

September 10, 2018

Seema Verma, MPH 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-1693-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

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') work to encourage improved care delivery across the health care industry. We are concerned, however, about the effect of cuts to Medicare payments for off-campus provider-based departments (PBDs) under the Bipartisan Budget Act of 2015 (BBA). These cuts deter hospitals from expanding access in communities with the most need for health care services and run counter to CMS' goal of integrated, coordinated health care. Compounding these cuts is CMS' proposal to consolidate payment rates for evaluation and management (E/M) visits, which will disproportionately affect specialty providers serving the nation's most complex patients.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to providing high-quality care for all. While our membership represents just 6 percent of hospitals nationally, they provide 20 percent of all charity care nationwide, or about \$3.5 billion, and 14.4 percent of all uncompensated care, or about \$5.5 billion.¹ The high cost of providing care to low-income and uninsured patients leaves essential hospitals with limited financial resources. Even with their limited means, our member hospitals demonstrate an ongoing commitment to serving vulnerable patients. Essential hospitals provide

¹ Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2016 Annual Member Characteristics Survey. America's Essential Hospitals. June 2018. www.essentialdata.info/. Accessed August 13, 2018.

specialized services that their communities otherwise would lack (e.g., trauma centers, emergency psychiatric facilities, burn care); expand access with their extensive networks of on-campus and community-based clinics; furnish culturally and linguistically appropriate care; train health care professionals; supplement social support services; and offer public health programs.

America's Essential Hospitals is encouraged by CMS' proposals to reduce administrative burden in the Medicare Shared Savings Program (MSSP), but we continue to have concerns about the unintended consequences if quality measures do not adequately account for sociodemographic factors. We also believe CMS should clarify how proposed changes to the program's quality measure set might affect performance by accountable care organizations (ACOs) given the agency's recent proposals to overhaul the MSSP by creating new participation tracks starting in 2019.

We support CMS' work to identify measures and activities that appropriately assess performance, promote quality of care, and improve outcomes through the Meritbased Incentive Payment System (MIPS) and alternative payment models (APMs) under the Quality Payment Program (QPP). We urge CMS to rigorously monitor, evaluate, and modify the QPP to ensure success across providers and settings as the program continues. 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) 2019 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. This balance is threatened by payment cuts to hospitals, such as those in CMS' proposed payment policy for non-excepted PBDs and E/M visits. To ensure our members have sufficient resources to advance their missions and are not unfairly disadvantaged for providing comprehensive care to complex patients, we urge CMS to consider the following recommendations when finalizing the above-mentioned proposed rule.

1. CMS should ensure that non-excepted PBDs are adequately reimbursed for the costs of care.

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 at no lower than 75 percent of the OPPS payment rate. Doing so would ensure hospital PBDs are adequately reimbursed for the cost of providing comprehensive, coordinated care to complex patient populations in underserved areas.

In the CY 2017 OPPS final rule, CMS 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 50 percent of the OPPS payment rate. CMS arrived at the

50 percent figure by comparing the PFS technical component payment rate to the OPPS payment rate for the 25 highest-volume services in off-campus PBDs, excluding office visits. Subsequently, CMS reduced the payment rate to 40 percent in the CY 2018 OPPS final rule. CMS in this year's PFS rule proposes to maintain the relativity adjuster at 40 percent of the OPPS payment rate. CMS has not conducted any analysis of how reduced reimbursement would affect patient access to care in PBDs or the differences in 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 withdraw its proposal and ensure hospitals are adequately reimbursed for complex services provided in their PBDs.

In the aggregate, members of America's Essential Hospitals operate on margins half that of other hospitals nationally. For safety-net hospitals operating on these narrow (often negative) margins, this payment rate reduction is unsustainable. The effect of the proposed payment rate would be felt even more profoundly by patients of essential hospitals, given our members' wide networks of ambulatory care in otherwise underserved 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 incentives for essential hospitals to bring health care into these communities of need. CMS' implementation of Section 603—especially the inadequate payment rate proposed in the PFS rule—already has caused essential hospitals to reevaluate plans to expand their provider networks into underserved areas.

We hope CMS recognizes the role the BBA and its implementation have played 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.² In fact, CMS uses a hospital's proportion of dual-eligible beneficiaries as a proxy for adjusting the 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

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² 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 August 24, 2018.

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 are not borne by freestanding physician offices.

CMS has acknowledged it cannot directly compare payment to hospital PBDs and freestanding clinics because payment under the OPPS accounts for the cost of packaging ancillary services to a greater extent than under the PFS. For many services paid under the OPPS, including comprehensive ambulatory payment classifications, CMS makes a single payment for the main service and related packaged services. Comparing payment under the OPPS and PFS without accounting for the higher level of packaging that occurs under the OPPS 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.³ **To** adjust for the higher level of packaging in the OPPS, as well as higher costs incurred by hospital PBDs compared with freestanding offices, CMS should revise its payment rate for non-excepted items and services to at least 75 percent of the OPPS payment rate.

By paying non-excepted hospital PBDs at 40 percent of the OPPS 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 to adequately account for the higher acuity of patients they treat compared with physician offices. 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 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 ensure that it preserves access to complex care provided by specialists at essential hospitals through adequate reimbursement for E/M visits.

America's Essential Hospitals opposes CMS' proposal to consolidate the payment rate for E/M visits, which would have a disproportionate impact on providers serving the most complex patients. While we are encouraged to see that

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³ 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 August 24, 2018.

CMS recognizes the burden of documentation requirements associated with coding different levels of E/M visits, reducing payment for complex visits does not solve the documentation issue. Currently, there are 10 E/M codes and payment amounts for office visits: levels one through five for new patients (current procedural terminology [CPT] codes 99201–99205) and levels one through five for established patients (CPT codes 99211-99215). Medicare reimbursement increases for higher code levels, which indicate increased complexity and higher costs associated with providing a service. CMS proposes to pay a single payment rate for levels two through five for new patients and a single payment rate for levels two through five for established patients. Consolidating the payment rate for different visit levels, which CMS uses to indicate increasing resource intensity, will undermine provider payment and patient access, particularly for vulnerable patients. Under the current payment system, a provider dedicating substantial time and resources to see a new patient with multiple chronic conditions could receive payment up to \$211. If CMS were to collapse the payment rate, a provider would only receive \$135, which would not account for the significant resources required to assess such a patient.

The impact of this proposal would be felt most profoundly by specialties providing high-acuity care, such as cardiology, oncology, cardiac surgery, advanced heart failure and transplant cardiology, critical care, and geriatrics. These specialties involve time-consuming and resource-intensive visits that require a thorough evaluation of patients who might have multiple comorbidities. Patients seeking care by a subspecialist will turn to hospitals with ambulatory networks staffed with practitioners who have the experience and capability to treat complex illnesses. The specialized care required for these patients is not readily available at community providers focused more on primary care, for example. The reduction in payment will be detrimental to patient access, particularly for these types of patients with the most complex conditions seeking care from subspecialists. MedPAC echoed this sentiment in its comment letter on the code consolidation proposal, noting that "clinicians who treat less complex patients would receive a payment increase at the expense of clinicians who treat more complex patients."

