

June 24, 2019

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 Avenue SW Washington, DC 20201

Ref: CMS-1716-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

#### Dear Administrator Verma:

Thank you for the opportunity to submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates and supports the Centers for Medicare & Medicaid Services' (CMS') work to improve the delivery of high-quality health care across the care continuum. We appreciate the agency's continued commitment to reduce provider reporting burden associated with hospital quality measurement, and to support proposals that recognize factors outside the control of hospitals—such as homelessness—that impact health outcomes. However, the structure of certain quality reporting requirements and programs to encourage the use of electronic health records (EHRs) has a disproportionately negative financial effect on essential hospitals, which provide stability and choice for people who face financial barriers to care. With that in mind, America's Essential Hospitals asks CMS to consider the challenges inherent in caring for our members' complex patient populations when finalizing this rule.

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 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-fifth that of other hospitals—1.6 percent

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on average compared with 7.8 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 address these social determinants of health and are committed to serving these vulnerable patients. These circumstances, however, compound essential hospitals' challenges and strain their resources, necessitating flexibility to ensure they are not unfairly disadvantaged for serving the vulnerable and can continue to provide vital services in their communities.

Our members offer specialized inpatient and emergency services not available elsewhere in their communities. The high cost of providing complex care to struggling Americans leaves our hospitals with limited resources, driving them to find increasingly innovative strategies for high-quality care. But improving care coordination and quality while staying true to a mission of helping those in need is a delicate balance. This balance is threatened by payment cuts to hospitals—especially the inequities built into the Affordable Care Act's (ACA's) payment reductions for quality improvement programs.

Members of America's Essential Hospitals constantly engage in robust quality improvement initiatives, from preventing falls to reducing readmissions, patient harm events, and blood stream infections. They have created programs to break down language barriers and engage patients and families to improve quality of care. To ensure our members have sufficient resources to continue these activities and are not unfairly disadvantaged for providing comprehensive care to complex patients, CMS should consider the following recommendations when finalizing the above-mentioned proposed rule.

1. CMS should ensure that data used to implement the ACA's Medicare disproportionate share hospital (DSH) payment methodology accurately capture the full range of UC costs hospitals sustain when caring for the disadvantaged.

The Medicare DSH program provides crucial funding for essential hospitals services, including UC. In 2017, our members provided \$6.7 billion in UC, representing 17.4 percent of all UC nationwide.<sup>3</sup>

As mandated by section 3133 of the ACA, the majority of Medicare DSH payments is distributed based on a hospital's UC level relative to all other Medicare DSH hospitals. While DSH hospitals continue to receive 25 percent of their otherwise payable Medicare DSH payments, the remaining 75 percent is decreased to reflect the change in the national uninsurance rate and distributed based on UC burden (referred to as UC-based

<sup>&</sup>lt;sup>1</sup> Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey. America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed May 29, 2019.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Ibid.

Medicare DSH payments). This change incorporates UC costs into the Medicare DSH formula to better target dollars to hospitals with the greatest need.

We agree it is important to better target DSH funds. However, we are concerned about the reductions to DSH payments that occurred because of the new DSH methodology. From fiscal years (FYs) 2014 to 2017, aggregate UC-based payments decreased rapidly, from \$9 billion in FY 2014 to less than \$6 billion in FY 2017—constituting a 33 percent cut in payments. Partly due to a change in the data source used to calculate the national uninsurance rate, aggregate UC-based DSH payments in FY 2018 and FY 2019 increased for the first time since the Medicare DSH cuts went into effect. CMS anticipates a much smaller increase in FY 2020, of about \$200 million. The agency estimates total DSH payments in FY 2020 of \$12.7 billion, which is \$4 billion—or 25 percent—lower than the nearly \$17 billion CMS would have paid hospitals under the pre-ACA methodology. Our members bear the burden of treating disproportionate numbers of uninsured and underinsured patients; as the number of uninsured individuals increases across the country due to various policy changes, it is imperative that essential hospitals receive adequate Medicare DSH payments to cover these costs.

Although the ACA has increased access to coverage nationally, essential hospitals still provide high levels of UC as part of their mission. Hospitals in states that have not expanded Medicaid are not experiencing the drop in UC that hospitals in expansion states have seen. Even in expansion states, hospitals continue to provide large amounts of UC in different forms, such as treating underinsured patients and increased Medicaid shortfalls. Targeting DSH payments based on a hospital's UC levels might mitigate the effect of the lack of Medicaid expansion, but the overall magnitude of cuts to the UC pool often outweighs any redistributive benefit. As a result, steep cuts to Medicare DSH payments are detrimental and unjustifiable for essential hospitals.

Acknowledging that statute largely dictates the size of the UC pool, CMS should consider how its policy choices will affect hospitals that are essential to the communities they serve. In particular, the agency should consider how it defines UC for purposes of allocating UC-based Medicare DSH payments among eligible hospitals. CMS should continue efforts to accurately capture all UC costs as data sources evolve and coverage patterns change. CMS should clarify the Medicare cost report and other guidance to ensure Medicare DSH payments are targeted toward hospitals that need them most.

CMS must ensure essential hospitals receive adequate Medicare DSH payments to provide vital care to vulnerable populations.

a. <u>CMS should continue its work to accurately capture hospital UC costs in its</u> calculation of Medicare DSH allocations.

Given the importance of UC to the Medicare DSH program, we urge CMS to continue to refine its methodology to accurately capture these costs. This should include providing clear and consistent guidance to auditors and contractors tasked with reviewing hospital-reported UC costs. Under the ACA's Medicare DSH methodology, CMS determines a hospital's qualifying UC burden by estimating its percentage of the total UC costs incurred by all DSH hospitals. CMS initially used a low-

income insured days proxy, which is a hospital's Medicaid days plus Medicare supplemental security income days as a percentage of all hospitals' low-income insured days. But beginning in FY 2017, CMS began using three years of data to determine a hospital's share of the UC burden (Factor 3), instead of the one year of data the agency previously used.

Hospitals report their UC costs and other indigent patient care costs on worksheet S-10 of the Medicare hospital cost report form. In FY 2018, CMS began phasing in one year of UC cost data from the S-10; in FY 2019, the agency incorporated two years of S-10 data. For FY 2020, CMS proposes to go back to using one year of data—from FY 2015 S-10—and eliminate the low-income insured days proxy. As CMS begins relying solely on S-10 for calculating UC costs, the accuracy and equity of S-10 data will be increasingly important to ensure consistency across the field. We urge the agency to incorporate the below recommendations to ensure a more accurate representation of each hospital's total UC costs.

i. CMS should provide clear guidelines on its audit protocols and ensure S-10 reviews are done equitably and uniformly across all hospitals.

