



# AMERICA'S ESSENTIAL HOSPITALS

June 13, 2017

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-1677-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 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals**

Dear Ms. 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 continuum. However, the structure of certain programs aimed at improving quality 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 association and champion for hospitals and health systems dedicated to providing high-quality care to all people. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care and devote approximately half of their inpatient and outpatient care to Medicaid or uninsured patients. Our members provide state-of-the-art, patient-centered care while operating on margins substantially lower than other hospitals— a zero percent aggregate operating margin, compared with 8.3 percent for all hospitals nationwide.<sup>1</sup> Through their integrated health systems, members of America's Essential Hospitals offer a full range of primary through quaternary care,

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<sup>1</sup>Landry C, Ramiah K, Rangarao S, Roberson B. 2014 Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2014 Annual Member Characteristics Survey. America's Essential Hospitals. June 2016. <http://essentialdata.info/>. Accessed June 13, 2017.

including trauma care, outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services.

Our members also 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 can be a delicate balance. This balance is threatened by payment cuts to hospitals—particularly 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, ranging 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 the 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 adopt 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 uncompensated care costs hospitals sustain when caring for the disadvantaged.**

The Medicare DSH program provides crucial funding for the care provided by essential hospitals, including uncompensated care. In 2014, our members provided nearly \$8 billion in uncompensated care, representing 18.2 percent of all uncompensated care nationwide.<sup>2</sup>

As mandated by Section 3133 of the ACA, a large portion of Medicare DSH payments is now distributed based on a hospital’s uncompensated care 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 uncompensated care burden (referred to as uncompensated care-based Medicare DSH payments). This change was in line with the Medicare Payment Advisory Commission’s (MedPAC’s) long-standing recommendation to incorporate uncompensated care into the Medicare DSH formula to better target dollars to hospitals with the greatest need. We agree with MedPAC’s assessment that DSH funds should be better targeted.

However, while effective targeting is important, we are concerned about the sustainability of reductions to the aggregate uncompensated care-based DSH payments that have occurred as coverage continues to expand and the national uninsurance rate

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<sup>2</sup>Landry C, Ramiah K, Rangarao S, Roberson B. 2014 Essential Data: Our Hospitals, Our Patients—Results of America’s Essential Hospitals 2014 Annual Member Characteristics Survey. America’s Essential Hospitals. June 2016. <http://essentialdata.info/>. Accessed June 13, 2017.

falls. From fiscal years (FYs) 2014 to 2017, aggregate uncompensated care-based payments have decreased rapidly, from \$9 billion in FY 2014 to under \$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 uncompensated care-based DSH payments in FY 2018 are estimated to increase for the first time since the Medicare DSH cuts went into effect. The increase will likely be a one-time occurrence, as the statute partly responsible for the shift does not call for another change in data source after 2018.

Although the ACA has increased access to coverage nationally, essential hospitals still provide high levels of uncompensated care as part of their mission. Further, hospitals in states that have not expanded Medicaid are not experiencing the drop in uncompensated care that hospitals in expansion states have seen. While targeting DSH payments based on a hospital's uncompensated care levels might mitigate this issue somewhat, the overall cuts have been severe, such that the magnitude of cuts in the uncompensated care 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 uncompensated care pool, CMS should consider how its policy choices will affect hospitals that are essential to the communities they serve—particularly with respect to how the agency defines uncompensated care for purposes of allocating the uncompensated care-based Medicare DSH payments among eligible hospitals. CMS should continue to work on accurately capturing all uncompensated care costs, particularly as data sources evolve and coverage patterns change. CMS should clarify the Medicare cost report and other guidance to ensure Medicare DSH payments target the hospitals that need them most.

The comments below are of particular importance to ensure essential hospitals receive adequate Medicare DSH payments to provide vital care to vulnerable populations.

- a. CMS should use the most accurate data source, as required by statute, to determine the change in the number of uninsured.

**America's Essential Hospitals is encouraged that aggregate uncompensated care-based payments are estimated to increase, partly due to the use of a different data source to calculate change in the national uninsurance rate.** The ACA directs CMS to reduce the total funds available for the uncompensated care-based Medicare DSH payment by a factor based on the estimated decline in the national uninsurance rate (Factor 2). Until FY 2017, CMS has been using estimates from the Congressional Budget Office (CBO), as required by the statute. However, CMS is allowed to begin using a different data source—such as data from the Census Bureau—to calculate Factor 2 when determining FY 2018 DSH payment reductions. CMS proposes using estimates of the uninsured rate from the National Health Expenditure Accounts (NHEA), produced by CMS' Office of the Actuary. The use of NHEA is preferable to CBO estimates. **We urge CMS to be transparent in providing the assumptions behind its calculations of the uninsurance rate, and to ensure that its data source for Factor 2 is the most accurate source available. Furthermore, CMS should update its**

**estimates in a timely manner to account for any legislative or policy changes that will have an effect on the uninsurance rate.**

- b. CMS should continue its work to accurately capture hospital uncompensated care costs in its calculation of Medicare DSH allocations.

