS proposes to add 13 HCPCS codes to the list of category-three services, which will be reimbursable as telehealth services until the end of the calendar year in which the COVID-19 PHE ends. The list includes levels one to three ED visit codes, as well as codes for psychological and neuropsychological testing.

We encourage CMS to permanently expand Medicare reimbursement for a wider variety of services. Provider and patient experiences with telehealth encounters during the pandemic make clear the value of telehealth to the provider-patient relationship. The ability to continue primary and specialty care visits remotely will be important as essential hospitals and their communities rebound from COVID-19. **To ensure continued access to lifesaving services, particularly for vulnerable populations facing barriers to care, CMS should permanently include those services added during the COVID-19 PHE to the list of Medicare reimbursable telehealth services.**

- b. CMS should allow reimbursement of certain services provided using audio-only technology.

Through other rulemaking during the pandemic, CMS allowed certain services to be provided using audio-only technology during the PHE. These codes include audio-only E/M services, as well as various codes for behavioral health assessments and evaluations. CMS also increased the reimbursement rate for audio-only E/M codes to equalize payment for these codes with in-person E/M visits. In the PFS rule, CMS does not propose to make permanent reimbursement for any audio-only E/M codes, which it added during the COVID-19 PHE. However, CMS seeks comment on making payment and coding changes that would reimburse for certain audio-only codes.

Essential hospitals and their patients benefited from this flexibility during the pandemic. The use of audio-only capabilities is beneficial 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. When the provider can deliver care and assess the patient without seeing the patient, it is entirely appropriate to offer these services through audio-only means. **We urge CMS to continue to reimburse a subset of services, and ensure parity for these services, conducted through audio-only technology.**

- c. CMS should include mobile phones in the definition of an “interactive telecommunications system” that can be used to participate in a telehealth service.

CMS should finalize its proposal to redefine “interactive telecommunications system” to include telephones with audio and visual capabilities. Under the Medicare statute, telehealth services must be provided through a qualifying telecommunications system. CMS previously defined the term “interactive telecommunications system” in its regulations as “video equipment permitting two-way, real-time interactive communication between the patient and [the provider].”⁵ However, that regulatory definition specifically excludes telephones from the definition. During the COVID-19 PHE, CMS redefined interactive telecommunications technology to include telephones that have two-way audio-visual functionality. Technology has evolved significantly since CMS first defined the term, to the extent that the vast majority of telephones possess video capabilities. Nearly all Americans (96 percent) own a mobile phone, and more than 4 in 5 Americans own a smartphone.⁶ The use of smartphone applications that meet appropriate privacy and security safeguards to participate in telehealth visits will enable more Americans to seamlessly access lifesaving health care services. We are encouraged that CMS has recognized this changing reality and is permanently redefining “interactive telecommunications system” to include mobile smartphones. **CMS should finalize this updated regulatory definition of interactive telecommunications system to permanently allow telephones with audio-visual capabilities to be used for the provision of a telehealth service.**

- d. CMS should facilitate the provision of communication technology–based services by allowing them for both new and established patients.

Separate from Medicare telehealth services, Medicare pays for communication technology–based services, which are services that do not have in-person equivalents, such as remote patient monitoring (RPM), virtual check-ins, and e-visits. Typically, these services are reimbursable by Medicare when they are provided to established patients of a provider or a patient of another provider in a practice. During the COVID-19 PHE, CMS permitted providers to offer these services to new and established patients. For RPM services, CMS allowed practitioners to monitor new and established patients for both acute and chronic conditions, as well as patients with only one disease. For example, RPM can be used to observe a patient’s oxygen levels through pulse oximetry. The benefits of communication technology–based services are equally applicable to new and established patients; this was demonstrated during the COVID-19 pandemic, when new patients sought to avoid exposure to health care facilities. This type of flexibility will be critical through the duration of the COVID-19 PHE, as well as in the future during new outbreaks of COVID-19 and in responding to other public health crises. **CMS should continue to allow these services to be reimbursed for new and established patients, and in the case of RPM, to be reimbursed for more types of conditions and for patients with only one condition.**

- e. CMS should remove restrictions on telehealth and continue to push for expanded access to high-quality care via telehealth services.