In the FY 2018 Inpatient Prospective Payment System (IPPS) proposed and final rules, CMS indicated it would instruct Medicare Administrative Contractors (MACs) to conduct audits of S-10 data beginning with FY 2017 information. In this year's proposed rule, CMS notes that it instead chose to focus its initial audits, which began in fall 2018, on FY 2015 cost reports. CMS has yet to make public its audit protocols; it is imperative that the agency do so to be transparent with stakeholders about which factors it will use to determine the need to audit a hospital. Hospitals and other stakeholders who were audited or involved in audits of FY 2015 data underscored the need for this transparency. We urge the agency to disclose the criteria it uses to identify hospitals for audits. Given the relative and redistributive nature of Medicare DSH payments, it is important to ensure audits are conducted consistently and equitably. Under the methodology of CMS' Medicare DSH calculation, a change in even one hospital's reported UC costs will alter its Factor 3 and, in turn, affect all other hospitals' Factor 3 values. As a hospital's Factor 3 changes, so does the amount of UC-based DSH payments it receives (as this is the product of Factor 3 and total UC-based payments). Thus, any inaccurate audits or audits conducted selectively for some hospitals but not others will skew Medicare DSH payments across the board. Further, CMS must minimize burden associated with audit documentation requests and conduct the audits well in advance of the use of the data for payment purposes so hospitals have the opportunity to address adverse findings.

For its audits of FY 2015 S-10 data, CMS and MACs worked with external auditing firms to review data for a subset of about 600 hospitals nationwide. These audits began with extremely burdensome documentation requests by MACs, requiring hospitals to compile and turn over large amounts of information not already available in their financial recordkeeping systems. The audits were conducted in a haphazard manner, with hospitals informed of last-minute unjustified reductions in their UC costs due to arbitrary decisions made by MACs or auditing firms. Numerous concerning auditing

practices were uncovered earlier this year as FY 2015 data was under the microscope, including:

- arbitrary selection of hospitals to audited, resulting in the inclusion of some hospitals in audits but the exclusion of the majority of hospitals eligible to receive DSH;
- voluminous data requests of hospital financial records, including detailed charity care listings with revenue and transaction codes for each claim;
- large reductions in hospitals' claimed charity care costs based on CMS' incorrect direction to MACs to offset such costs with related artificial "expected and actual payments" stemming from flawed cost report instructions for FY 2015. This resulted in substantial downward adjustments, leaving negative or no charity care costs for hospitals that actually provided large amounts of charity care;
- other retroactive adjustments to hospitals' UC amounts based on flawed interpretations of S-10 instructions, such as deeming that insured patients' copayments could not be claimed as charity care, based on a distinction made by MACs between copays and coinsurance; and
- inconsistent audit findings by MACs, such that certain hospitals received negative adjustments for a given issue while others did not.

The timeline with which these changes were made compounded the troubling adjustments, with substantial implications for hospitals' DSH amounts. After initial documentation requests in fall 2018, MACs made negative adjustments in January of this year, providing hospitals no time to contest or correct the adjustments before the proposed rule establishing FY 2020 DSH policies. In an acknowledgement of its flawed interpretation of charity care write-offs, CMS instructed MACs to reverse the charity care cost adjustments, which were the most contentious of the S-10 audit adjustments. However, these changes were not completed until March, meaning the most up-to-date UC values are not reflected in the Factor 3 values CMS posted along with the proposed rule. Therefore, CMS' posted Factor 3 values are incorrect for many hospitals that were audited, resulting in hospital uncertainty and stakeholder inability to accurately verify and replicate CMS' posted values as they evaluate the proposed rule.

CMS can avoid these issues in the future by providing more transparency on its audit protocols. Publishing the audit protocols in advance will allow the hospital community more time and opportunity to respond to audits and address any findings. Because of the relative nature of UC-based payments, CMS also must select hospitals for audits in an equitable and systematic way. CMS also should review audit findings to ensure MACs and subcontractors consistently apply audit protocols across hospitals nationwide. Finally, CMS should complete audits well in advance of its rulemaking for a given year to ensure the cost report data used is accurate and final.

ii. CMS should not adjust hospital UC costs or cost-to-charge ratios (CCRs) of hospitals reporting accurate values.

Because some hospitals report what CMS refers to as anomalous UC costs, the agency proposes MACs review cost reports of hospitals with "extremely high" ratios of UC costs to total operating costs on the cost report year used for calculating Medicare DSH

payments. If a hospital cannot justify high UC costs to its MAC, CMS would scale those costs. The agency would base this scaling factor on the ratio of UC costs to total costs from the next year's cost report—for FY 2020 DSH payments, that would mean the FY 2016 cost report if CMS finalizes its proposal to use FY 2015 UC costs. CMS also proposes to target hospitals with large changes from 2015 to 2017 cost reports if the agency decides to use 2017 data. In addition to the lack of clarity on how these hospitals are identified, CMS does not account for situations in which a hospital might legitimately have high UC costs due to their payer mix. We agree with the need for data integrity and accurate reporting of UC costs. However, CMS should quickly discern erroneous data from legitimate instances in which a hospital might incur very high UC costs. Essential hospitals serve as the primary health care safety net in their communities, especially in heavily populated metropolitan areas, and have very high volumes of uninsured and low-income patients that drive up their UC costs. We call on CMS to ensure MACs work collaboratively with hospitals to distinguish inaccurate UC values from legitimately high values. If a hospital can justify its high values, these costs should not be reduced by another year's ratio of UC costs to total operating costs.

CMS proposes identifying hospitals with abnormally high CCRs and applying a trim methodology to assign an alternate CCR. The proposed methodology would assign the respective urban or rural statewide average to hospitals with CCRs greater than three standard deviations above the national geometric mean CCR. CMS then would use this alternate CCR, instead of the CCR reported on the S-10, to convert the hospital's UC charges to costs. We urge CMS to consider the negative impact this proposal would have on some hospitals and to consider the reasons that hospitals subject to the trim might report high CCRs.