The disproportionate impact this policy will have on providers for vulnerable patients is borne out by the data. Physicians treating the most complex patients would see the biggest payment cut from the policy. For example, the impact of this policy is more pronounced for physicians at major teaching hospitals compared to non-teaching hospitals—negative 9.8 percent to negative 0.8 percent, respectively. Physicians treating vulnerable patients at essential hospitals would see a negative 7.3 percent decrease in reimbursement compared to negative 5.5 percent for all other hospitals. This correlation holds for other hospital characteristics as well, such as hospital bed size or hospital ownership type, with larger hospitals, nonprofit

http://medpac.gov/docs/default-source/comment-

⁴ Medicare Payment Advisory Commission. Comment Letter to Seema Verma. September 4, 2018.

letters/09042018_macra_feeschedule_1693p_medpac_comment_v2_sec.pdf. Accessed September 10, 2018.

⁵ Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2018.

hospitals, and public hospitals expected to receive the disproportionate share of the cuts from the code consolidation proposal.

CMS proposes add-on codes that would provide approximately \$5 in additional payment for primary care E/M visits and \$14 in additional payment for certain specialty visits. These add-on payments, however, are insufficient to cover for the large decrease in payments to the most affected specialties. For example, nephrologists at essential hospitals would experience a 19 percent reduction in reimbursement and advanced heart failure and transplant cardiologists would experience a 25 percent reduction in payments, even after accounting for the add-on codes. Medical oncologists and radiation oncologists also would see double-digit payment decreases. Such drastic reductions in payment will have downstream effects on cancer patients, patients with complex heart conditions, and patients being treated for kidney failure.

America's Essential Hospitals recommends that CMS withdraw its multiple procedure payment reduction (MPPR) proposal for E/M visits conducted on the same day as another procedure by the same physician or a physician in the same practice. This proposal has an across-the-board negative effect on all specialties and is not grounded in any policy rationale. It will be an impediment to the provision of coordinated care and runs counter to the realities of the health care delivery system. It should be expected that a beneficiary appearing at a physician's office for an E/M visit with a previously undiagnosed illness might be diagnosed with a condition that requires a procedure be performed on the same day by the same practice. This is especially true for large, integrated systems and practices that have the capability to provide same-day procedures within the four walls of the system. One of the primary purposes of an E/M visit is to determine whether additional treatment is required; the MPPR policy will undercut clinical judgment by reducing payment for E/M visits when a same-day procedure is deemed necessary by a clinician. This policy proposal would be particularly harmful to vulnerable patients who infrequently interact with the health care system. For example, low-income patients with multiple social risk factors, including lack of transportation, face barriers to access that would only be exacerbated if they are unable to receive same-day treatment when available. To ensure practitioners are providing medically necessary, coordinated care to their patients, CMS should withdraw the MPPR proposal.

3. CMS should offer physicians flexibility regarding E/M coding documentation requirements.

We applaud the agency for recognizing the burden associated with arduous documentation requirements. **CMS should finalize its proposed changes to Medicare documentation requirements and work with stakeholders to encourage other payers to adopt similar changes.** Under current coding rules, practitioners must provide justification for the level of E/M visit they bill for by

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 $^{^6}$ Data from internal analysis conducted for America's Essential Hospitals by Dobson DaVanzo & Associates. August 2018.

following one of two sets of extensive documentation rules, known as the 1995 and 1997 guidelines. Both sets of guidelines are similar in terms of the key clinical elements required to document a level of E/M visit: a history of the patient's present illness, a physical exam, and medical decision-making. CMS proposes that practitioners may continue to use the 1995 or 1997 guidelines or choose to document an E/M visit using only medical decision-making or time. This change would apply only to the 10 physician office and outpatient visit codes for E/M visits, and not to E/M visits provided in other settings, such as in the inpatient setting or the emergency department (ED).

America's Essential Hospitals is encouraged that CMS has acknowledged that the amount of time and resources practitioners must dedicate to following detailed documentation can detract from the time spent focusing on patient care. However, these proposals alone will not reduce physician documentation burden because other payers still require the use of the 1995 or 1997 guidelines. Until other payers follow CMS' lead and simplify documentation guidelines, practitioners will have to either continue using the 1995 or 1997 guidelines or maintain two workflows—one for CMS' simplified guidelines and another for other payer guidelines. CMS should work with these other payers and with stakeholders in the provider community to identify ways to streamline documentation requirements and ensure practitioners are dedicating their time to patient care.

CMS also can decrease provider burden and improve patient access to care by eliminating the prohibition on billing for same-day visits. CMS guidance prohibits payment for multiple E/M visits provided by a physician or physicians in the group practice on the same day. CMS is seeking comment on eliminating this prohibition. We recommend that CMS eliminate this prohibition, because there are circumstances in which physicians of a group practice, while enrolled in the same specialty, might have expertise in providing services for other conditions. For example, cardiologists or obstetrician-gynecologists could also provide primary care services. A patient could seek care from one physician for a gynecological issue and another physician in the same practice for a regular primary care visit. Under current guidance, this practice could not be paid for both distinct services unless the services are provided on different days. This is inconvenient for both the provider and the patient, especially if a provider must schedule these services on separate days when they could be provided on the same day. CMS can resolve this issue and streamline the provision of care by eliminating the same-day billing prohibition.

4. CMS should continue to refine the measure set used to establish ACO quality performance standards under the MSSP so it contains measures that provide an accurate representation of quality of care.

America's Essential Hospitals supports programs that encourage quality improvement. However, CMS must verify that quality improvement program measures are properly constructed and do not lead to unintended consequences and administrative burden on hospitals. This is especially important for essential hospitals, which already operate with limited resources.

a. CMS should account for sociodemographic factors, including socioeconomic status, by risk adjusting the measures used to establish ACO quality performance.

America's Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. However, before including measures in the MSSP, CMS must verify they would not lead to unintended consequences. More than half of the 31 quality measures in the MSSP are related to outcomes. As quality reporting programs focus more on outcomes and move away from process measures, CMS must ensure measures chosen for these programs accurately reflect quality of care and account for factors beyond the control of a hospital. 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.

In previous comments on hospital inpatient quality reporting programs, we urged CMS to consider the sociodemographic factors—language and existing level of post-discharge support, for example—that might affect patients' outcomes and include such factors in the risk-adjustment methodology. We made these comments out of a preponderance of evidence that patients' sociodemographic status affects outcomes of care. Outcome measures, especially those focused on readmissions, do not accurately reflect quality of care if they do not account for sociodemographic factors that can complicate outcomes. For example, patients who do not have a reliable support structure are more likely to be readmitted to a hospital or other institutional setting. Reducing preventable readmissions is of paramount concern to America's Essential Hospitals and its members. We believe that any program directed at reducing readmissions and improving beneficiaries' health through the episode of care must target readmissions that are preventable and include appropriate risk-adjustment methodology.