**Given the importance of uncompensated care to the Medicare DSH program, we urge CMS to continue to refine its methodology to accurately capture uncompensated care costs.** Under existing Medicare DSH methodology, CMS determines a hospital's qualifying uncompensated care burden by estimating its percentage of the total uncompensated care costs incurred by all DSH hospitals. CMS has been using a low-income insured days proxy, which is a hospital's Medicaid days plus Medicare supplemental security income (SSI) 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 uncompensated care burden (Factor 3), instead of the one year of data the agency previously used.

Hospitals are required to report their uncompensated care costs and other indigent patient care costs on worksheet S-10 of the Medicare hospital cost report form. CMS previously concluded that shortcomings with the worksheet S-10 required deviation from the common definition of uncompensated care; instead, the agency used the low-income insured days proxy to estimate hospital uncompensated care costs. However, CMS proposes in FY 2018 to begin phasing in the use of one year of FY 2014 uncompensated care data from the S-10, while using two years of low-income insured days data. As CMS transitions to the worksheet S-10, we urge the agency to incorporate the below recommendations to ensure a more accurate representation of each hospital's total uncompensated care costs.

- z. CMS should measure uncompensated care costs, as well as low-income insured days, to capture all uncompensated costs incurred by hospitals treating low-income patients.*

**CMS should use a hybrid methodology that includes both a hospital's low-income insured days and uncompensated care costs from the S-10 to calculate its Factor 3.** Specifically, we recommend that instead of transitioning entirely to the S-10—presumably in FY 2020—the agency use a weighted average of low-income insured days and uncompensated care costs from the S-10, with low-income insured days weighted 25 percent and S-10 data weighted 75 percent. The association has long supported MedPAC's recommendation to account for care provided to *all* low-income patients, including those with no ability to pay, and to incorporate the costs of such care into the Medicare DSH formula.<sup>3</sup> But any measure of uncompensated care should account for the different sources of uncompensated care burden hospitals incur as they treat low-income patients in a changing coverage landscape.

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<sup>3</sup>See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare Payment Policy. March 2000. [http://www.medpac.gov/docs/default-source/reports/Mar00\\_Entire\\_report.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/Mar00_Entire_report.pdf?sfvrsn=0). Accessed June 13, 2017.

By continuing to partially incorporate low-income insured days in the calculation of DSH payments, CMS will ensure that hospitals that treat Medicaid patients and low-income Medicare dual-eligible beneficiaries can continue to fulfill their mission to treat the vulnerable. Beneficiaries dually eligible for Medicare and Medicaid are more likely to experience chronic illness and typically are costlier to treat.<sup>4</sup> By omitting the low-income insured days proxy once it transitions to the S-10, CMS would overlook the important role of certain hospitals that treat disproportionate numbers of dually eligible beneficiaries. Because of the high cost of treating these patients and the underpayment associated with Medicaid, including a low-income insured days proxy in the Factor 3 calculation will provide a more complete measure of each hospital's commitment to providing uncompensated care.

The need to use low-income insured days also is underscored by the different nature of uncompensated care hospitals provide, as some states expand Medicaid and others do not. As the Medicaid population grows, hospitals' costs for treating these previously uninsured patients would be captured by the inclusion of the low-income insured days proxy. Weighting the S-10 at 75 percent and low-income insured days at 25 percent will ensure that hospitals with high levels of uncompensated care costs receive targeted DSH payments, while not minimizing the importance of treating dual-eligible patients and the associated costs.

Including low-income insured days also is a reasonable policy choice from a logistical perspective. Because the updated worksheet S-10 currently in use is relatively new, hospitals still are gaining experience in using it to accurately report data. Moreover, certain lines of the S-10 and the corresponding instructions are unclear and will require further clarification by CMS. Since FY 2014, CMS has used the low-income insured days metric, noting it is an acceptable proxy for the treatment costs of uninsured patients.<sup>5</sup> Further, CMS plans to include two years of low-income insured days in FY 2018 and will presumably continue to use a combination of low-income insured days and S-10 data in 2019. Including low-income insured days in future years, instead of transitioning entirely to the use of the S-10, would be an extension of this policy and would ensure continuity and prevent disruptions in Medicare DSH payments to hospitals.

By considering this recommendation, along with the following refinements to the worksheet S-10, CMS can ensure data accurately represent uncompensated care costs.

- ii. CMS should not trim hospital cost-to-charge ratios (CCRs) and should give hospitals using different methodologies adequate time to produce CCRs that are usable for converting costs to charges on the cost report.*

Because some hospitals report what CMS refers to as anomalous uncompensated care costs, CMS in the rule proposes identifying hospitals with abnormally high CCRs and

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<sup>4</sup>Kasper J, O'Malley M, and Lyons B. Chronic Disease and Co-Morbidity Among Dual Eligibles: Implications for Patterns of Medicaid and Medicare Service Use and Spending. Kaiser Commission on Medicaid and the Uninsured. July 2010.

<sup>5</sup>See, e.g., Centers for Medicare & Medicaid Services. Fiscal Year 2014 Inpatient Prospective Payment System Proposed Rule. 78 Fed. Reg. 27486, 27589. May 10, 2013.