Due to their differing charge structures, some hospitals have used alternative, CMS-approved methodologies to apportion costs on their cost reports. For example, some hospitals are all-inclusive rate providers that use CMS-approved cost apportionment methodologies. These hospitals' charge structures are not the same as other hospitals, because they do not charge on a service-specific basis. Accordingly, the CCRs calculated on their cost reports might end up higher than other hospitals. These hospitals are not falsely reporting information or inflating their costs. In fact, as essential hospitals treating many patients eligible for no-cost or discounted care, they often have charges lower than other hospitals in their community. Applying a trimmed CCR to lower charges will underrepresent the true UC costs for these hospitals.

Instead of subjecting these hospitals to the CCR trim, which penalizes them by drastically reducing their UC costs, CMS should focus on understanding the underlying reasons for varying CCRs. Many all-inclusive rate providers are revising their charge structures, but this change requires time as hospitals transition their revenue cycle and billing software. If CMS intends to require hospitals revise their charge structures and cost apportionment methodologies, the agency should give hospitals sufficient lead time to bring their systems in line with these requirements. While CMS waits for hospitals to make these necessary updates, the agency could consider using the CCR as reported on the cost report or the CCR that a hospital's MAC uses for other payment purposes, such as hospital outlier payments.

iii. CMS should include all patient care costs when using the S-10 to determine UC costs.

The S-10 does not account for all patient care costs when converting charges to costs. Most important, the current worksheet ignores substantial costs hospitals incur in training medical residents, supporting physician and professional services, and paying provider taxes associated with Medicaid revenue. As CMS begins using the S-10 as the data source for measuring UC costs, the agency should refine the worksheet to incorporate all patient care costs—including those for teaching—into the CCR. In particular, CMS should:

- use the total of worksheet A, column 3, lines 1 through 117, reduced by the amount on worksheet A-8, line 10, as the cost component; and
- use worksheet C, column 8, line 200, as the charge component.

The line items above are not limited to Medicare-allowable costs and include additional patient care costs, such as the cost of graduate medical education (GME). Because of this, the result would more accurately reflect the true cost of hospital services, compared with the CCR currently in S-10.

CMS should include GME costs when calculating a hospital's CCR. Excluding these costs will disproportionately affect teaching hospitals by reducing their share of the UC pool in relation to other hospitals. Essential hospitals are committed to training the next generation of health professionals. In 2017, the average member hospital trained 239 physicians, more than three times as many as other U.S. teaching hospitals.<sup>4</sup> Further, our members trained an average of 41 physicians above their GME funding cap, versus nine at other teaching hospitals. 5 So, the costs associated with direct GME constitute a significant portion of overall costs at essential hospitals. Leaving out these costs in the CCR understates teaching hospitals' UC costs when it converts those hospitals' UC costs to charges. Incorporating GME costs into the CCR would reflect the full range of costs incurred by teaching hospitals. By excluding these costs, CMS' proposed CCR for determining UC costs will penalize hospitals, such as academic medical centers, which tend to provide high levels of UC. We strongly urge CMS to include teaching costs when converting charges to ensure accurate distribution of UC pool funds to hospitals with the highest levels of UC.

CMS also should include the cost of providing physician and other professional services when calculating UC. In addition to employing physicians and paying community specialists directly for providing care to patients, many essential hospitals subsidize the cost of physician services to ensure vulnerable patients have access to necessary care. Because hospitals regularly incur these costs when providing charity care and other UC, CMS should recognize them when determining UC. By refining the S-10 to reflect

<sup>5</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey. America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed May 29, 2019.

these issues, CMS will accurately measure the UC costs hospitals incur to serve low-income and uninsured patients.

iv. CMS should issue clarifying guidance as soon as possible to improve the consistency and accuracy of S-10 data and, in particular, the accuracy of UC amounts on the S-10.

A review of S-10 data indicates an inconsistency in how hospitals categorize and report charity care versus bad debt. While CMS can overcome this data limitation using the sum of charity care and bad debt, the agency still should issue clarifying guidance so there is consistency across the field in how hospitals report these costs.

CMS should treat the unreimbursed portion of state or local indigent care programs as charity care. Many state or local indigent care programs are not insurance programs, but rather sources of funding to help subsidize hospitals' overall UC costs. These programs typically support the same populations that qualify for hospital charity care policies. Just as the unreimbursed costs for charity care patients is recognized in the S-10, so should the unreimbursed portion (i.e., the shortfall) of state or local indigent care programs.

Moreover, the agency must revise the S-10 so data on Medicaid shortfalls better resemble actual shortfalls incurred by hospitals. CMS is not proposing to include Medicaid shortfalls from the S-10 in the calculation of UC costs. We agree that Medicaid shortfalls, as currently reported on the S-10, should not be included in the calculation of UC. But data on Medicaid shortfalls increasingly will be useful for informational purposes as previously uninsured low-income individuals gain access to health coverage through Medicaid. Data on the unreimbursed costs of providing care to Medicaid patients (many of whom formerly were uninsured) will provide valuable information on Medicaid underpayment and, thus, should be accurate. Current data underestimate the amount of Medicaid shortfalls. First, GME-related costs are excluded, while GME-related reimbursements are included. Without the necessary revision to the CCR mentioned above, counting payments but not costs is an inaccurate way to measure shortfall. Second, the S-10 should consistently allow hospitals to reduce their Medicaid revenues by the amount of any Medicaid nonfederal share funding they provide, whether through provider taxes, intergovernmental transfers (IGTs), or certified public expenditures (CPEs). Like provider taxes and assessments, providerfunded IGTs and CPEs are contributions to the nonfederal share of Medicaid payments and often are critical to a state's ability to make such payments.

Allowing offsets for one such type of contribution—for example, provider taxes and assessments—and not others distorts shortfall amounts and might create inequities among hospitals. Because of this discrepancy in the instructions and the different types of financing mechanisms used by states, the S-10 in its current form provides an incomplete picture of Medicaid shortfalls and should be revised to allow hospitals to deduct IGTs, CPEs, and provider taxes from their Medicaid revenues.

CMS also should clarify the instructions on line 29 regarding non-Medicare bad debt for insured patients. The agency should allow hospitals to include coinsurance

and deductibles on the S-10 without multiplying these amounts by the CCR. CMS' cost report instructions and guidance, as revised last year, dictate hospitals do not have to multiply nonreimbursed Medicare bad debt by the CCR, because coinsurance and deductibles are actual amounts expected from the patient (as opposed to charges, which are not the actual amounts a patient is expected to pay). However, CMS' September 2017 transmittal states that hospitals still should multiply their non-Medicare bad debt by the CCR.