⁵ 42 CFR 410.78.

⁶ Pew Research Center. Mobile Fact Sheet. June 12, 2019. <https://www.pewresearch.org/internet/fact-sheet/mobile/>. Accessed July 13, 2020.

During the pandemic, CMS has used its amended Section 1135 authority to waive geographic and site-of-service restrictions on originating sites, allowing Medicare patients to receive telehealth services in a wide variety of settings, including their own home. In addition, CMS has allowed hospitals to bill an originating-site facility fee when the patient receives the service at their home. These changes have been transformative in paving the way for increased access to telehealth services, both for providers in the early stages of adoption and those with established telehealth footprints. It is imperative that these providers are able to reach patients facing barriers to care.

CMS should work with Congress to permanently eliminate the geographic and site-of-service restrictions on Medicare telehealth services. In practice, lack of transportation and other barriers to access prohibit more than just rural patients from timely access to care. Large populations in many urban areas are in health care deserts and are classified as medically underserved. Drawing a distinction between rural and urban underserved populations artificially restricts access to health care for those who need it most. Even if these patients live in heavily populated urban areas, receiving a timely telehealth service from a physician can result in the early diagnosis of a life-threatening condition and play an important role in providing cost-effective follow-up care. Outside the context of COVID-19, CMS allows originating-site flexibility in limited circumstances, such as for telestroke services and ACOs. CMS can encourage the continued push toward coordinated care and improved care access by working with Congress to remove geographic and site-of-service restrictions to care.

CMS should appropriately reimburse hospitals for the costs associated with maintaining technology, staff, and overhead expenses related to health information technology (IT) infrastructure that is capable of supporting telehealth services. When a Medicare service is provided in-person, hospitals typically are reimbursed for the facility fee under the OPPS to cover the costs of personnel, equipment, supplies, and other overhead. Though furnishing telehealth services to patients doesn't require the patient's physical presence within the walls of a hospital, these services nonetheless require significant hospital and staff resources. Hospitals incur substantial costs investing in telehealth technology and maintaining staff and equipment to ensure operation of their platforms. CMS recognized this by allowing hospitals to bill an originating-site facility fee for services provided through telehealth as long as the patient is a registered outpatient of the hospital, even if the patient receives the service from their home. **We encourage CMS to work with Congress to ensure adequate hospital reimbursement for costs associated with providing Medicare telehealth services.**

3. CMS should continue to refine the methodology and measure set used to establish ACO quality performance under the MSSP, delay implementation of the APP for MSSP ACOs, and retain the pay-for-reporting year for ACOs.

CMS proposes significant changes to quality reporting under the MSSP, effective for performance year 2021 and subsequent performance years. Specifically, CMS would require ACOs in the MSSP to report quality data via the newly proposed APP. Under this new approach, ACOs would report a smaller set (six versus 23) of quality metrics

that would satisfy the reporting requirements under both MIPS and the MSSP. We urge CMS to be thoughtful in its approach for adoption of the APP, and other drastic changes to the MSSP, at a time when ACOs are faced with ongoing concerns related to the COVID-19 pandemic.

- a. CMS should further engage stakeholders before implementing the APP for ACOs participating in the MSSP, and the agency should seek feedback on the APP measure set to ensure reliability and fairness and prevent unintended consequences.

We understand CMS' desire to align the MSSP quality performance standard with the proposed APP under the QPP, such that participants in the MSSP also would report quality via the APP. While we support greater alignment and reduced burden, introducing a new pathway such as the APP requires careful consideration.

CMS notes the APP was designed for all MIPS APMs. However, the agency believes the APP measure set also would be appropriate for ACOs participating in the MSSP. The APP contains a narrower measure set than previously used in MSSP quality measurement—six measures versus the current 23 scored measures. The six measures are related to patient experience, diabetes, depression screening, blood pressure control, all-cause unplanned readmissions, and all-cause unplanned admissions for multiple chronic conditions.