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 worksheet S-10, to convert the hospital's uncompensated care charges to costs. We urge CMS to consider the negative impact this proposal would have on many 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 been using 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 free or discounted care, these hospitals have charges lower than other hospitals in their community. In anticipation of the use of the S-10 for calculating uncompensated care-based payments, some of these all-inclusive rate providers reduce the charges (or report costs) on their S-10 to account for the fact that they have a higher CCR due to their all-inclusive rate structure. Applying a trimmed CCR to already-reduced charges will underrepresent the true uncompensated care costs for these hospitals. Instead of subjecting these hospitals to the CCR trim, which penalizes them by drastically reducing their uncompensated care costs, CMS should focus on understanding the underlying reasons for varying CCRs. **If CMS intends to require that 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.**

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

The worksheet S-10 does not account for all patient care costs when converting charges to costs. Most importantly, 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 uncompensated care 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 used in worksheet S-10.

CMS should include GME costs when calculating a hospital's CCR. The decision not to include these costs will disproportionately affect teaching hospitals by reducing their share of the uncompensated care pool in relation to other hospitals. Essential hospitals are committed to training the next generation of health professionals. In 2014, our average member hospital trained 270 physicians, more than six times as many as other U.S. teaching hospitals.<sup>6</sup> Further, our members trained an average of 50 physicians above their GME funding cap, versus 21 at other teaching hospitals.<sup>7</sup> So, the costs associated with direct graduate medical education constitute a significant portion of overall costs at essential hospitals. Leaving out these costs in the CCR understates teaching hospitals' uncompensated care costs when it converts those hospitals' uncompensated care 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 uncompensated care costs will penalize hospitals, such as academic medical centers, which tend to provide high levels of uncompensated care. **We strongly urge CMS to include teaching costs when converting charges to ensure accurate distribution of the uncompensated care pool funds to hospitals with the highest levels of uncompensated care.**

CMS also should include the cost of providing physician and other professional services when calculating uncompensated care. 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 continue to have access to necessary care. Because hospitals regularly incur these costs when providing charity care and other uncompensated care, CMS should recognize these costs when determining uncompensated care. **By refining the worksheet S-10 to reflect these issues, CMS will accurately measure the uncompensated care 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 worksheet S-10 data and, in particular, the accuracy of charity care reported on the S-10.*

A review of worksheet 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 hospital industry in how charity care and bad debt are reported.

**America's Essential Hospitals commends CMS for issuing a transmittal revising the charity care instructions on the S-10 to include all charity care written off in a cost reporting period.** Without this change, the use of charity care from the S-10 provided an incomplete picture of actual costs of charity care. The previous instructions called for charity care that was *delivered* (not necessarily written off) during the period

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<sup>6</sup>Landry C, Ramiah K, Rangarao S, Roberson B. 2014 Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2014 Annual Member Characteristics Survey. America's Essential Hospitals. June 2016. <http://essentialdata.info/>. Accessed June 13, 2017.

<sup>7</sup>Ibid.

to be recorded on line 20.<sup>8</sup> However, due to the amount of time involved in determining if a patient is eligible for a hospital's charity care policy, hospitals often determine and write off charity care outside of the fiscal year in which they provide the services. Therefore, if a hospital determines other services also should have been characterized as charity care after the cost report is filed, such costs would not be captured on the worksheet S-10 for any year. This results in an understatement of actual charity care costs. For this reason, we have urged CMS to revise its instructions to capture all charity care written off during the period (as opposed to delivered in that period), and we are pleased to see that CMS revised the charity care instructions accordingly.

**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 uncompensated care costs. The populations supported through these programs are typically the same populations who 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 worksheet 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 uncompensated care costs. We agree that Medicaid shortfalls as they are currently reported on the S-10 should not be included in the calculation of uncompensated care at this time. But data on Medicaid shortfalls will be increasingly 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 measured accurately. 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 worksheet should be consistent in allowing 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, provider-funded 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.**

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<sup>8</sup>Medicare Provider Reimbursement Manual, Part 2, Provider Cost Reporting Forms and Instructions, Form CMS 2552-10S-10 Instructions, § 4012.

**In addition to ensuring all uncompensated care costs incurred by hospitals are used to target DSH payments, CMS should conduct educational outreach to hospitals as the agency transitions to using data from the S-10.** Because the S-10 will assume increased importance if it becomes the basis for uncompensated care-based Medicare DSH payments, it is critical that CMS provide the necessary guidance to hospital staff tasked with completing Medicare cost reports. Hospitals have reported 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 affect hospital reimbursement, CMS should work with hospitals to ensure they have appropriate direction when completing the S-10.

- v. CMS should consider modifying the low-income insured days proxy to more accurately measure each hospital's uncompensated care burden.*

As CMS continues to use its low-income insured days proxy, the agency should consider these shortcomings:

- The existing methodology, which uses a hospital's low-income insured days as a proportion of all hospitals' low-income insured days, does not capture the extent to which low-income patients make up a hospital's overall patient population;
- The use of only inpatient days does not capture the significant amount of low-income care hospitals provide in the outpatient setting. In addition to their commitment to treating the most vulnerable in the inpatient setting, essential hospitals provide comprehensive, coordinated care in the outpatient setting to disproportionately high numbers of uninsured patients, many of whom have multiple comorbidities and chronic conditions. These hospitals should not be penalized in the distribution of uncompensated care payments by excluding the high levels of uncompensated care they provide in the outpatient setting; and
- The use of only inpatient days does not account for the full variation in the amount of resources required to treat certain patients, such as those with complex conditions.