The different treatment of nonreimbursed Medicare bad debt and non-Medicare bad debt is inconsistent, and the agency provides no justification for the inconsistency. Coinsurance and deductible amounts for those other than Medicare fee-for-service patients, such as Medicare Advantage patients, are actual amounts the hospital expects the patients to pay. Therefore, hospitals should list unpaid co-insurance and deductible amounts as bad debt in their entirety and CMS should not reduce those amounts by the CCR. Making this change would be consistent with the way CMS treats charity care amounts for insured patients. CMS has clarified that charity care amounts for insured patients—that is, coinsurance and deductible amounts that patients do not have the ability to pay—do not have to be reduced by the CCR. CMS should clarify the instructions for bad debt expenses to treat all coinsurance and deductibles for non-Medicare bad debt the same—not multiplying them by the hospital CCR.

v. CMS should allow hospitals to revise their 2016 and 2017 cost reports, and the agency should clearly communicate S-10 changes to stakeholders.

America's Essential Hospitals urges CMS to allow hospitals to submit revisions to their FY 2016 and 2017 cost reports. Additionally, CMS should provide ample opportunities for stakeholder feedback and education before issuing substantive revisions to the S-10. We urge the agency to clearly communicate to stakeholders any revisions, as well as information about extended deadlines. We also urge the agency to allow stakeholders who already submitted their FY 2016 and 2017 cost reports to reopen them for revisions.

CMS also should conduct additional educational outreach to hospitals as the agency transitions to using S-10 data. The S-10 will assume increased importance if it becomes the sole basis for UC-based Medicare DSH payments; as such, it is critical that CMS provide necessary guidance to hospital staff tasked with completing Medicare cost reports. Hospitals report that the S-10 and its corresponding instructions are ambiguous in certain respects, including directions on how hospitals should report non-Medicare bad debt. CMS should provide educational resources to hospitals in the form of agency conference calls, webinars, frequently asked questions documents, and examples illustrating how to report values on the S-10. Because the data entered on the S-10 will significantly affect hospital reimbursement, CMS should work with hospitals to ensure they have appropriate and thorough direction when completing the worksheet.

2. CMS should implement policies that reduce administrative burden on hospitals in the Medicare and Medicaid Promoting Interoperability Programs (PIPs) and allow hospitals to dedicate their resources to providing patient-centered care.

CMS proposes changes to the Medicare and Medicaid PIPs for calendar year (CY) 2021 that will provide some relief from burdensome program requirements. We applaud CMS for recognizing these regulatory burdens and providing flexibility for providers. Through these proposals, CMS acknowledges that eligible hospitals still face obstacles to the meaningful use of health information technology (IT). CMS also seeks comment on additional topics about the future direction of the PIPs, including revising existing measures and incorporating additional measures requiring patient action. In looking to develop future policies, CMS should take additional steps to reduce provider burden and enable hospitals to deliver high-quality, patient-centered care. The recommendations below will ensure providers have sufficient time and flexibility to attain true interoperability and extend the benefits of EHRs to their patients.

a. CMS should finalize a 90-day reporting period for CY 2021.

CMS should finalize its proposal to shorten the 2021 PIP reporting periods to 90 days, which will offer much-needed relief as providers continue to work toward interoperability. CMS previously reduced the CY 2019 and 2020 reporting periods to 90 days, and in this year's rule, again proposes a 90-day reporting period for CY 2021. America's Essential Hospitals strongly supports a 90-day reporting period, which allows providers the flexibility to develop their reporting infrastructure and make necessary updates to their EHRs to comply with evolving PIP requirements. As CMS makes changes to the measures and scoring methodology of the PIPs, hospitals will benefit from additional preparation time resulting from a shorter reporting period. The shorter reporting period will give hospitals time to adjust to these changes and make system changes necessitated by revised measures. Accordingly, CMS should finalize the 90-day reporting period for CY 2021.

b. CMS should remove the two opioid-related measures until the agency ensures adequate standards and specifications.

CMS should remove the two opioid-related measures under the electronic prescribing objective because of the lack of uniformity across states in the adoption of these practices, as well as a lack of 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. As key stakeholders in combating the opioid epidemic, essential hospitals stand ready to implement practices that have proved effective in reducing opioid dependence. While the intent of using EHRs to fight the opioid crisis is commendable, there are significant barriers to the use of IT to report the two measures CMS includes in the PIPs.

CMS currently includes two opioid-related measures for the electronic prescribing objective:

- Query of Prescription Drug Monitoring Program: For at least one Schedule II
  opioid e-prescribed using certified EHR technology (CEHRT) during the EHR
  reporting period, the eligible hospital or critical access hospital (CAH) 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 e-prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting 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 eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into the patient's EHR using CEHRT.

These measures were voluntary in 2019; for 2020, the opioid treatment agreement is voluntary and the PDMP measure is required. CMS now proposes to eliminate the opioid treatment agreement beginning in 2020 and to make the PDMP measure voluntary for 2020. CMS also proposes to change the PDMP measure to require a "yes" or "no" attestation instead of reporting a numerator and denominator. We welcome these changes as a necessary step in the right direction. However, we urge the agency to continue to work toward PDMP integration before making the measure mandatory.

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 governing PDMPs. 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 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 provide 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 remove or keep voluntary the PDMP measure.** 

c. <u>CMS should not include measures contingent on patient action outside of hospitals' control.</u>

In the proposed rule, CMS requests information on the potential inclusion of measures requiring integration of patient-generated health data into EHRs. CMS previously

included a measure requiring integration of patient-generated health data from nonclinical settings into the EHR as part of initial PIP Stage 3 requirements but removed the measures before the beginning of Stage 3. Hospitals struggle with reporting measures dependent on patient action because they rely on factors out of hospitals' control. These challenges are even more pronounced for essential hospitals, which treat vulnerable patient populations that often have less access to and knowledge of how to use IT. CMS should not penalize providers for failing to meet thresholds when performance on a measure is outside their control. Requiring patients to incorporate health data into the EHR will be very onerous, especially for hospitals that serve disadvantaged populations. In addition, a patient discharged from a hospital setting for a single episode of treatment might have less need to transmit information back to the provider than a patient who regularly visits a primary care physician or specialist and needs to update their personal health information. Therefore, CMS should not include measures that could penalize hospitals for circumstances outside their control.

d. CMS should finalize its proposal to require four electronic clinical quality measures (eCQMs) for one self-selected calendar quarter reporting period.