We applaud CMS' intent to move the quality measure set used in the MSSP toward more outcome-based, primary care measures. However, **we do not feel the current proposed APP measure set achieves this goal.** As quality reporting programs focus more on outcomes and move away from process measures, CMS must ensure that measures chosen for these programs accurately reflect quality of care and account for factors beyond a hospital's control. **The agency should ensure the measure set includes metrics that are valid and reliable; aligned with other existing measures; and risk adjusted for sociodemographic factors.** CMS should not include measures in ACO quality performance standards until they have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status. Without appropriate risk adjustment for outcomes measures, such as the proposed readmission measure, the APP measure set could disproportionately impact the performance of essential hospitals.

We urge CMS to take time to gather more stakeholder input, such as through a request for information and listening sessions. Further, CMS should seek endorsement by organizations with measurement expertise, such as the National Quality Forum (NQF) and its Measure Applications Partnership (MAP). Through NQF processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders. Measures should undergo review and obtain NQF endorsement before inclusion in the APP.

- b. CMS should not remove the pay-for-reporting year for MSSP ACOs.

Currently, in the first year of an ACO's first agreement period, all measures are scored as pay-for-reporting, meaning ACOs must completely and accurately report all quality data used to calculate and assess their quality performance. In the second and third year of the first agreement period and all years of subsequent agreement periods, measures are scored as pay-for-performance.

CMS notes that under its proposal to require that ACOs report quality via the APP, there would be "no quality 'phase in.'" In other words, all ACOs, regardless of performance year and agreement period, would be scored on all measures in the APP for purposes of the MSSP quality performance standard. There is value and necessity in providing ACOs, their clinicians, and staff at least one year of preparation before they are held accountable for performance on these measures. **We oppose the removal of the pay-for-reporting year, as it would harm ACOs new to the program.**

4. CMS should continue to refine the QPP by delaying implementation of the new MIPS Value Pathways (MVPs), increasing the complex patient bonus for MIPS, and seeking further input from stakeholders before implementing the new APP.

Implementation of the QPP in CY 2017 consolidated three existing physician quality programs into the MIPS. CMS previously finalized a methodology for assessing the total performance of each MIPS-eligible clinician through a composite score based on four categories: quality, cost, clinical practice improvement activities, and promoting interoperability.

CMS proposes changes to the QPP starting January 1, 2021. The 2021 performance period impacts clinicians' payment in 2023. Among those changes is CMS' decision to delay implementation of MVPs, while simultaneously proposing another pathway—the APP—as a voluntary MIPS reporting and scoring pathway for eligible clinicians participating in MIPS APMs.

- a. CMS should delay implementation of the new MVPs and seek feedback from stakeholders on specific MVP proposals to ensure this approach is responsive to clinician needs.

CMS intended to begin transitioning to MVPs in the 2021 MIPS performance year; however, due to the COVID-19 PHE and need for clinician focus on response, CMS has shifted its timeline such that the proposal for initial MVPs will be delayed until at least the 2022 performance year. **We thank CMS and support the delay in implementing these new pathways for clinicians.**

The agency limits its MVP-related proposals to updates to the MVP guiding principles and further definition of the MVP framework. We support the agency's desire to thoughtfully approach the framework and principles that ultimately will guide the development of this new pathway for clinicians. However, to ensure success in adoption of MVPs, clinicians and other stakeholders will need to review and respond to specific proposals, not yet formulated by the agency. CMS itself notes that implementation of

MVPs likely will be informed by future recommendations, such as those resulting from National Health Quality Roadmap activities that have yet to transpire.

Additionally, we encourage CMS to consider the populations served by essential hospitals—those with complex medical and social needs—as part of the MVP development process. The mission to integrate health equity into care delivery and develop initiatives that target social determinants of health is embedded in the fabric of essential hospitals. Our members reach beyond their walls to understand what promotes or hinders health in their communities and to partner with local organizations to deliver community-integrated health care. **We urge the agency to examine the unique role clinicians at essential hospital play in reducing disparities, as well as improvement activities that promote health equity.** We look forward to responding to future proposals related to the MVPs.