**These considerations further highlight the need to capture accurate uncompensated care data so CMS can refine its methodology for distributing uncompensated care-based Medicare DSH payments.** Until CMS refines its distribution methodology for uncompensated care-based Medicare DSH payments using uncompensated care data, the agency should weigh each hospital's SSI and Medicaid days by total patient days, rather than using the SSI and Medicaid days without any weights. This way, the data used to compare hospitals will capture the disproportionate nature of some hospitals' commitment to low-income populations.

## **2. CMS should examine ways to account for social risk factors in Medicare programs and continuously engage stakeholders to ensure transparency and reduced administrative burden.**

While the health of the U.S. population overall has improved, socioeconomically disadvantaged populations continue to experience a disproportionate share of many diseases and adverse health conditions. Essential hospitals are called to fulfill the complex clinical and social needs of all patients that come through their doors. Our members treat a high proportion of patients with social risk factors—factors outside the control of the hospital—such as lack of transportation for follow-up care or access to nutritious food, which can affect health outcomes.

Essential hospitals support quality and accountability. What they want—and what their patients and communities deserve—is to be on equal footing with other hospitals for purposes of evaluating quality. When calculating quality measures, Medicare programs should account for the socioeconomic and sociodemographic complexities of vulnerable 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; by ignoring them, CMS will skew quality scores against hospitals that provide essential care to the most complex patients, including those with sociodemographic challenges and the uninsured.

It is important to strive for quality and performance improvement, and essential hospitals show they are doing that every day—in innovative ways, with limited resources. But these penalties might be counterproductive for essential hospitals that treat patients who often are sicker and higher utilizers than those at other hospitals. One recent study found that some programs—like the Hospital Readmissions Reduction Program (HRRP)—lead to persistent penalization for certain hospitals and limited capacity to reduce penalty burden; alternative structures might prevent persistent penalization, while motivating hospitals to reduce hospital readmissions.<sup>9</sup>

As required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act, HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) in December 2016 released the first of two reports in which the connection between social risk factors and health care outcomes was clearly shown.<sup>10</sup> 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.

The ASPE report illustrates that hospitals and other providers caring for large numbers of low-income patients are more likely to receive penalties under the HRRP and several other pay-for-performance programs. Unfortunately, failing to adjust measures for

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<sup>9</sup>Thompson M, et al. Most Hospitals Received Annual Penalties For Excess Readmissions, But Some Fared Better Than Others. *Health Affairs*. 2017;36(5):893-901.

<sup>10</sup>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. <https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf>. Accessed June 13, 2017.

sociodemographic factors when necessary and appropriate can adversely affect patients and worsen health care disparities, because penalties divert resources away from hospitals and other providers treating vulnerable populations. It also can mislead and confuse patients, payers, and policymakers by shielding them from important community factors that contribute to worse outcomes.

Policies aiming to improve quality of care should be expanded to include a specific focus on improving population health for the most vulnerable and underserved. **We urge CMS to further examine the recommendations found in the ASPE report for future incorporation in Medicare programs.**

As noted by the National Academies of Sciences, Engineering, and Medicine (NAM), 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.”<sup>11</sup> We urge CMS to closely examine the considerations provided by NAM for risk adjustment in federal programs. Among them, the ad-hoc group’s reports recommend four domains of risk indicators:

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

Like the growing body of research on socioeconomic risk adjustment, NAM found that community-level elements that providers are not able to change can indicate risk unrelated to quality of care.<sup>12</sup> We urge CMS to examine these criteria, as identified by NAM, for 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 is not modifiable through the provider’s actions; and
- risk factor resistance to manipulation or gaming.

**We urge CMS to examine NAM’s report for examples of currently available data that could be included in measure risk adjustment. 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, such as readmissions, might drive outcomes and

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<sup>11</sup>National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment*. Washington, DC: The National Academies Press; January 2017. <http://nationalacademies.org/hmd/Reports/2017/accounting-for-social-risk-factors-in-medicare-payment-5.aspx>. Accessed June 13, 2017.

<sup>12</sup>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 June 13, 2017.

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, and lowered costs. We look forward to working with CMS in accounting for social risk factors and reducing health disparities across Medicare programs.

**3. 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 that any program directed at reducing readmissions must target readmissions that are preventable and include appropriate risk-adjustment methodology. America's Essential Hospitals previously has expressed concern that the HRRP unduly penalizes hospitals that serve the nation's most vulnerable populations because it fails to account for external factors that explain higher readmission rates.

Accurately measuring readmissions, when appropriately risk adjusted, supports essential hospitals' ability to provide care to all patients, including the vulnerable.

- a. CMS should closely monitor the implementation of risk-adjustment methodology, as mandated by law, for unintended consequences and provide hospitals with data to improve understanding of the new methodology.