Essential hospitals support quality and accountability. What they want, and what their patients and communities deserve, is an equal footing with other hospitals for quality evaluation. When assessing quality measures, Medicare programs should account for the sociodemographic and socioeconomic complexities of disadvantaged populations to ensure hospitals are assessed on their work, rather than on the patients they serve. Differences in patients' backgrounds might affect complication rates and other outcome measures; ignoring these differences would skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured.

As required by the Improving Medicare Post-Acute Care Transformation Act, HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) in December

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⁷ See, e.g., America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. October 21, 2015. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed August 2017.

2016 released a report clearly showing the connection between social risk factors and health care outcomes. The report provides evidence-based confirmation of what essential hospitals and other providers have long known: patients' sociodemographic and other social risk factors matter greatly when assessing the quality of health care providers. We urge CMS to further examine the recommendations found in the ASPE report for future incorporation in MSSP.

As noted by the National Academies of Sciences, Engineering, and Medicine (the Academies) in its series of reports on accounting for social risk factors in Medicare programs, "Achieving good outcomes (or improving outcomes over time) may be more difficult for providers caring for patients with social risk factors precisely because the influence of some social risk factors on health care outcomes is beyond provider control." We urge CMS to closely examine the considerations provided by the Academies for risk adjustment in federal programs.

Like the growing body of research on socioeconomic risk adjustment, the Academies found that community-level elements outside providers' control can indicate risk unrelated to quality of care. ¹⁰ We urge CMS to examine these criteria, as identified by the Academies, when choosing the risk factors for an adjustment methodology:

- conceptual relationship with the outcome of interest;
- empirical association with the outcome of interest;
- risk factor presence at the start of care;
- risk factor modifiability through the provider's actions; and
- risk factor resistance to manipulation or gaming.

We urge CMS to examine the Academies' report for examples of available data to include in measure risk adjustment in the MSSP. The agency also should develop analytic methods for integrating patient data with information about contextual factors that influence health outcomes at the community or population level. Identifying which social risk factors might drive outcomes and determining how to best measure and incorporate those factors into payment systems is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, lower costs, and transparency. We look forward to working with CMS to account for social risk factors and reduce health disparities across Medicare programs, including the MSSP.

https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf. Accessed April 7, 2017.

⁸ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Washington, D.C.; December 2016.

⁹ National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment. Washington, D.C.: The National Academies Press; January 2017. http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx. Accessed April 7, 2017.

¹⁰ America's Essential Hospitals. Sociodemographic Factors Affect Health Outcomes. April 18, 2016. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed May 2017.

b. CMS should align and simplify quality reporting across programs and settings.

We urge the agency to seek greater alignment in quality measurement across Medicare programs and to focus measurement on areas of highest priority—i.e., areas that represent the best opportunities to drive better health and better care, based on available literature. As highlighted by the Institute of Medicine's Committee on Core Metrics for Better Health at Lower Cost, there is a need to mitigate the burden of unnecessary and unproductive reporting by reducing the number, sharpening the focus, and improving the comparability of measures. We, along with other hospital organizations, support the committee's core measure set of "vital signs" for tracking progress toward improved health and health care in the United States. This starting measure set emphasizes the importance of streamlining measures to promote greater alignment and harmonization and to reduce redundancies and inefficiencies in health system measurement.

CMS proposes to reduce the total number of measures in the MSSP quality measure set, beginning in performance year 2019, to enable ACOs to better use their resources to improve patient care. Specifically, the agency proposes to eliminate 10 measures and add one measure to the quality measure set. We support CMS' proposed removal of measures that no longer are valid indicators of quality.

5. CMS should implement the facility-based measurement option for the MIPS, include on-campus outpatient hospital services in the definition of facility-based clinicians, and ensure clear communication to MIPS-eligible clinicians about their facility-based status.

With the implementation of the QPP in CY 2017, three existing physician quality programs were consolidated 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. The QPP also gives eligible clinicians incentives to participate in Advanced APMs. An eligible clinician that participates in an Advanced APM can become a qualifying APM participant (QP) by meeting specified thresholds. America's Essential Hospitals supports CMS' implementation of a facility-based measurement option under the MIPS that applies hospitals' quality and resource use performance measures to their employed physicians.

a. CMS should implement the facility-based measures scoring option.

America's Essential Hospitals supports including a facility-based measures scoring option in the MIPS. We believe such an option will help clinicians and hospitals improve care coordination, align quality improvement goals, and improve the value of quality measurement by simplifying the measure set, rather than merely

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¹¹ Blumenthal D, Malphrus E, McGinnis JM. *Vital Signs: Core Metrics for Health and Health Care Progress.* Washington, D.C.: The National Academies Press; 2015.

incorporating all the current programs into the MIPS. The hospital-based measurement option distinguishes a MIPS-eligible clinician who furnishes a defined amount of services at certain sites as "facility-based" and enables them to apply their facility's value-based purchasing (VBP) program performance score to the quality and cost categories of their total MIPS score. We support leveraging existing quality data sources and VBP experiences to reduce reporting burden on facility-based, MIPS-eligible clinicians. We also support implementation of the facility-based measurement option in the 2019 performance period.

b. CMS should consider a clinician's presence in an on-campus outpatient hospital when determining eligibility for the facility-based measurement option.

As previously finalized, a facility-based clinician is defined as one who furnishes 75 percent or more of covered professional services in an inpatient hospital or ED. In previous comments to CMS, we expressed concern that some clinicians primarily practicing in hospitals will not be eligible for facility-based measurement due to the complicating factor of observation services. Specifically, that the lists of services used to determine eligibility for facility-based measurement does not include place of service (POS) code 22, which is used for on-campus outpatient hospitals. This POS code is used for observation services, which often are provided in the same physical space as inpatient services and, as such, are indistinguishable from inpatient services. We support CMS' proposal to add on-campus outpatient hospital POS code 22 to the list of sites of services used to determine eligibility for facility-based measurement. Doing so will more fully capture services provided by eligible clinicians.

c. CMS should provide clear communication to MIPS-eligible clinicians about their facility-based status. The agency also should provide hospitals a report of all clinicians who meet the threshold for the facility-based measurement option.

CMS proposes to automatically assign a facility-based measurement score to a clinician or group if they would benefit from such scoring (i.e., higher combined quality and cost performance category score). As such, there is no submission requirement for individual clinicians in facility-based measurement. CMS has not proposed a formal opt-out process. Rather, if higher combined quality and cost scores are achieved using data submitted by or on behalf of a clinician, CMS would use that higher score in lieu of the hospital VBP score associated with that clinician.