CMS should finalize its proposal that hospitals reporting eCQMs in the Inpatient Quality Reporting (IQR) Program and PIPs choose four measures for one self-selected quarter. A shorter eCQM reporting period and fewer required measures will help hospitals undergoing EHR upgrades. The additional flexibility CMS provides also will give the agency more time to verify these measures are reliable and valid and have accurate specifications. CMS should work with EHR vendors to make electronic reporting of measures a viable option for all hospitals. The extracted EHR data differ from data obtained from chart-abstracted measures and, thus, are not reliable for display in a publicly reported program. For example, chart-abstracted measures allow trained staff to mediate inconsistent provider documentation, whereas only structured, encoded documentation is acceptable for EHR data. Because of the differences between data extracted from eCQMs and chart-abstracted quality measures, CMS should adopt a validation process and conduct robust testing to ensure data from eCQMs are accurate and comparable to chart-abstracted information.

Further, it would be premature for CMS to require electronic reporting before all measures are fully electronically specified and field tested. In general, electronic measures have specific requirements for what type of information should be documented; they require more standardization than nonelectronic measures. Without detailed electronic specifications available far in advance, many providers will not have enough time to bring their reporting systems up to date. Providers are adapting their workflows to ensure meticulous entry of standardized data into their EHRs. However, it is a process that requires extensive training and resources. Often, the data produced by chart-abstracted measures and eCQMs vary significantly. Therefore, it is unwise to finalize any electronic measure until there is enough evidence of its validity in the field to justify its inclusion as a truly meaningful measure.

Due to the unresolved issues with electronic reporting for providers, vendors, and the agency, we support CMS' proposal to require four eCQMs and allow hospitals to choose any one calendar quarter for electronic reporting.

## 3. CMS should provide additional funding to drive parity in wage index values, rather than redistributing funds across hospitals.

CMS proposes changes to the Medicare wage index calculation for certain hospitals with low wage index values. Specifically, for at least four years, beginning in FY 2020, CMS would increase wage index values for hospitals for which wage index value falls within the bottom quartile of all hospitals. To make this proposal budget neutral, CMS would decrease the wage index values of hospitals in the top quartile. CMS proposes capping the negative adjustment at 5 percent in FY 2020, to avoid extreme adjustments.

America's Essential Hospitals recognizes the need to address low wage index values. We share CMS' goal of improving access and decreasing disparities; however, any adjustment to the wage index that is redistributive in nature will not advance these goals. Essential hospitals are the backbone of our nation's health care system, serving rural, urban, and suburban communities. If CMS chooses to adjust wage index values, the agency should allocate additional funds to ensure parity in these values.

#### 4. CMS should reinstitute its imputed floor policy.

Beginning in FY 2019, CMS eliminated the imputed floor policy for calculating the hospital wage index in all-urban states. Under the rural floor policy, hospitals in urban areas of a state could not be assigned a wage index lower than the wage index assigned to hospitals in rural areas in the states. Because all-urban states do not benefit from the protection of a rural floor, CMS since 2005 had used its statutory authority to apply an imputed floor policy. Realizing the necessity of this policy to treat all-urban states equitably compared with states that have rural areas, CMS repeatedly extended the imputed floor policy. In FY 2019, however, CMS finalized a proposal to discontinue the policy.

The imputed floor was intended as a temporary solution for hospitals in all-urban states, but the agency has failed to implement a long-term solution to protect these hospitals from the adverse effects they face due to an anomaly in the wage index. In the year since the imputed floor policy was eliminated, hospitals in all-urban states have already experienced adverse effects on reimbursement. **Absent any alternative policies that could replace the imputed floor policy, we urge CMS to reinstitute this policy.** 

# 5. CMS should continue to refine the hospital IQR Program measure set so it contains only reliable, valid measures that provide an accurate representation of care quality.

CMS should continue to tailor the IQR Program measure set so it helps hospitals improve care quality and benefits the public by accurately reflecting the care hospitals offer. America's Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. However, before including measures in the IQR Program, CMS must verify that the measures are properly constructed and do not lead to unintended consequences.

Additionally, CMS seeks input from stakeholders about expanding its confidential reporting of certain measures stratified by patient dual eligibility status. The following recommendations will ensure the IQR Program provides accurate information on hospital quality of care and does not unfairly penalize certain hospitals.

a. CMS should finalize its proposal to remove the claims-based hospitalwide readmissions measure and continue to refine the hybrid readmission measure—including appropriate risk adjustment for sociodemographic and other related factors.

Overall, a hospitalwide readmission measure is a relatively imprecise and crude measure of quality, which could be misleading and cause erroneous evaluation of hospitals and patient confusion. We seek clarification from CMS as to how the hospitalwide approach would enhance or further quality improvement efforts beyond information reported through existing condition-specific readmission measures.

In addition, the claims-based hospitalwide readmissions measure is an inaccurate representation of quality. Since claims data are not clinically validated, the data do not accurately represent the quality of care provided at a hospital. Hospitals track clinical data and monitor patients' progress based on the entirety of their clinical record. Placing excessive emphasis on claims-based data presents an unreliable representation of a hospital's progress in improving quality. As such, we support CMS' proposal to remove the claims-based hospitalwide readmission measure. We encourage CMS to remove this claims-only measure sooner than the FY 2026 payment determination, as proposed.

Hospital EHRs have the potential to support better data collection and analysis. In previous rulemaking, CMS stated an intent to consider the use of core clinical data elements from hospital EHRs in conjunction with other sources of data, such as administrative claims, to calculate "hybrid" outcome measures. One such hybrid measure has been developed: a hospitalwide 30-day readmission measure. CMS proposes a two-year voluntary reporting period before requiring hospitals to report this hybrid measure for the FY 2026 payment determination. CMS must undertake thorough public testing and vetting for accuracy and usability before making any data publicly available. CMS must ensure accuracy and completeness of the data submitted. Further, hospitals and CMS need adequate time to become familiar with the measure and this new hybrid form using more than one data source. We urge CMS to allow additional time before this measure becomes mandatory in the IQR Program.