Pursuant to Section 15002 of the recently enacted 21st Century Cures Act, for the HRRP, the secretary of health and human services (HHS) shall "assign hospitals to groups . . . and apply the applicable provisions of this subsection using a methodology that allows for separate comparison of hospitals within each such group. . .".<sup>13</sup> The legislation further specifies that the groups are to be "based on their overall proportion, of the inpatients who are entitled to, or enrolled for, benefits under Part A, and who are full-benefit dual eligibles." CMS proposes the inclusion of dually eligible patients for payment adjustment beginning in FY 2019.

CMS proposes to identify full-benefit dual status using dual eligibility status data from the State Medicare Modernization Act (MMA) file, which states submit monthly to CMS. CMS believes the State MMA file is the most up-to-date and accurate source of data for identifying dual-eligible beneficiaries. **We ask CMS to provide hospitals the MMA data used so that hospitals can model these calculations for themselves and ask questions about the methodology.**

CMS proposes two alternative definitions of total number of Medicare patients that could be used to calculate a hospital's proportion of dual eligible patients: proportion of dual eligible patients among all Medicare fee-for-service (FFS) and Medicare Advantage (MA) stays or only Medicare FFS stays. We recognize CMS' preferred approach is to include managed care patients with FFS patients, to account for States with high managed care penetration rates. But the HRRP payment adjustment ultimately is

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<sup>13</sup>H.R.34—21st Century Cures Act: P.L. 114-255, section 15002.

applied only to Medicare FFS payments and is based on excess readmissions among only Medicare FFS patients. If CMS finalizes its definition of total Medicare patients as equaling all FFS and MA stays, **we ask that the agency closely monitor for any unintended consequences among hospitals in states with high managed care penetration, compared with those that have low penetration, and modify the methodology to adjust for future growth in managed care.**

Further, CMS proposes three methodologies for assigning hospitals to peer groups, with the agency's preferred approach being stratification of hospitals into quintiles — i.e., five peer groups. Alternative proposed approaches include using two or 10 peer groups. While stratification into two peer groups is a simpler method, we agree with CMS that this approach weakens the relationship between payment adjustment and the hospital's patient population, due to the more heterogeneous mix of hospitals assigned to each group. **We support CMS' proposed use of quintiles, but we urge CMS to closely monitor the effect of this peer grouping approach, continuously evaluate it, and make adjustments as necessary to avoid unintended consequences for essential hospitals.**

Finally, CMS proposes four methodologies to ensure the peer-grouping approach is budget neutral. CMS' preferred approach is the "median excess readmission ratio (ERR) plus a neutrality modifier," whereby a hospital's ERR is subject to a reduction when the hospital's performance—as measured by the ERR—is worse than that of half the other hospitals in its peer group. This differs from the existing "mean ERR plus neutrality modifier" approach, in that the mean ERR approach would compare hospitals' performance to the mean of their peer group.

Regardless of the payment adjustment formula calculation adopted by CMS, **it is important that the methodology is transparent so hospitals and stakeholders can replicate CMS' calculations.** For that reason, we agree with CMS that comparing a hospital's ERR to the mean or median for each peer group is a more straightforward methodology than re-standardizing ERRs, which is offered by the other methods under consideration. However, in choosing between those two approaches—mean ERR plus neutrality modifier versus median ERR plus neutrality modifier—**we encourage CMS to conduct further testing, publicly share the results, and seek stakeholder input, before adopting one method over the other.**

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

We are pleased that CMS included provisions of the 21st Century Cures Act related to risk adjustment in the HRRP rulemaking process. But the rule is only the first step toward true risk adjustment for hospitals treating patients with social and economic challenges. The agency must go a step further and adjust measures so that quality comparisons are accurate and fair.

CMS should ensure the methodology for calculating a hospital's excess readmissions includes 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. As proposed, 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.<sup>14</sup>

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.<sup>15</sup> Risk adjusting measures for these factors will ensure that 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.

Essential hospitals go above and beyond medical treatment to provide for vulnerable patients every day; for example, one hospital in Florida introduced a program that ensures discharged patients have nutritious food—something vital to their recovery. The program combines a team of clinicians, social workers, and other health care professionals to determine whether patients are malnourished or at risk for malnutrition after discharge. At-risk patients then are provided nutritional counseling during their hospital stay and are eligible to receive nutritionally balanced meals after discharge.

By not considering the full range of differences in patients' backgrounds that might affect readmission rates, readmission measure calculations inevitably will be skewed against hospitals providing essential care to low-income individuals, including the uninsured. The failure to risk adjust could cause hospitals 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.<sup>16</sup> **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.**

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<sup>14</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>15</sup> See, e.g., National Quality Forum Technical Report. Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. August 2014.

[http://www.qualityforum.org/Publications/2014/08/Risk\\_Adjustment\\_for\\_Socioeconomic\\_Status\\_or\\_Other\\_Sociodemographic\\_Factors.aspx](http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx). Accessed June 13, 2017.

<sup>16</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.