We recognize and support CMS' proposal to provide an option for facility-based clinicians that might reduce their participation burden. However, in this era of evolving delivery and practice models, it is important to give clinicians, practices, and health systems the opportunity to assess the advantages and disadvantages of various reporting options under the MIPS. We encourage CMS to seek input from stakeholders as the agency develops a process to notify clinicians that their MIPS quality and costs scores will be derived from the hospital's VBP. **CMS should communicate clinicians' eligibility status under the facility-based measurement**

option in a timely manner. Further, CMS should notify facilities of the number of their clinicians automatically assigned to this measurement option.

6. CMS should continue to refine the measures included in the MIPS—risk adjusting when warranted—and streamline efforts to focus on the highest-priority measures.

America's Essential Hospitals supports creating and using measures that lead to quality improvement. However, CMS should verify measures finalized for inclusion in the MIPS to ensure they are properly constructed and will not lead to unintended consequences. For the 2019 performance period, CMS proposes measures, activities, and data submission standards for each of the four MIPS performance categories: quality, cost, improvement activities, and promoting interoperability.

a. CMS should remove MIPS quality measures that require data collection burden without added value for participating clinicians and groups.

CMS should continue to refine the measures in the MIPS and seek greater alignment to avoid reporting multiple versions of measures that assess the same aspect of care. Further, measures should focus on areas of highest priority, including those that represent the best opportunities to drive better health and better care, based on available literature. Beginning with the 2019 performance period, CMS proposes to begin incrementally removing process measures from the MIPS. We applaud CMS' efforts to reduce provider reporting burden, and we support the removal of process measures that are topped out. We encourage the agency to continue this work, with input from all stakeholders, to promote improved outcomes while minimizing costs.

Additionally, CMS proposes to amend the definition of a high-priority measure to include quality measures that relate to opioids. Under the MIPS, participants must submit quality data for at least six measures, including at least one outcome measure; if there is no applicable outcome measure, a participant can submit a high-priority measure instead. Beginning with the 2021 MIPS payment year, CMS proposes to define a high-priority measure as "an outcome, appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure." America's Essential Hospitals supports efforts to monitor the prescribing and administration of opioids for purposes of hospital quality improvement efforts. However, it is important to closely examine Medicare performance measures or policies that are tied to payment and that aim to encourage hospitals to use workflows facilitating evidence-based use and monitoring when administering opioids. Hospitals and physicians should be able to monitor opioid administration and make improvements in pain management care without the potential undue pressure of their performance practices or patterns linking to payment. We support CMS' proposal to include opioid-related measures among high-priority measures; however, we urge the agency to closely examine opioid-related measures under consideration for inclusion in the MIPS and mitigate potential unintended consequences.

b. <u>CMS should incorporate social risk factors in the risk adjustment of quality</u> measures in the MIPS when warranted.

CMS should ensure the measure set includes metrics that are valid and reliable; aligned with other existing measures; and risk adjusted for sociodemographic factors to accurately represent the quality of care hospitals provide. Disadvantaged populations experience a disproportionate share of many diseases and adverse health conditions. Essential hospitals meet the complex clinical and social needs of all patients that come through their doors. As such, our members treat a high proportion of patients with social risk factors that fall outside the hospital's control and that can affect health outcomes, including lack of transportation for follow-up care and limited access to nutritious food. As CMS implements and monitors the third year of the QPP, we continue to urge the agency to incorporate risk adjustment for social risk factors, including socioeconomic status, in the quality measures chosen for the MIPS.

When calculating quality measures, Medicare programs should account for the sociodemographic and socioeconomic complexities of vulnerable populations to ensure clinicians are assessed on their work, rather than on factors outside their control. In addition, differences in patients' backgrounds might affect complication rates and other outcome measures. For example, patients who do not have a reliable support structure at discharge are more likely to be readmitted to a hospital or other institutional setting. By ignoring these factors, CMS will skew quality scores against hospitals and clinicians that provide care to the most complex patients, including those with sociodemographic challenges and the uninsured.

As previously stated, we urge CMS to examine the recommendations found in the ASPE report and the series of reports from the Academies on accounting for social risk factors in Medicare programs, which includes examples of available data that could be included in measure risk adjustment. We look forward to working with CMS to account for social risk factors and reduce health disparities across Medicare programs, including the QPP.

c. CMS should adopt the public health emergency criterion for nominating new activities in the improvement activities performance category and continue to refine this category to reflect services provided by essential hospitals.

The improvement activities performance category in the MIPS gauges participation in activities that improve clinical practice. Eligible clinicians can choose from an inventory of activities to show their performance, including: ongoing care coordination, clinician and patient shared decision-making, regularly using patient safety practices, and expanding access. To place attention on public health emergencies, such as the opioid epidemic, CMS proposes the inclusion of a new criterion when considering improvement activities in the MIPS inventory. Specifically, by considering activities related to public health emergencies to count toward performance in this MIPS category, CMS believes clinicians will increase awareness and promote adoption of best practices to combat public health

emergencies. We support the addition of this criterion to the improvement activities performance category.

Further, we urge CMS to consider the vital role essential hospitals play in communities nationwide when refining the inventory of activities clinicians can count toward performance in this category. Our members fill a public health role by improving population health outside their walls and helping their communities prepare for and respond to natural disasters and other crises. Essential hospitals also provide health care access in a broad variety of settings, from rural regions to the nation's largest cities—namely, in areas with high rates of poverty, homelessness, food insecurity, and other socioeconomic barriers to good health. Activities that contribute to and support these efforts should count toward performance under the improvement activities category.

7. CMS should implement 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 make changes to the PI category in the MIPS 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 advancing care information performance category, which counts for 25 percent of the composite performance score of the MIPS. CMS proposes requiring eligible clinicians participating in the MIPS to transition to more stringent requirements under this category, now known as the PI category, for CYs 2019 and 2020. Specifically, CMS proposes that beginning in CY 2019, clinicians must exclusively use the 2015 version of CEHRT. In addition, CMS proposes to restructure the PI category scoring methodology and reconfigure the objectives and measures in the program.

While providers work toward the overarching goals of using health information technology (IT) to promote interoperability and ensure patient access, the reality of provider electronic health record (EHR) usage does not yet match CMS' timeline. We applaud CMS for acknowledging that eligible clinicians still face obstacles to the meaningful use of health IT, such as by proposing to remove measures dependent on patient action and by providing additional flexibility in the proposed new scoring approach. In many respects, however, CMS leaves some of the underlying difficulties with the PI category unchanged, such as the heavy reliance on information exchange with outside providers. Below, we provide recommendations specific to CMS' proposals in the rule that will ensure providers are afforded sufficient time and flexibility to attain true interoperability and extend the benefits of EHRs to their patients.

a. <u>CMS should remove measures contingent on patient action outside of providers' control.</u>

America's Essential Hospitals is encouraged that CMS has proposed to remove measures dependent on patient action, and we strongly urge the agency to finalize its proposal to remove these measures from the PI category beginning with the 2019 performance period. In the rule, CMS proposes to remove four measures related to patient-specific education; secure messaging; view, download, or transmit; and patient-generated health data. Clinicians have struggled with reporting these measures because successfully doing so requires patient action. These challenges are even more pronounced for clinicians at essential hospitals, whose vulnerable patient populations often have less access to and knowledge of how to use IT. Providers should not be penalized for failing to meet thresholds when performance on a measure is outside of their control. We are pleased that CMS has proposed the removal of these measures; reducing this burden will enable providers to dedicate their resources and staff time to measures more relevant to clinicians and their patients.

b. CMS should finalize a 90-day reporting period for CYs 2019 and 2020.