Additionally, as with other outcome measures, this readmission measure must include appropriate risk adjustment. CMS should not add any proposed measure until it is appropriately risk adjusted and should suspend or remove other readmissions measures until they incorporate appropriate risk-adjustment methodology. A growing body of literature shows that race, homelessness, cultural and linguistic barriers, low literacy, and other socioeconomic factors can skew performance on certain quality measures,

such as those for readmissions.<sup>6</sup> Outcomes measures, especially those for readmissions, do not accurately reflect hospitals' performance if they do not account for sociodemographic factors that can complicate care. Patients who do not have a reliable support structure upon discharge are more likely to be readmitted to a hospital or other institutional setting. CMS should not include in the IQR Program outcome measures sensitive to sociodemographic factors—e.g., readmissions, mortality, episode payments—until the measures have been risk adjusted for those factors.

b. Before implementation in the IQR Program, CMS should conduct further testing and obtain National Quality Forum (NQF) endorsement of the two proposed opioid-related eCQMs.

America's Essential Hospitals supports the development of eCQMs and the work of CMS to identify measures that appropriately assess performance, promote quality of care, and improve outcomes associated with the opioid crisis. However, we urge CMS to clarify the extent to which the two proposed measures (safe use of opioids—concurrent prescribing; hospital harm—opioid-related adverse events) would better the quality of care associated with opioid administration.

The proposed safe use of opioids eCQM seeks to assess nationwide rates of concurrent prescribing of opioids and benzodiazepines at the hospital level. The hospital harm-opioid-related adverse events eCQM is designed to assess the administration of naloxone as an indicator of harm to reduce adverse events associated with the administration of opioids in the hospital setting.

We encourage further development and field testing of these measures, with input from stakeholders, to ensure the information collected accurately reflects quality of care. Before introducing more measures, it is necessary to balance the usefulness of information reported through EHRs with the challenges of extracting such data and the accuracy of the information captured. Providers still are working to incorporate EHR data entry into their workflows; additional testing across a broad array of providers and settings is necessary to ensure accuracy and validity. We urge CMS to examine whether these eCQMs are a viable option for all hospitals and to vet new eCQMs across EHR vendors and hospitals before considering the measures for program inclusion.

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 performance measures or policies in Medicare that are tied to payment and that incentivize hospitals to implement workflows facilitating evidence-based use and monitoring when administering opioids. NQF endorsement and Measures Application Partnership (MAP) approval are imperative to ensure measure validity and reliability. Through these processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders. **CMS should not include these two** 

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<sup>&</sup>lt;sup>6</sup> Sociodemographic Factors Affect Health Outcomes. America's Essential Hospitals. http://essentialhospitals.org/institute/sociodemographic-factors-and-socioeconomic-status-ses-affect-health-outcomes/. Accessed May 31, 2019.

opioid-related eCQMs in public reporting until the measures are more fully developed and tested, including attaining NQF endorsement.

c. CMS should continue to refine the hospital harm-severe hypoglycemia and hospital harm-pressure injury eCQMs, and obtain NQF endorsement of both measures, before including them in the IQR Program.

America's Essential Hospitals supports the development of measures to reduce harm events in hospitals. However, we are concerned the eCQM harm measures proposed for future inclusion in the IQR Program could have unintended consequences. The first measure assesses the rate at which severe hypoglycemia events caused by hospital administration of medications occur in the acute-care hospital setting. The second measure assesses the rate at which new hospital-acquired pressure injuries occur during an acute-care hospitalization. Both measures were reviewed in December 2018 by the MAP Hospital Workgroup and received conditional support, pending NQF review and endorsement. NQF review of these measures is scheduled for June 2019.

We support CMS' development of measures to assess critical patient safety issues, such as severe hypoglycemia and pressure injury. However, CMS should not include these measures in public reporting programs until they are fully tested and receive NQF endorsement. In particular, the MAP raised concerns about the hypoglycemia harm measure—specifically, the feasibility of a subsequent lab test for glucose within five minutes of a low glucose reading. The MAP also expressed concern about a lack of risk adjustment or stratification, where appropriate, for the pressure injury harm measure.

Current specifications for the proposed hospital harm eCQMs do not include risk adjustment for sociodemographic factors or stratification. When conceptual and empirical basis exists, quality measures should account for the socioeconomic and sociodemographic complexities of vulnerable populations to ensure the measures reflect quality of care, rather than factors outside of hospitals' control. For example, the pressure injury measure does not account for factors that might influence the likelihood of a patient developing pressure injury, such as lack of nutrition due to food insecurity. As noted by the MAP, appropriate risk adjustment might be necessary to ensure the measure does not disproportionately penalize facilities that might treat more complex patients—e.g., academic medical centers or safety-net providers. We encourage further development and field testing of these measures, with input from stakeholders, as well as NQF endorsement before inclusion in federal programs.

d. CMS should seek more input from stakeholders on the usefulness of confidential preview reports on stratified quality data before publicly reporting such data.

In the FY 2019 IPPS final rule, CMS moved forward with plans to provide confidential reporting of certain quality measures stratified by patient dual-eligibility status—specifically, the pneumonia readmission and pneumonia mortality measures. By providing confidential reports to hospitals, CMS hopes to illuminate differences in outcome rates among patient groups within a hospital and allow comparison of those differences across hospitals. CMS will continue to confidentially report stratified data

for the two pneumonia measures by dual eligibility, as a method "to distinguish vulnerable patients with social risk factors, such as poverty." The agency proposes to expand these reports to include all six readmission measures in the Hospital Readmissions Reduction Program (HRRP).

America's Essential Hospitals supports the stratification of quality measurement data to discern potential disparities and support active improvement. We applaud CMS for developing stratified performance rates by social risk, which is supported by recommendations in the Assistant Secretary for Planning and Evaluation (ASPE) report to Congress. However, we urge CMS to seek further input from stakeholders before publicly reporting stratified data—specifically, whether these separate reports support continuous quality improvement efforts.

We also urge CMS to expand social risk beyond dual eligibility as a marker of poverty; this proxy is used in the HRRP to account for differences among hospitals for payment purposes. While a good first step, we urge CMS to fully consider differences in patients' backgrounds that might affect outcomes, such as readmission rates. In reporting stratified data, CMS notes that the measures would remain unchanged. If CMS' stated goal of stratification is to drive consumer choice, then the risk-adjustment methodology of these measures must reflect a complete and accurate picture of care. In the absence of appropriate risk adjustment at the measure level, there is a very real chance that the consumer will be misled with regard to the quality of care provided. America's Essential Hospitals urges CMS to incorporate factors related to a patient's background—sociodemographic status, language, and postdischarge support structure—in its risk-adjustment methodology.