**4. CMS should provide flexibility on electronic reporting of clinical quality measures and adopt policies that will reduce burden on providers in the Medicare and Medicaid Electronic Health Records (EHR) Incentive Programs.**

CMS proposes changes to the Medicare and Medicaid EHR Incentive Programs for calendar years (CYs) 2017 and 2018 that will provide limited flexibility for eligible hospitals in the program. These proposals include a shorter period for electronic reporting of clinical quality measures (CQMs), as well as a 90-day reporting period in 2018 for attestation in the EHR Incentive Programs. Through these proposals, CMS acknowledges that eligible hospitals still face obstacles to the meaningful use of health information technology. In many respects, however, the proposals fall short of overcoming the challenges eligible hospitals continue to face in the program. CMS should take additional steps to reduce provider burden and enable hospitals to deliver high-quality, patient-centered care. Below, we provide recommendations specific to CMS' proposals in the final rule. In addition to these specific steps, we believe CMS can take additional actions more broadly, such as indefinitely delaying Stage 3, changing the all-or-nothing structure of the EHR Incentive Program, and aligning the program across provider types. We outline these recommendations in more detail in our response to the Request for Information on achieving transparency, flexibility, program simplification, and innovation (see Section 9).

- a. CMS should reduce the reporting period and required number of measures for electronic reporting of CQMs.

CMS should reduce the reporting period and minimum number of measures for electronic reporting of CQMs in the Inpatient Quality Reporting (IQR) Program and EHR Incentive Programs. In the proposed rule, CMS reduces the CY 2107 reporting period for electronic reporting of CQMs to any two calendar quarters, down from four calendar quarters. For CY 2018 CQM reporting, CMS proposes that hospitals electronically report data from the first three calendar quarters of the year. For both years, CMS reduces the required number of CQMs from eight to six. There still are unresolved issues with electronic reporting, such as questions about the reliability, validity, and accuracy of the specifications. **Until CMS has resolved these issues, the agency should reduce to four the required number of CQMs and allow hospitals to choose any one calendar quarter.**

A shorter CQM reporting period and fewer required measures will help hospitals that are experiencing vendor issues as they upgrade their certified EHR technology (CEHRT). CMS requires that hospitals upgrade to the newer 2015 edition of CEHRT by 2018. As hospitals make this transition, many will face delays (as was the case during the last required upgrade to the 2014 edition) as they work with their vendor to ensure the seamless operation of the 2015 edition CEHRT across their hospital. The upgrade process will make it even more difficult for hospitals to electronically report CQMs for more than one calendar quarter, particularly if they are not able to complete the upgrade to the new CEHRT until the end of the year.

The additional flexibility CMS provides also will give the agency additional time to verify that these measures are reliable, valid, and have accurate specifications. CMS

should work with EHR vendors to make electronic reporting of measures a viable option for all hospitals. The data extracted from EHRs differ from the data obtained from chart-abstracted measures and, therefore, are not reliable for display in a publicly reported program. These issues also have been highlighted by the Government Accountability Office, which noted that “HHS has not yet developed a comprehensive strategy to address concerns with the reliability of CQMs collected using certified EHRs.”<sup>17</sup> Due to the differences between data extracted from CQMs and chart-abstracted quality measures, CMS should adopt a validation process and conduct robust testing to ensure data being extracted from CQMs 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 about what type of information should be documented; they require more standardization than non-electronic measures. Without detailed electronic specifications available provided far enough 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 CQMs vary widely. 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 electronic measure. Moreover, CMS should ensure that its systems are capable of receiving and processing electronic CQM data from hospitals in the quality reporting document architecture category I format.

**Due to the unresolved issues with electronic reporting for providers, vendors, and the agency, we urge CMS to reduce the required number of CQMs to four and allow hospitals to choose any one calendar quarter for reporting.**

b. CMS should finalize a 90-day reporting period for CY 2018.

CMS should finalize its proposal to shorten the 2018 reporting period for the EHR Incentive Programs to 90 days, which will offer much-needed relief as providers transition to a new version of CEHRT and to more demanding Stage 3 measures. While we continue to advocate for an indefinite delay of Stage 3, the flexibility of a 90-day reporting period will be critical in 2018 if CMS does not change the current timeline for Stage 3. Many of the Stage 3 objectives—such as those requiring the use of application programming interfaces (APIs) and patient-generated data—differ from Stage 2 measures for hospitals, so hospitals will benefit from additional preparation time resulting from a shorter reporting period. The shorter reporting period will give hospitals time to adjust to the higher percentage thresholds of Stage 3 and make system changes necessitated by new measures and thresholds. Accordingly, CMS should finalize the 90-day reporting period in 2018.

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<sup>17</sup>Government Accountability Office. Electronic Health Record Programs: Participation has Increased, but Action Needed To Achieve Goals, Including Improved Quality of Care. March 2014. <http://www.gao.gov/assets/670/661399.pdf>. Accessed June 13, 2017.

- c. CMS should ease the transition to Stage 3 and new CEHRT by allowing hospitals to use 2014 Edition CEHRT in 2018.