CMS should finalize its proposal to shorten the 2019 and 2020 PI category reporting periods to 90 days, which will offer much-needed relief as clinicians transition to a new version of CEHRT and to more demanding PI measures. The flexibility of a 90-day reporting period will be critical in 2019 and 2020 for providers still implementing the 2015 CEHRT and becoming familiar with more difficult measures. Many of the PI category measures—such as those requiring the use of APIs and health information exchange—are difficult for clinicians, so they will benefit from additional preparation time resulting from a shorter reporting period. The shorter reporting period will give clinician practices 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 CYs 2019 and 2020.

c. CMS should not finalize the inclusion of the two opioid-related measures until there are adequate standards and specifications for these measures.

CMS should not finalize the inclusion of two opioid-related measures, due to the lack of uniformity across states in the adoption of these practices, as well as a lack of standards and certification criteria. CMS proposes two opioid-related measures for the electronic prescribing (e-prescribing) objective, which would be optional in 2019 and required in 2020:

- Query of Prescription Drug Monitoring Program: For at least one Schedule II opioid electronically prescribed using CEHRT during the performance period, the MIPS-eligible clinician uses data from CEHRT to conduct a query of a prescription drug monitoring program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law; and
- Verify Opioid Treatment Agreement: For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the MIPS-eligible clinician using CEHRT during the performance period, if the total duration of the patient's Schedule II opioid prescriptions is at least 30 cumulative days within a six-month look-back period, the MIPS-eligible clinician seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's EHR using CEHRT.

Clinicians at 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. As key stakeholders in combating the opioid crisis, essential hospitals stand ready to implement practices that have proved effective in reducing opioid dependence. While the intent behind using EHRs to fight the opioid crisis is commendable, the measures CMS proposes are not ready for inclusion in the PI category of the MIPS.

The PDMP and opioid treatment agreement measures are not ready to be included because they lack uniformity of adoption across states and providers. PDMPs are state-level databases that can be used to increase provider awareness of at-risk patients and thus reduce prescription drug abuse. Due to varying state requirements governing PDMPs, their use is uneven across the country. Not all states require the use of PDMPs and one—Missouri—does not even have a PDMP. Additionally, platforms differ by state, creating a lack of uniformity in accessing PDMP data and difficulty in establishing standards for the use of EHRs to access PDMP data. There are no standards or certification criteria governing the use of PDMPs, so clinicians have no guarantee that their CEHRT will include the functionality to query a PDMP.

Like the difficulties associated with the use of PDMPs, opioid treatment agreements are not integrated into CEHRT by all providers. Aside from the technological challenges with the opioid treatment agreement measure, there is a difference of opinion among providers, as well as patients, about the usefulness of these agreements. There also is wide variation in what constitutes an opioid treatment agreement, with no uniform definition of what elements are required for such an agreement for the purposes of the proposed measure. Both this measure and the PDMP measure would require significant changes in provider workflows. Due to these issues, it would be premature for CMS to add these measures to the PI category. We urge the agency to continue to evaluate provider and EHR vendor readiness for these measures and not finalize the measures at this time.

8. CMS should continue to weigh the cost category at 10 percent and ensure developing measures are fully vetted before including them in this MIPS performance category.

America's Essential Hospitals and its members understand that the assessment of cost is vital to ensure clinicians provide high-value care to Medicare beneficiaries. For the first year of the QPP, the cost performance category was weighted at zero percent of the final MIPS score to give clinicians an opportunity to transition into the QPP. The weight was increased to 10 percent for the 2020 MIPS payment year.

CMS proposes to again increase the cost category weighting (to 15 percent) for the 2021 MIPS payment year. MIPS-eligible clinicians have limited experience being scored on cost measures for purposes of MIPS. We urge the agency to continue

the weighting of 10 percent for the cost category for the 2021 MIPS payment year. In doing so, clinicians and CMS will have the opportunity to become more familiar with measures in this category and data generated, without affecting to a greater extent a clinician's total MIPS score.

The cost category includes a total per capita cost measure and a Medicare spending per beneficiary (MSPB) measure. CMS proposes to adopt eight episode-based measures beginning in the 2019 performance year. Episode-based measures are designed to let attributed clinicians know the cost of the care clinically related to their initial treatment of a patient and provided during the episode's timeframe. CMS only recently completed field testing of the proposed episode-based measures, and the measures have not yet been endorsed by the National Quality Forum (NQF). Further, for the 2018 MIPS performance period, CMS chose to delay incorporating episode-based measures into the cost category. We supported this decision, as it would be premature to adopt these measures before understanding whether there might be unintended consequences or a need to adjust for social risk factors. For example, cost measures could disadvantage and/or discourage clinicians from providing care to the sickest and most complex patients. These patients with high care needs then could lose or face more limited access to care. We urge CMS to use the initial years of the QPP to provide feedback on the new episode-based measures, for informational purposes only, and to seek NQF endorsement before their inclusion in the cost category.

9. We support CMS' proposal to maintain its policy of bonus points for MIPS-eligible clinicians who care for complex patients. We urge the agency to set a higher cap for such points and to consider social risk factors (in addition to the Hierarchical Condition Category [HCC] and dual-eligible status) when determining patient complexity.

For the 2020 MIPS payment year, CMS finalized a policy that provides consideration for MIPS-eligible clinicians who care for complex patients. Specifically, a complex patient bonus of up to five points will be added to the final score. CMS' intent is that this bonus structure serves as a short-term strategy to mitigate the impact patient complexity might have on final scores. However, the need for such a bonus is continuous and the effect of the bonus on the final score likely will be modest. As such, we support CMS' proposal to maintain the complex patient bonus points for the 2021 MIPS payment year. We believe it is necessary to continue to provide such a bonus in future years of the QPP and potentially to increase the cap to more than five bonus points. We urge CMS to extend its bonus strategy beyond the 2019 performance year.

Further, CMS should do more to incorporate social risk factors into the MIPS scoring methodology. As the ASPE report to Congress indicated, providers filling a safety-net role have unmeasured differences in patient characteristics that might contribute to differences in outcome quality outside the control of the hospital. Facilities and clinicians that care for patients with social risk factors—such as essential hospitals—face greater challenges than other hospitals, potentially disadvantaging MIPS-eligible clinicians who care for complex patients under the program.