- b. CMS should finalize its proposal to increase the bonus points for MIPS-eligible clinicians who care for complex patients.

For the 2020 through 2022 MIPS payment years, CMS finalized a policy that provides consideration for MIPS-eligible clinicians who care for complex patients by adding a complex patient bonus of up to five points to their final score. CMS proposes to double the maximum complex patient bonus for the 2020 performance period (2022 MIPS payment year) due to the anticipated increase in patient complexity resulting from the COVID-19 PHE. Patients served by essential hospitals, who already are high-risk due to social factors beyond the control of the clinician, are disproportionately likely to be severely affected by COVID-19. **We support CMS' proposal to double the bonus points, from five to 10, available for MIPS-eligible clinicians who care for complex patients, and we urge the agency to consider further increasing the maximum points available.**

In looking at the first year of the MIPS, researchers found an association between patient social risk and physician performance. Namely, physicians with the highest proportion of socially disadvantaged patients (based on dual eligibility) had significantly lower MIPS scores.⁷ We urge the agency to create a permanent complex patient bonus for the MIPS and consider social risk factors—in addition to the Hierarchical Condition Category (HCC) and dual-eligible status—when determining patient complexity.

- c. CMS should seek further input from stakeholders before implementing the new APP and consider the impact of eliminating the APM Scoring Standard.

As proposed, ACOs in the MSSP would be required to report through the APP. However, for the QPP, CMS proposes that the APP would be an optional MIPS reporting and scoring pathway for MIPS-eligible clinicians participating in any MIPS APM. The APP approach would score MIPS-eligible clinicians on a fixed quality measure set. For performance year 2021, CMS proposes the same APP measure set (i.e., six measures) as discussed under proposals for the MSSP.

⁷ Khullar D, Schpero WL, Bond AM, Qian Y, Casalino LP. Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. *JAMA*. 2020;324(10):975–983.

We reiterate our concerns about the APP measure set, and in particular, the applicability of the proposed six measures for all APMs subject to MIPS. Further, as previously noted, the APP measure set should undergo review through a consensus-building approach that involves the NQF, MAP, and other such entities.

Additionally, CMS proposes to eliminate the APM Scoring Standard for the 2021 performance year. Instead, beginning January 1, 2021, APM participants would be allowed to participate in MIPS as individuals, groups, virtual groups, or APM entities and could report through any MIPS reporting and scoring pathway, including the new APP.

The APM Scoring Standard was designed to reduce reporting burden by eliminating the need for MIPS APM participants to submit data for both MIPS and their respective APMs. In other words, the APM Scoring Standard is tailored to and accounts for activities already required by the APM to reduce duplication of reporting and allow clinicians to focus on the goals of the APM. It is unclear whether the new APP, with its fixed quality measure set, is appropriate for MIPS APMs. **We urge CMS to ensure elimination of the APM Scoring Standard does not result in more burden for APM participants and to seek further input on the appropriateness of the APP's one-size-fits-all approach to quality measurement for MIPS APMs.**

5. CMS should finalize policies that reduce burden on clinicians in the promoting interoperability (PI) category of the MIPS and provide flexibility as providers transition to more difficult PI category requirements.

We urge CMS to finalize changes to the PI category that will reduce burden and enable providers to deliver high-quality, patient-centered care. Since CY 2017, CMS has required eligible clinicians to use certified electronic health record technology (CEHRT) to report on measures in the PI category, which counts for 25 percent of the MIPS composite performance score. In the 2019 final rule, CMS required clinicians exclusively to use the 2015 version of CEHRT. For 2020, CMS proposes to continue using the 2015 version of CEHRT. Further, CMS proposes several changes to the category to promote stability and reduce burden for providers.

- a. CMS should finalize a 90-day reporting period for CY 2022.