CMS should offer flexibility regarding the edition of CEHRT a provider must use in 2018. **Specifically, CMS should give providers the option of using 2014 Edition CEHRT, 2015 Edition CEHRT, or a combination of both for the 2018 reporting period.** As finalized in the 2015 EHR Incentive Program final rule, providers must use the new 2015 Edition of CEHRT to report Stage 3 objectives and measures beginning in 2018. The 2015 certification criteria are tailored to enable new capabilities in EHR products in Stage 3, such as the use of APIs and the electronic exchange of information. However, vendors have not made sufficient progress in making 2015 Edition products available. A recent search of the Certified Health IT Product List shows that there are only 72 products currently certified to the 2015 requirements. Of these, only a few are complete hospital EHR platforms that can be used to meet the Stage 3 requirements—the remainder are limited modules for other types of providers and specialties or are limited to specific functionalities, such as a patient portal. In comparison, there are nearly 3,800 EHR products certified to the 2014 criteria.

Aside from the paucity of available products, the upgrade process to a new edition involves many different parties—both within and outside the hospital—and requires a substantial investment of time and staff resources. Once providers begin upgrading their EHRs, there inevitably will be issues that need to be resolved by working with the provider’s IT staff and vendor. Fully implementing a new EHR platform and ensuring it is ready to use involves training staff, updating workflows, and testing the technology. In 2014, some providers faced significant obstacles in upgrading their EHRs to the 2014 Edition, and in response, CMS provided flexibility by allowing hospitals to use the 2011 Edition. Similar flexibility in 2018 will be critical for providers as they transition to Stage 3.

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

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.

Voluntary measures, such as the proposed hospitalwide readmissions measure, should only be required after performing extensive analyses of information from voluntary reporting and receiving stakeholder input. As highlighted by the Institute of Medicine’s Committee on Core Metrics for Better Health at Lower Cost, there is a need to reduce the burden of unnecessary and unproductive reporting by requiring fewer, more focused

measures that improve comparability.<sup>18</sup> The committee set forth a measure set of “vital signs” for tracking progress toward improved health and health care in the United States. While this starting set might be imperfect, it emphasizes the importance of streamlining measures to promote greater alignment and harmonization and to reduce redundancies and inefficiencies in health system measurement.

CMS previously finalized the removal of 15 measures from the IQR Program for the FY 2019 payment determination. In the FY 2018 proposed rule, CMS does not propose any measures for future removal. CMS proposes refining two measures—the hospital consumer assessment of health care providers and systems (HCAHPS) survey measure and the 30-day mortality measure for stroke for FYs 2020 and 2023 payment determination, respectively. CMS also proposes adding a voluntary hybrid hospitalwide readmission measure to the IQR Program for reporting discharge data over a six-month period in the first two quarters of CY 2018. Additionally, CMS seeks input from stakeholders about the potential option for confidential and public reporting of certain measures stratified by patient dual eligibility status.

The following comments provide specific recommendations to ensure the IQR Program provides accurate information on hospital quality of care and does not unfairly penalize certain hospitals. In response to the agency’s request for input on future incorporation of social risk factors in the IQR Program, refer to comments in Section 2.

- a. CMS should only include pain management measures in the IQR Program that are evidenced-based, National Quality Forum (NQF)-endorsed and supported by NQF’s Measure Applications Partnership (MAP).

CMS proposes to refine two IQR Program measures—the pain management questions in the HCAHPS survey measure and the 30-day mortality measure for stroke—for FYs 2020 and 2023, respectively.

America’s Essential Hospitals agrees that patient-centered care improves patient outcomes and satisfaction. In 2006, CMS implemented the HCAHPS survey as one method of formally recognizing that patient experience is central to health care, shifting quality metrics from the provider to the patient perspective. However, it is important that CMS continuously monitor and refine the questions in the HCAHPS survey to avoid unintended consequences and ensure the right questions are asked.

We applauded CMS’ removal of the pain dimension questions of the HCAHPS for payment purposes under the Hospital Value-Based Purchasing (VBP) program for FY 2018, found in the CY 2017 Outpatient Prospective Payment System (OPPS) final rule. This action was taken in response to the health care community’s concerns of unintended consequences related to changes in physician prescribing practices. In particular, concerns were raised about the link between the pain management dimension questions in the HCAHPS surveys and payment incentives in the hospital VBP program. The pain management dimension used in the VBP program is identical

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<sup>18</sup>Blumenthal D, Malphrus E, McGinnis JM. Vital Signs: Core Metrics for Health and Health Care Progress. Institute of Medicine Committee on Core Metrics for Better Health at Lower Cost. Washington, D.C.: *The National Academies Press*; 2015.

to measures in the IQR Program. In the CY 2017 OPPS final rule, CMS also stated that it would follow the standard survey development process to make changes to the pain management dimension of the HCAHPS survey, including drafting alternative questions, field testing, and seeking NQF endorsement.

America's Essential Hospitals continues to believe that well-designed measures of pain management are important for facilitating improvements in the delivery of patient-centered care, as well as proper pain management. CMS proposes updating and refining the existing HCAHPS survey pain management questions to focus more directly on communication with patients about their pain during the hospital stay. Shared decision-making and patient-provider communication related to pain management are important dimensions of care. We support the refinement of these questions and feel the proposed questions are an improvement. However, we caution CMS not to publicly report measures that have yet to be fully vetted through the NQF processes.