6. CMS should continue to refine the HRRP risk-adjustment methodology, mandated by law, to mitigate unintended consequences, including disproportionate penalties against essential hospitals.

Reducing preventable readmissions is of paramount concern to America's Essential Hospitals and its members. We believe any program directed at reducing readmissions must target preventable readmissions and include appropriate risk-adjustment methodology. America's Essential Hospitals previously expressed concern that the HRRP unduly penalizes hospitals that serve the nation's most vulnerable populations because it fails to account for all external factors that explain higher readmission rates. Accurately measuring readmissions, when appropriately risk adjusted for factors outside a hospital's control, supports essential hospitals' ability to provide care to all patients, including the vulnerable.

a. CMS should address inadequacies in the risk-adjustment methodology for the HRRP by examining methods beyond payment adjustment and accounting for social and community factors at the measure level.

As stated in previous comments to the agency, we believe the peer grouping approach, mandated by provisions of the 21st Century Cures Act, is only the first step toward true risk adjustment for hospitals treating patients with social and economic challenges. The

agency must take the additional step to adjust measures so that quality comparisons are accurate and fair.

Recent studies examining the impact of CMS' peer grouping approach note that the old HRRP methodology forced essential hospitals and other providers that serve vulnerable patients to absorb a greater proportion of readmissions penalties, leaving them with even fewer resources to treat disadvantaged people. These studies acknowledge that the new methodology, using peer-grouping to compare hospitals, is a step in the right direction. However, they also conclude that the new payment adjustment method has not eliminated the previously unbalanced penalty burden carried by essential hospitals. The studies' authors believe more work is needed to address disparities in readmissions related to factors beyond dual-eligibility, as a proxy for poverty.<sup>7,8</sup>

The methodology for calculating a hospital's excess readmissions should include adequate risk adjustment for the program's six applicable conditions: acute myocardial infarction; heart failure; pneumonia; acute exacerbations of chronic obstructive pulmonary disease; elective total hip arthroplasty and total knee arthroplasty (or hip and knee replacement, respectively); and hospital-level, 30-day, all-cause, unplanned readmission following coronary artery bypass graft. The methodology used to calculate the readmission measures does not incorporate risk adjustment for sociodemographic status, language, postdischarge support structure, or other factors that reflect the challenges involved in caring for disadvantaged populations. We encourage CMS to consider various risk adjustment and stratification approaches and refine measures to account for differences, unrelated to quality of care, among hospitals.

Race, homelessness, cultural and linguistic barriers, low literacy, and other socioeconomic factors can skew results on certain quality measures, such as those for readmissions. It is well known that patients who lack reliable support systems after discharge are more likely to be readmitted to a hospital or other institutional setting. These readmissions result from factors beyond the control of providers and health systems and do not reflect the quality of care provided. Risk adjusting measures for these factors will ensure patients receive accurate information about a hospital's performance. Without proper risk adjustment, providers—many of them essential hospitals—could be forced to absorb a greater proportion of readmissions penalties, leaving them with even fewer resources to treat disadvantaged populations.

<sup>&</sup>lt;sup>7</sup> McCarthy CP, Vaduganathan M, Patel KV, et al. Association of the New Peer Group–Stratified Method With the Reclassification of Penalty Status in the Hospital Readmission Reduction Program. *JAMA Network Open.* 2019;2(4):e192987.

<sup>&</sup>lt;sup>8</sup> Joyny Maddox KE, Reidhead M, Qi AC, et al. Association of Stratification by Dual Enrollment Status With Financial Penalties in the Hospital Readmissions Reduction Program. *JAMA Internal Medicine*. 2019;179(6):769-776.

<sup>&</sup>lt;sup>9</sup> Nagasko EM, et al. Adding Socioeconomic Data to Hospital Readmissions Calculations May Produce More Useful Results. *Health Affairs*. 2014;33(5):786–791.

<sup>&</sup>lt;sup>10</sup> See, e.g., National Quality Forum Technical Report. Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. August 2014.

https://www.qualityforum.org/Publications/2014/08/Risk\_Adjustment\_for\_Socioeconomic\_Status\_or\_O ther\_Sociodemographic\_Factors.aspx. Accessed May 31, 2019.

Failing to fully consider the differences in patients' backgrounds that might affect readmission rates will skew readmission measure calculations against hospitals providing essential care to low-income individuals, including the uninsured. The failure to risk adjust could cause providers treating a large proportion of complex patients to face penalties at an increased rate, further diminishing resources at hospitals that often operate at a loss. America's Essential Hospitals urges CMS to encourage the inclusion of factors related to a patient's background—including sociodemographic status, language, and postdischarge support structure—in measure development and risk-adjustment methodology.

b. CMS should refine the definition of "dual eligible" to ensure reliability in the peer grouping approach under the HRRP and be judicious in its use of the subregulatory process to make nonsubstantive changes to the program.

CMS identifies full-benefit dual status using data from the State Medicare Modernization Act files. A hospital's dual proportion is the proportion of Medicare feefor-service and Medicare Advantage stays where the patient was dually eligible for Medicare and full-benefit Medicaid.

In the proposed rule, CMS updates the definition of dual eligible beginning in FY 2021 to allow a one-month look-back period within the data from the State Medicare Modernization Act files to determine the status for beneficiaries who die during the discharge month. CMS cites as its reasoning for the updated definition a misidentification of the dual-eligible status of beneficiaries who die in the month of discharge, which can occur under the current definition. We support CMS' proposal to ensure validity and accuracy in its calculation of the proportion of dual-eligible patients.

The agency also proposes adoption of a subregulatory process to address nonsubstantive changes to the payment adjustment factor components in the HRRP (e.g., dual proportion, peer group assignment, and peer group median excess readmission ratio). CMS cites the above-proposed update to the dual-eligible definition as an example of a nonsubstantive change. We encourage CMS to continue to use notice-and-comment rulemaking for substantive changes and be judicious in its use of the subregulatory process to make nonsubstantive changes in the HRRP. We urge CMS to closely monitor the effect of its peer grouping approach in the HRRP, continuously evaluate it, and adjust as necessary to avoid unintended consequences for essential hospitals.