CMS should finalize its proposal to keep the 2022 PI category reporting period at 90 days, which will offer much-needed relief as clinicians continue to work toward interoperability. Following implementation of the 2015 version of CEHRT in 2019 and 2020, as well as additional measure changes in 2021, it will be crucial to provide physicians continuity in the PI category by maintaining a 90-day reporting period for 2022. Additionally, many PI category measures—such as those requiring the use of APIs and health information exchange (HIE)—are difficult for clinicians, so clinicians will benefit from more preparation time resulting from a shorter reporting period. Keeping a 90-day reporting period in place for 2022 will give clinician practices additional time to adjust to the new measures and make system changes necessitated by

new measures and the new scoring methodology. Accordingly, CMS should finalize the 90-day reporting period for CY 2022.

- b. CMS should keep the prescription drug monitoring program (PDMP) measure voluntary until the agency has adequate standards and specifications.

CMS should keep the PDMP measure voluntary until there is uniformity across states in the adoption of these practices, as well as adequate standards and certification criteria. Essential hospitals are on the front lines of treating patients most affected by the opioid crisis and have implemented innovative strategies to reduce opioid dependence. As leaders in population health, essential hospitals continue to develop programs that prevent opioid misuse among vulnerable populations. They partner with pharmacies, public health departments, law enforcement, emergency medical services, and other community providers to combat the crisis. Essential hospitals stand ready to implement practices proved effective in reducing opioid dependence. Using EHRs to fight the opioid crisis is a commendable goal, but there are significant barriers to the use of IT to report the PDMP measure in the Promoting Interoperability Programs (PIPs).

The PDMP measure requires eligible hospitals and critical access hospitals to use data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law. After initially proposing to require this measure in 2019, CMS reversed course and kept it voluntary. CMS again proposes to keep the measure voluntary in 2022, and we applaud the agency for this decision. While the measure is voluntary, we urge CMS to work with stakeholders toward PDMP integration.

The PDMP measure is not ready for inclusion in the PIPs because it lacks uniformity of adoption across states and providers. PDMPs are state-level databases that can increase provider awareness of at-risk patients and thus reduce prescription drug misuse, but they are unevenly used across the country due to varying state requirements. Not all states require the use of such programs and one—Missouri—does not even have a PDMP. Additionally, platforms differ by state, creating a lack of uniformity in accessing data and difficulty establishing standards for the use of EHRs to access such data. There are no standards or certification criteria for the use of PDMPs or their integration into EHRs. **CMS should work with other agencies to rectify this lack of uniform governance before requiring the use of these databases as part of the PIPs.**

In addition to the lack of standards and certification criteria, the use of PDMPs can cause workflow disruptions when practitioners check a patient's opioid medication history. Our members have indicated to us that accessing PDMPs can be an arduous process that requires the provider to close the EHR and input credentials to log on to a state PDMP website. In other words, a provider cannot always seamlessly access PDMP information from within the EHR when electronically prescribing a medication. **Until CMS can confirm PDMP integration and workflow issues are resolved, it should keep the PDMP measure voluntary.**

- c. CMS should continue to promote interoperability and HIE before adding requirements on HIE to the PI category of MIPS.

In the rule, CMS proposes adding an optional alternative measure—HIE bidirectional exchange—to the PI category of MIPS. This measure under the HIE objective would be worth a maximum of 40 points; it could be reported by clinicians instead of the two current measures (support electronic referral loops by sending health information and support electronic referral loops by receiving and reconciling health information) worth a maximum of 20 points each. For the alternative yes-or-no measure, clinicians would attest to three statements confirming they participated in an HIE that enables secure, bidirectional exchange, can exchange information across a broad network of unaffiliated exchange partners, and use CEHRT for this measure. While we appreciate that CMS is looking at ways to encourage information exchange across providers, there still is much progress to be made on HIEs and on providers' ability to participate in HIEs to exchange information. **To that end, we agree this should be a voluntary alternative measure because of the uneven uptake of HIE participation across the country.**

Clinicians at essential hospitals struggle with difficult measures in the PI category, particularly those requiring information exchange with other providers that might not have the same level of EHR functionality to engage in information exchange. All providers do not necessarily have the functionality to exchange information with other providers through HIEs. Some community providers might not have the functionality or might not even have CEHRT. Policymakers have taken steps to facilitate information exchange, but it will take more time before seamless information exchange is a reality.