For purposes of defining patient complexity, CMS examined two well-established indicators in the Medicare program: medical complexity as measured through HCC risk scores and social risk as measured through the proportion of patients dually eligible for Medicaid and Medicare. CMS acknowledged that these indicators are interrelated and, as such, paired the average HCC risk scores with the proportion of dual-eligible patients for the 2020 MIPS payment year. While we appreciate CMS seeking to create a more complete complex patient indicator, this is but a first step. **CMS should consider and test additional variables when accounting for social risk factors to structure a bonus for treating complex patients.** We continue to urge the agency to closely examine the Academies' four recommended domains for risk indicators in federal programs:

- income, education, and dual eligibility;
- race, ethnicity, language, and nativity;
- marital/partnership status and living alone; and
- neighborhood deprivation, urbanicity, and housing.

Additionally, it is important that the methodology CMS uses is transparent, so hospitals and stakeholders can replicate the agency's calculations. We urge CMS to continue to engage stakeholders to develop a long-term complex patient bonus for the MIPS.

10. CMS should continue to engage stakeholders in development of other payer Advanced APMs, such as Medicaid APMs, adopt a multiyear determination process, and develop a simple attestation process related to this QPP pathway.

An eligible clinician might become a QP in two ways: the Medicare option, which only includes Medicare fee-for-service (FFS), not Medicare Advantage; or the All-Payer Combination Option. Beginning in the 2019 performance period, if eligible clinicians participating in Advanced APMs do not become QPs under the Medicare option, CMS will perform QP determinations for those eligible clinicians under the All-Payer Combination Option, which incorporates participation in other payer Advanced APMs, including Medicaid APMs. CMS will compare these scores with the relevant QP thresholds, applying the most advantageous result to eligible clinicians.

Essential hospitals understand the importance of creating partnerships to manage the clinical and social needs of the most at-risk members of their community. **CMS** should continue to engage stakeholders in developing other payer Advanced APMs, such as Medicaid APMs, to encourage broader participation in risk arrangements by clinicians participating in the QPP.

Additionally, CMS proposes to establish a process to extend other payer determinations for longer than a single year, if the design and structure of the arrangement have not changed since previous determination. **We support establishing a process that allows determinations for multiple years.** As proposed, absent the submission by the requester of updated information to reflect

changes to the payment arrangement, CMS would continue to apply the original other payer Advanced APM determination for each successive year through the end of that multiyear arrangement. We urge CMS to develop a simple attestation process, using only information necessary to verify there have been no changes since prior determination, to minimize burden on both clinicians and the agency.

11. CMS should engage stakeholders in the development of future models to appropriately encourage participation by essential hospitals in Advanced APMs.

America's Essential Hospitals supports CMS' efforts to develop the use of APMs and delivery models that strive to achieve the Triple Aim of better care, lower costs, and improved health. Shifting providers to APMs is one of the goals of the Medicare Access and CHIP Reauthorization Act, as reflected in the QPP, which offers bonus payments to eligible clinicians who participate in an Advanced APM and meet certain thresholds.

However, providers differ in their readiness to adopt new delivery and payment models, such as the MIPS and APMs. Further, improving care coordination and quality while maintaining a mission to serve the vulnerable is a delicate balance. Essential hospitals often face challenges finding the resources necessary to upgrade technology, redesign processes, and develop a network; these challenges can preclude them from participation as ACOs. Our members are not alone—many in the field struggle to effectively transition to APMs. We urge CMS to implement flexible requirements for new models to promote participation among providers serving complex patients. Additionally, we continue to encourage the agency to consider all organizations with any downside risk, required savings or discounts, or significant upfront investment as potentially eligible Advanced APMs.

12. CMS should improve patient access to critical services by expanding Medicare coverage and payment for services provided through telecommunications technology.

America's Essential Hospitals is encouraged that CMS has increased the list of services that are reimbursable as Medicare telehealth services. We also are pleased that CMS has added services for which Medicare will provide reimbursement that are not restricted by the statutory limitations on telehealth services. However, we urge the agency to expand vulnerable populations' access to lifesaving services by broadening the scope of telehealth reimbursement and lifting barriers to Medicare reimbursement for these services.

Technology can play a key role in linking patients to quality care. For example, telehealth expands the geographic reach of specialists and other providers, efficiently leveraging workforce capacities to connect patients to high-quality care, expand access, and improve population health. One essential hospital in West Virginia launched a telehealth program in 1993 and since has provided more than 20,000 telemedicine outpatient consultations, including for pediatrics, telestroke, and nephrology, to rural residents. Another essential hospital, in Utah, uses

telehealth to manage complex patients with multiple chronic conditions through virtual visits and remote patient monitoring. In addition to providing dermatology, cardiology, prenatal care, and burn care through telehealth, this hospital provides state-of-the-art behavioral health services without requiring the patient to travel long distances for in-person care.

Coverage of telehealth services is limited to a list of specified services and subject to geographical limitations on the telehealth patient's location (the "originating site") for the provider to receive Medicare reimbursement. In practice, there are a multitude of scenarios beyond those involving rural patients in which a patient might be unable to reach a hospital in time for needed care. This is particularly true of patients lacking access to transportation and facing other barriers to access. 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 their follow-up care.

CMS is proposing to reimburse separately for virtual check-ins and remote evaluation of prerecorded patient information. Payment for both services would not be subject to Medicare telehealth restrictions imposed by the Social Security Act. Instead, because the services are not typically provided in-person, Medicare would provide reimbursement notwithstanding where the patient located. For example, virtual visits are an important part of care plans for patients, as in the case of managing opioid use disorders through medication-assisted treatment regiments. We urge CMS to finalize its policy to pay for these policies, and to continue to explore other services that can be added to the list.

In addition to paying for these non-telehealth services, CMS proposes to add two Healthcare Common Procedure Coding System (HCPCS) codes—for prolonged preventive services in the office or other outpatient setting—to the list of telehealth services that are reimbursable by Medicare. We urge the agency to continue to keep the list of telehealth services up-to-date and in line with other payers, which tend to cover a wider variety of telehealth services than Medicare.

Federal lawmakers and policymakers have realized the importance of telehealth in expanding access and are seeking ways to encourage providers to use telehealth. Congress eased some restrictions on telehealth reimbursement in the Bipartisan Budget Act of 2018, including lifting the requirement that a patient is located in a rural area in specific contexts, such as for telestroke services and for ACOs. These changes represent an incremental step in the right direction and will enable some providers to reach more patients in need of care at a time and place that works for the patient. To encourage a continued push toward coordinated care and improved care access, we urge CMS to explore additional policy changes using its regulatory authority, including through payment demonstrations. For example, CMS could consider lifting the geographical limitation on telehealth services in the FFS system.

In addition to their immediate implications for Medicare telehealth reimbursement and provider and patient access, policy changes will have downstream effects on other payers. As private payers and governmental agencies look to Medicare in determining what constitutes a patient-provider relationship, it will be important that Medicare not unreasonably restrict the scope of telehealth services.

13. CMS should ensure any efforts to improve transparency account for existing reporting requirements, as well as sociodemographic variation among patients at essential hospitals, and do not add administrative burden to providers.