### 7. CMS should finalize its proposal to reclassify the Z code for homelessness as a comorbid condition.

The last chapter of the International Statistical Classification of Diseases, 10th revision (ICD-10) provides codes (Z00-Z99) to specify other factors that influence a patient's health status. CMS proposes to change the severity level designation of Z59 (homelessness) from a noncomorbid condition to a comorbid condition. CMS cites data

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<sup>&</sup>lt;sup>11</sup> Reiter KL, Jiang HJ, Wang J. Facing the Recession: How Did Safety-Net Hospitals Fare Financially Compared with Their Peers? *Health Services Research.* 2014;49(6):1747–66.

that suggest when Z59 diagnosis code is reported as a secondary diagnosis, the resources involved in caring for the patient justify increasing the severity level to a comorbid condition. We urge CMS to finalize this proposal.

Issues associated with housing have profound impact on health. The most dramatic of these is homelessness, but housing instability also includes difficulty paying rent, spending more than 50 percent of household income on housing, frequently moving, living in overcrowded conditions, or staying with friends and relatives. Housing instability and poor health can create a vicious cycle. Homelessness and unstable housing produce significant stress and make it difficult to adhere to medications, healthy eating, and proper hygiene.

Recognizing the impact of upstream factors outside a hospital's control, essential hospitals increasingly work to mitigate social determinants of health (SDOH), such as housing instability, in various ways. In many cases, the first step is to identify the needs of the population treated. Many essential hospitals screen patients for housing instability and other SDOH, such as food insecurity or lack of transportation, and refer those who screen positive to community resources to help meet their social needs.

Communities served by essential hospitals include more than 360,000 homeless individuals. These individuals are more likely to use the emergency department and be admitted to the hospital for conditions that would have been amenable to primary care. Several essential hospitals work to overcome this SDOH by offering temporary housing or long-term rental assistance, developing new affordable housing capacity, and other approaches. For example, an essential hospital in Maryland developed and operates hundreds of affordable housing units in the neighborhood surrounding the hospital, partnering with local organizations to build the housing facilities and coordinate related services for residents. In Illinois and Vermont, essential hospitals provide temporary housing and case management to meet the needs of homeless patients.

The proposal to classify Z59 (homelessness) as a comorbid condition is a step toward recognizing that SDOH impact the resources provided by a hospital to improve the outcomes for a patient. We encourage CMS to examine the full spectrum of SDOH, beyond homelessness, to determine the resources required to address these factors and whether social risk factors should be reclassified as a comorbid condition.

<sup>13</sup> Clark D, Roberson B, Ramiah K. Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey. America's Essential Hospitals. April 2019. www.essentialdata.info. Accessed May 31, 2019.

<sup>&</sup>lt;sup>12</sup> Essential Communities. America's Essential Hospitals. https://essentialcommunities.org. Accessed May 31, 2019.

<sup>&</sup>lt;sup>14</sup> Schrag J. Health Care for the Homeless: Essential Hospitals and Community Partnerships. June 2015. http://essentialhospitals.org/wp-content/uploads/2015/07/Homelessness-Quality-Brief-June-2015.pdf. Accessed May 31, 2019.

8. CMS should be transparent and conduct thorough public testing of new SDOH data collection methods before using such information to inform measures and other purposes.

CMS proposes to adopt new standardized patient assessment data elements for future years in the long-term care hospital quality reporting program. Specifically, CMS proposes to form a new category of data collection—SDOH—and to collect data on seven standardized patient assessment data elements relating to race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. We applaud CMS for its recognition that factors outside the control of a provider or health care setting can impact patients' health outcomes.

In health care delivery, data is a key driver to inform providers about patient needs while helping to engage patients in their own care. SDOH data must be captured appropriately, with standards for adding such data to, and extracting it from, EHRs. Collecting and reporting SDOH data will require accuracy and validity to ensure appropriate use. To the extent that providers collect such data, it is important to establish standards to validate collection methods and the data itself. For example, in the context of quality measurement, NQF, the MAP, and other organizations with measurement expertise serve as multistakeholder partnerships tasked with providing recommendations to guide CMS' selection of performance measures for federal health programs. We support a consensus-building approach to determine which social factors are most important to capture and how to do so in a standardized way.

Further, more data is needed on patients' socioeconomic and sociodemographic characteristics, including, but not limited to, housing and food insecurity—neither of which are proposed under the SDOH category. We support CMS' efforts to identify factors outside the control of the hospital that impact health outcomes and patient experience. CMS must be thoughtful in its approach for collecting SDOH data and ensure that the full spectrum of social needs is examined. Dry-run testing of data collection for this new category will allow CMS and providers adequate time to become familiar with, and provide feedback on, the collection and reporting of SDOH data. We urge CMS to be fully transparent in the potential use of this data and to conduct thorough public testing and vetting for accuracy and usability.

Additionally, CMS proposes to expand the data element for race and ethnicity from one to two questions. Currently, there is a combined question for race and ethnicity collected in the LTCH Continuity Assessment Record and Evaluation Data Set. The 2011 Department of Health and Human Services data standards require a two-question format when self-identification is used to collect data on race and ethnicity. CMS proposes to conform to this standard, which would also meet the 1997 Office of Management and Budget standards, by using two separate data elements: one for race and one for ethnicity. The race question—"What is your race?"—would include 14 response options; the ethnicity question—"Are you Hispanic, Latino/a, or Spanish origin?"—would include five options.

America's Essential Hospitals supports gathering accurate, standardized information on patient race and ethnicity. In 2011, the association partnered with

other industry leaders in the National Call to Action to Eliminate Health Care Disparities, which promotes the culturally appropriate collection of patient race, ethnicity, and language (REL) information. We believe the collection of REL data supports hospitals' efforts to identify preferences and needs and to tailor a care plan to specific patient characteristics. Our members are actively engaged in efforts to collect data on race and ethnicity in a standardized and useful way.

Standardized categories must enable patients to self-identify with the categories and improve data utility. The proposed question to gather information on patient race includes categories that are not supported in the existing Office of Management and Budget framework for race categories, such as "Guamanian" and "Filipino." It is unclear why the race response categories would include additional granularity for Asian and Pacific Islander groups, but not for other races—e.g., white, black, or Native American. This lack of clarity in CMS' rationale creates unnecessary confusion among patients and providers. Health care organizations across the country have collected data on race and ethnicity for years in a standardized and useful manner. CMS should not impede hospitals' existing efforts to collect this data in a culturally appropriate and standardized way. Further, CMS must ensure such data is collected without offending large numbers of patients whose self-identified race and ethnicity is not included in the proposed response categories. We urge CMS to engage stakeholders, including patients, and seek consensus on response categories for the capture of race and ethnicity data.

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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