The Office of the National Coordinator for Health IT (ONC) has conducted important work in promoting new technology for providers and encouraging increased interoperability. As directed in the 21st Century Cures Act, ONC in April 2019 released the second draft of the Trusted Exchange Framework and Common Agreement (TEFCA), which outlines a set of principles for trusted exchange to enable interoperability.⁸ ONC is expected to release a final version of the TEFCA later this year. CMS should allow ONC to continue its work of promoting interoperability before proposing new information exchange requirements.

In addition to creating the TEFCA, earlier this year, ONC and CMS finalized complex rules implementing information blocking and interoperability requirements of the 21st Century Cures Act. ONC's rule on information blocking and exchange addresses many important barriers to HIE and imposes new requirements on providers and EHR developers. These steps by ONC and CMS will set the groundwork for more widespread information exchange and use of HIEs. CMS should allow stakeholders to respond to this rulemaking and take necessary steps to implement its conditions before adding any required HIE measures.

⁸ Office of the National Coordinator for Health Information Technology. Trusted Exchange Framework and Common Agreement Draft 2. April 2019. <https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf>. Accessed September 14, 2020.

6. CMS should provide a more gradual transition away from the Web Interface reporting option in the MSSP and QPP to give providers time to assess alternatives and implement a new reporting method.

The CMS Web Interface is an internet-based data submission mechanism for ACOs and groups (or virtual groups) of 25 or more clinicians to report quality data to the QPP. CMS proposes to discontinue use of the Web Interface submission method in both programs for performance year 2021.

This is an abrupt end to a reporting option used by ACOs for many years. The remaining reporting methods include MIPS clinical quality measures (CQMs) and eCQMs. We appreciate options for ACOs to report quality measures. However, removing the Web Interface and pivoting quickly to an alternative reporting method will require time and resources to change workflows, pay for registries, and adapt EHRs to comply with eCQMs.

As noted, CMS also would sunset the Web Interface as a collection type for groups and virtual groups with 25 or more eligible clinicians, starting with the 2021 MIPS performance period. For clinicians in groups who previously used Web Interface as a collection type, CMS assumes these groups would use the other two collection types (MIPS CQMs and eCQMs) available in the 2021 MIPS performance period. CMS acknowledges in the proposed rule that the removal of the Web Interface might be burdensome to current groups submitting quality data through this channel. These groups will need to select a different collection type, redesign their systems to interact with the new collection/submission type, and modify clinical and MIPS data reporting workflows.

We urge CMS to provide a more gradual transition away from the use of the Web Interface reporting option to allow more consideration of practical implementation. We encourage CMS to, at minimum, continue the Web Interface for one additional year to provide ACOs and clinicians time to assess alternatives and implement a new reporting method.

7. CMS should expand the definition of opioid use disorder (OUD) treatment services to include naloxone and overdose education; adjust bundled payment rates accordingly for OUD treatment services furnished by opioid treatment programs (OTPs); and account for the resource costs involved with initiation of medication for the treatment of OUD in the ED.

As pillars of their communities and trusted providers for all, essential hospitals have seen firsthand how OUDs impact both the individuals affected and their surrounding communities. Essential hospitals continue to develop innovative programs to prevent opioid misuse among the most vulnerable populations and provide treatment to all who need it.

- a. CMS should include all three forms of naloxone and overdose education in the expanded definition of OUD treatment services, and adjust the bundled payment rates accordingly for OUD treatment services furnished by OTPs.

In the CY 2020 PFS final rule, CMS created new coding and payment options describing a bundled episode of care for treatment of OUD furnished by OTPs. In the same rule, CMS finalized a definition of OUD treatment services covering oral, injected, and implanted opioid agonist and antagonist treatment medications approved by the Food and Drug Administration (FDA). CMS proposes to extend the definition of OUD treatment services to include naloxone; this would increase access to this important emergency treatment, as well as allow Medicare payment to OTPs for dispensing the drug to beneficiaries receiving other OUD treatment services, such as medication-assisted treatment. America's Essential Hospitals supports increased access and care coordination in the treatment of OUD and other behavioral health conditions. **We support CMS' proposal to expand the definition of OUD treatment services to include naloxone.**