In the proposed rule, CMS seeks feedback from stakeholders about transparency. We support CMS' efforts to improve transparency and ensure patients have access to vital information to make informed decisions about their care.

When considering price transparency initiatives or policies, we urge CMS to consider the unique role essential hospitals play in serving patients who face social, linguistic, and economic obstacles, as well as the high costs associated with tackling these challenges. The following are specific recommendations to ensure transparency measures provide appropriate and usable information, without duplication or additional administrative burden.

a. CMS should ensure publicly shared cost information is meaningful and accurate, avoids consumer confusion, and reflects vulnerable patients' sociodemographic circumstances, including socioeconomic status.

America's Essential Hospitals supports patient empowerment to foster shared decision-making and engage beneficiaries in their health care choices. Each patient's out-of-pocket costs must be communicated to the patient individually. Providers must work in partnership with insurers to communicate to patients about their financial responsibilities. This individualized communication should be done in a timely manner, in the language the patient prefers, and in a format the patient can understand.

While America's Essential Hospitals supports sharing out-of-pocket costs with patients, physicians might lack the knowledge or training to provide this information before furnishing a service. Without a system in place to ensure that physicians can provide accurate calculations of out-of-pocket costs, this information is not useful for patients and could lead to confusion. Further, requiring physicians to provide such information likely would increase administrative burden.

Calculating out-of-pocket costs is complex. The final amount patients pay often is dependent on insurance benefit design, including deductibles, coinsurance, copayments, out-of-pocket maximum amounts, and payer-provider contract negotiations. A standard list of prices is no more useful for patients without insurance, as they often are eligible for hospital charity care policies or other significant discounts. No single list at an institution or in a physician's office can capture this information. Posting standard charges will create more confusion for patients and ultimately generate more administrative costs and burden on providers.

Patients should receive adequate and clear information and support regarding financial assistance for the cost of their care so that the fear of responsibility for all or part of a health care bill does not cause a patient to forgo necessary care. While essential hospitals strive to connect eligible individuals to coverage, they acknowledge some individuals will be ineligible or slip through coverage cracks. Essential hospitals are proud of their mission to provide access to quality care for all. They recognize that interacting with the health care system can be daunting to some individuals, and they strive to implement not only robust charity care policies, but also financial navigation assistance.

Physicians who provide care to populations with socioeconomic and sociodemographic challenges are likely to need more resources to provide meaningful education related to prices, costs, and quality of care. For example, communication to such populations requires resources to overcome language barriers and low health literacy, including staff time dedicated to oral explanation and the use of interpreters. It is important that transparency policies fully capture these factors, minimize their effect, and provide additional support to essential hospitals, which already operate with limited resources.

The growing number of patients with limited English proficiency (LEP) experience significant communication barriers when they enter the health care system. ¹² Communication to beneficiaries about prices and costs must be developed and administered in a manner that ensures comprehension by all beneficiaries and, in particular, those with LEP. Further, essential hospitals treat a population that often has a combination of low educational completion along with a language barrier, which places many LEP patients at double the risk of not understanding critical information. It is important to communicate—both in text and through oral explanations—in a language understood by the patient or the patient's representative. Further, terminology should be crafted to enhance comprehension by all patients.

b. <u>Transparency requirements should not increase administrative or regulatory burden on physicians at essential hospitals.</u>

America's Essential Hospitals commends the administration for its attempts to reduce regulatory and administrative burden. Last year, CMS announced its Patients over Paperwork initiative to increase efficiency in the delivery system by allowing providers to focus their time and resources on patient care. We urge CMS to consider the administrative burden that its policies on transparency would impose on essential hospitals.

¹² Hasnain-Wynia R, Yonek J, Pierce D, et al. Hospital language services for patients with limited English proficiency: Results from a national survey. Health Research & Educational Trust and National Health Law Program; 2006.

A variety of provider regulatory requirements increase the demand on resources to deliver care, and ultimately the cost of care, without necessarily improving quality. CMS should require hospitals and physicians to only report information that has proved meaningful to consumers and providers and will lead to increased quality of care for all. The agency should also work to examine the usefulness of data already reported. If stakeholders are required to provide specific data beyond what is currently reported, we urge CMS to mitigate the administrative burden associated with additional reporting requirements.

c. CMS should encourage transparency, while recognizing that physicians at essential hospitals already comply with multiple transparency requirements on both the state and federal levels.

Essential hospitals, many of which are fully or partially governed by state or local governments, are, by definition, more transparent than most other hospitals. Public hospitals often are subject to more stringent requirements under state and/or local laws intended to increase accountability to the public. For example, public hospitals often must periodically report to local government entities and undergo government audits; conform to open meeting and open records laws; take part in competitive bidding before entering contracts; and follow stringent procurement requirements to ensure appropriate spending of public dollars.

In addition, other essential hospitals (including some public hospitals) are nonprofit organizations under section 501(c)(3) of the Internal Revenue Code. In 2009, Congress and the Internal Revenue Service (IRS) implemented reforms on nonprofit hospitals to ensure greater transparency in their activities. These transparency requirements include the creation of the IRS Form 990, Schedule H, which requires nonprofit hospitals to disclose financial assistance and means-tested government program information and other benefits to their communities. Section 501(r) also requires nonprofit hospitals to publicize their financial assistance policies and limit the amount they charge patients who are eligible for financial assistance. Nonprofit hospitals face the very real threat of losing their tax-exempt status if they do not comply with these requirements.

In addition to federal regulations, physicians face varying transparency requirements from their state and local governments. In some states, data on physician prices for common procedures are posted online to allow consumers to compare potential charges at hospitals in their area. Any new reporting requirements should not be duplicative of other efforts to increase transparency.

Physicians also face a multitude of quality reporting standards intended to improve quality and reduce costs. While America's Essential Hospitals supports these efforts, many quality reporting standards serve only to increase administrative burden without necessarily meeting their goals. For example, through the MIPS, eligible clinicians must report on metrics in four performance categories—quality, cost, improvement activities, and promoting interoperability. **Before implementing new**

price transparency guidelines, CMS should consider the full scope of reporting requirements with which providers already comply.

14. CMS should encourage improved communication between providers and patients, as well as improved care transitions, without putting further burden on essential hospitals by requiring additional information exchange through Conditions of Participation (CoPs).

America's Essential Hospitals appreciates the opportunity to respond to CMS' request for information on the potential use of Medicare and Medicaid CoPs to further advance the electronic exchange of information. We support the agency's efforts to improve interoperability among providers and the use of EHR technology to improve the flow of information between providers and patients. However, future proposed changes regarding interoperability should account for the unique patient population served by essential hospitals and the challenges to interoperability and information exchange that the industry has yet to overcome. Using CoPs in this way would create administrative burden and duplicative reporting requirements.