Additionally, CMS seeks comment on whether the definition of OUD treatment services should include education related to overdose prevention, and whether to establish an add-on payment for when such services are furnished by OTPs. Community education, as well as overdose education to the beneficiary and their family, helps increase awareness of treatment options and plays a key role in decreasing overdose deaths. Beneficiary communication about adverse effects of opioid use should address language barriers and low health literacy among patients served by essential hospitals. The populations that essential hospitals treat are likely to require more resources in the administration of educational materials related to opioid use, adverse effects, and alternative treatment options—both in staff time dedicated to oral explanation and the use of interpreters, as needed. It is important to provide additional support to essential hospital-based OTPs, which already operate with limited resources. **We support the inclusion of education in the definition of OUD treatment services, and we encourage CMS to establish an appropriate payment rate when such services are furnished by OTPs.**

Consistent with its proposal to expand the definition of OUD treatment services to include naloxone, CMS proposes to adjust the bundled payment rates to account for instances in which OTPs provide the drug. FDA approved injectable naloxone, intranasal naloxone, and naloxone auto-injector as emergency treatments for opioid overdose. As proposed, CMS would make payment for only two forms of naloxone—nasal and auto-injector—through an add-on code. **We support establishment of add-on codes for nasal and auto-injector naloxone, and we urge CMS to create an add-on payment for injectable naloxone.** In doing so, CMS will provide access to all three FDA-approved forms of naloxone as options for community distribution and use by individuals with or without medical training to reverse the effects of opioid overdose.

- b. CMS should account for the resource costs involved with initiation of medication for the treatment of OUD in the ED.

Essential hospitals are dedicated to prevention, both inside and outside their walls. These hospitals are leaders in implementing innovative programs that provide alternatives to opioids and working with their communities to increase awareness about the dangers of substance misuse. When substance misuse already is present, essential

hospitals use evidence-based, integrated approaches to identify and treat OUD, including medication-assisted treatment, peer addiction counseling, and referral to community-based services.

To account for the resource costs involved with initiation of medication for the treatment of OUD in the ED and referral for follow-up care, CMS proposes to create an add-on HCPCS G code to be billed with E/M visit codes used in the ED setting. This code would include payment for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services. CMS notes it would pay for the drug separately. **We support the creation of an add-on G code for initiation of medication for OUD treatment in the ED setting.**

Their disproportionately low-income, vulnerable patient populations put essential hospitals in a unique position to make a real and lasting impact on those living with OUD or in communities where the opioid epidemic is rampant. But treating this population presents challenges. Patients seeking this care at essential hospitals often face comorbid conditions or multiple addictions that make them more difficult and costly to treat. For example, for patients impacted by OUD as well as social determinants of health—lack of transportation or housing instability, for example—arranging access to supportive services requires more extensive time and coordination. CMS should adequately account for the increased resource costs involved with this patient population. We encourage CMS to increase the proposed 1.30 work relative value unit. Further, CMS should continue to monitor the use and effectiveness of the add-on G code to account for increased complexity and adjust the add-on code as necessary to ensure adequate reimbursement for OUD services.

8. CMS should continue allowing practitioner supervision requirements to be met using audio-video communications technology.

During the COVID-19 PHE, CMS modified the requirements for direct supervision by physicians or practitioners, allowing them to supervise the provision of services using real-time interactive audio-video communications technology. CMS proposes a continuation of this change, allowing direct supervision requirements to be met using real-time interactive audio-video communications technology through December 31, 2021. Similarly, during the COVID-19 PHE, CMS allowed teaching physicians to meet resident supervision requirements through audio-video real-time communications technology. CMS seeks comment on whether to extend this policy, as well. We are encouraged that CMS acknowledges the importance of using technology to meet supervision requirements. The requirements on physician and teaching physician supervision are outdated and do not account for the ability of physicians to oversee other practitioners, including medical residents, using interactive audio-video communications technology. **America's Essential Hospitals urges CMS to extend this flexibility as the agency removes unnecessary obstacles to the timely provision of patient care.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have 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