We support CMS' goal of promoting communication between providers and improving care transitions and outcomes by highlighting the importance of discharge planning. Essential hospitals understand the need for providers across the care continuum to have ready access to patients' health information. However, there are obstacles—many of which are outside of the control of providers—that inhibit their ability to seamlessly exchange information. The Government Accountability Office has highlighted the many remaining challenges to attaining a truly interoperable nationwide health IT infrastructure. There are multiple private—and public-sector initiatives to improve the interoperability landscape, but much work remains to allow providers to easily exchange information. Requiring such information exchange through CoPs—for which noncompliance might result in the inability to participate in the Medicare and Medicaid programs—would hold providers to an exacting standard for health information exchange that is not in line with the reality of nationwide progress with this technology.

We also urge CMS to consider the special challenges essential hospitals face in caring for those who require a more extensive discharge planning process—one that accounts for complex needs, such as socioeconomic and literacy barriers, limited access to medications, and little availability of non–health care services—and to not add administrative burden.

a. CMS should encourage patient-centered care and care transitions while recognizing the challenges physicians at essential hospitals face in caring for vulnerable patients with complex postdischarge needs and implementing CEHRT.

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¹³ U.S. Government Accountability Office. Nonfederal Efforts to Help Achieve Health Information Interoperability. GAO-15-817. September 2015. http://www.gao.gov/assets/680/672585.pdf. Accessed August 21, 2018.

In 2015, CMS proposed revisions to discharge planning requirements for hospitals. In response, America's Essential Hospitals urged CMS to consider the additional challenges faced by essential hospitals and their patients in the discharge planning process. The patients treated at essential hospitals are among the most vulnerable and require extensive time and resources to ensure the discharge planning process is tailored to their clinical needs. Discharge planning for this population also requires consideration of social risk factors outside the control of the provider, such as homelessness, cultural and linguistic barriers, and low literacy.

In caring for vulnerable populations, physicians at essential hospitals face compounded challenges. They must identify a patient's or caregiver's capability and availability to provide necessary postdischarge care, as well as the availability of community-based support, including transportation, meals, housing, and other non-health care services. The successful transfer of patients from one level of care to another, or from one setting to another, requires careful attention to patient care goals and treatment preferences.

CMS' discharge planning proposed rule was never finalized, and yet the agency's proposals under consideration for this RFI seek to go beyond the proposed rule by requiring electronic sharing of discharge planning information. This introduces additional complexity and resource allocation for essential hospitals. Existing EHR technology remains a challenge for essential hospitals as they adapt to the Promoting Interoperability Programs (formerly the EHR Incentive Programs). While many essential hospitals are leaders in implementing CEHRT, the health care field in general has not reached a point where CMS can reasonably expect the seamless sharing of information, particularly between hospitals and community providers.

b. To avoid duplicative reporting requirements, CMS should not require the electronic exchange of information through CoPs.

CMS has listed relieving administrative and regulatory burden from providers as an agency priority. As part of the Patients over Paperwork initiative, the agency issued an RFI on ways to reduce regulatory burden on providers. Further, as part of CMS' Meaningful Measures Initiative, the agency proposed the elimination or deduplication of a significant number of measures across its quality programs. We applaud the administration's efforts to allow essential hospitals to focus more of their time and resources on patient care instead of onerous administratively burdensome actions. However, the addition of new CoPs would be a step backward and represent a new administrative challenge for essential hospitals.

As major providers of care to Medicaid and Medicare patients, essential hospitals adhere to the regulatory requirements and CoPs they must meet to participate in these programs. CoPs are process-oriented and cover every hospital service and department. These requirements were put in place to protect the health and safety of patients. However, compliance with frequently changing CoPs can place administrative burden on some hospitals, as well as financial stress to invest funds into compliance efforts.

Additionally, for eligible clinicians participating in the MIPS, CMS has outlined measures aimed at promoting interoperability, such as the electronic exchange of information with other providers and patient access to health records. CMS now is considering adding requirements for clinicians to ensure a patient's right and ability to electronically access his or her medical information without undue burden. Imposing duplicative requirements through CoPs would force clinicians to use resources to report the same information twice and would not benefit patients. The addition of CoPs to improve the electronic exchange of information is overly burdensome to physicians and an inappropriate means to improve patient access to health records.

Moreover, adding requirements for health information exchange and patient access through CoPs is premature, given that physicians now are focused on updating their systems and training their staff on new CEHRT to meet requirements in the PI category of the MIPS. In the PI category, eligible clinicians can receive points for health information exchange and patient access, including the use of application programming interfaces for enabling patient access to their records. The PI category also includes measures related to clinicians' sending and receiving health information from other providers. Physicians are focusing their resources on ensuring they have implemented the appropriate version CEHRT and that they can successfully report on these measures. As such, CMS should not impose additional requirements through CoPs while physicians work to ensure compliance with requirements for participation in the MIPS.

c. <u>CMS should recognize and mitigate the barriers that prevent health</u> information exchange before imposing new requirements.

The commitment essential hospitals and their physicians make to serve 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 electronic patient information, including poverty, homelessness, language barriers, and low health literacy. Many patients served at essential hospitals struggle to access technology that would enable them to access discharge planning documents electronically. Members of America's Essential Hospitals predominantly serve a diverse mix of patients who face significant socioeconomic challenges and who are uninsured or covered by public programs. Some of these patients are homeless and seek care at programs designed for their needs, including respite programs at essential hospitals. In addition to homelessness, patients' ability to access the technology is affected by a variety of other sociodemographic factors, including income, education, and primary language. Many of our members' patients do not have electronic access to their health information outside of the hospital. While internet service might be readily available in most urban areas, many families do not have a computer at home or cannot afford the monthly cost of internet access. We urge CMS to recognize the patient challenges that make sharing information even more difficult for physicians serving this population.

In addition to the challenges they face due to their unique patient populations, clinicians at essential hospitals struggle with difficult measures in the PI category of the MIPS, such as the measure requiring electronic exchange of a summary of care document and the measure requiring a certain percentage of patients to electronically access their health information. The consequences for failing to report or meet benchmarks through CoPs would be even more damaging—noncompliance is far more punitive when compared with the MIPS and could result in hospitals losing the ability to participate in the Medicare program. With the multitude of challenges essential hospitals still face in ensuring their EHR technology is properly implemented, the use of CoPs in this area could be devastating to the communities these hospitals serve.

The Office of the National Coordinator for Health IT (ONC) has made strides in promoting new technology for providers and encouraging increased interoperability, but substantial work remains. As directed in the 21st Century Cures Act, ONC in January 2018 released the Trusted Exchange Framework and Common Agreement (TEFCA), which outlines a set of principles for trusted exchange and is intended to enable interoperability. ONC has yet to release the final TEFCA based on stakeholder input. In addition, ONC is planning to engage in the rulemaking process later this year on interoperability and information blocking requirements as mandated by the 21st Century Cures Act. ONC should be allowed to continue its work of promoting interoperability. However, a great deal of progress is needed before seamless health information exchange is possible.

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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 & CEO

¹⁴ Office of the National Coordinator for Health Information Technology. Draft Trusted Exchange Framework. January 2018. https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf. Accessed August 21, 2018.