NQF endorsement and approval by the MAP—a multi-stakeholder partnership that guides HHS' selection of performance measures for federal health programs—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 notes that the proposed "Communication About Pain" composite measure was reviewed by the MAP in December 2016. However, results of field testing in 2016 were not yet available for the MAP's review in December 2016. These results are only now complete. The proposed composite measure is not yet endorsed by NQF. **We urge CMS to suspend the existing pain questions, refine and resubmit the new pain composite measure to the MAP, and submit them to NQF for review and endorsement. The new pain composite measure should be reviewed annually for appropriateness in the IQR Program.**

Additionally, we encourage CMS to continue to refine the HCAHPS survey by reviewing all questions and survey administration. This will improve response rates and ensure the information collected accurately reflects patient experience in a meaningful way.

- b. Before implementation in the IQR Program, CMS should obtain NQF endorsement of the refined stroke mortality measure and minimize any administrative burden associated with measure collection.

CMS proposes to incorporate a stroke severity assessment—specifically, the National Institutes of Health (NIH) Stroke Scale—in the measure of 30-day mortality following acute ischemic stroke hospitalization for FY 2023 payment determination. The current measure does not include assessment of stroke severity because this severity assessment previously was not available in claims data and was not routinely performed by all providers.

Risk assessment for severity is necessary to accurately assess and report hospital-level outcomes. Studies have highlighted the importance of including a valid, specific measure of stroke severity in hospital risk models for mortality after acute ischemic stroke; the studies found stroke severity measures were essential to optimally ranking

hospitals with respect to 30-day mortality.<sup>19,20</sup> Additionally, an American Heart Association/American Stroke Association (AHA/ASA) analysis of its Get With The Guidelines data set for stroke found that hospitals treating patients with greater stroke severity were substantially more likely to provide care for patients who were black, Hispanic, and transported by emergency medical services rather than private vehicle.<sup>21</sup> Essential hospitals, which care for a large number of these and other minority patients, are at risk of being disproportionately affected by a measure that does not account for stroke severity.

CMS references increased use of the NIH Stroke Scale, as well as the ability to obtain scores through claims data by incorporation of ICD-10, as the basis for the proposed refinement of the stroke mortality measure. ICD-10 codes for the NIH Stroke Scale were implemented in October 2016. The refined risk assessment was submitted to NQF in January 2016 and did not obtain endorsement, primarily due to the inability to test the validity of the measure using ICD-10 codes, since the codes were not yet implemented. While we support updating a measure model to better differentiate the risk of mortality among patients, we are concerned about the lack of testing available for this measure and the absence of NQF endorsement. **We encourage the agency to reevaluate the new refined measure after more complete data is available, to perform a dry run, and to seek NQF endorsement before implementation in the IQR Program.**

A hybrid approach to risk adjustment for stroke severity—combining the NIH Stroke Scale with Medicare claims and EHR data—would allow for use of more than one data source. However, this approach will require hospitals to take additional steps and expend additional resources to collect and report the data. **We urge CMS to closely monitor any increase in administrative burden associated with collection of this measure, including adoption of new workflows.**

CMS should incorporate sociodemographic factors in its selection of variables for severity risk adjustment so that results are accurate and reflect differences in stroke patients. Research supports this recommendation; one study found that patients living in impoverished areas are twice as likely to have a severe stroke.<sup>22</sup> Without proper risk adjustment, an essential hospital that serves many of the most complex stroke patients, who also have low incomes and other compounding sociodemographic factors, might appear through public reporting to have poorer outcomes than other hospitals. But this is an inaccurate and misleading picture created by factors outside the control of the hospital and its providers. **CMS should consider sociodemographic factors in stroke**

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<sup>19</sup>Fonarow GC, Saver JL, Smith EE, et al. Relationship of National Institutes of Health Stroke Scale to 30-day Mortality in Medicare Beneficiaries With Acute Ischemic Stroke. *J Am Heart Assoc.* 2012;1:42–50.

<sup>20</sup>Fonarow G, Pan W, Saver J, Smith EE, et al. Comparison of 30-Day Mortality Models for Profiling Hospital Performance in Acute Ischemic Stroke With vs Without Adjustment for Stroke Severity. *JAMA.* 2012;308:257–264.

<sup>21</sup>American Heart Association/American Stroke Association. Which Hospitals Treat Patients with the Most Severe Acute Ischemic Strokes? Implications for Hospital Mortality Reporting. [http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\\_459477.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_459477.pdf). Accessed June 13, 2017.

<sup>22</sup>Kleindorfer D, Lindsell C, Alwell KA, et al. Patients Living in Impoverished Areas Have More Severe Ischemic Strokes. *Stroke.* 2012;43:2055-2059.

**severity risk adjustment so that results are accurate and reflect differences in patients across hospitals.**

- c. Before any voluntary measure—such as that for hospitalwide readmissions—becomes required reporting in the IQR Program, it must be fully vetted and include appropriate risk adjustment for sociodemographic and other related factors.

In previous rulemaking, CMS stated an intent to consider the use of core clinical data elements—extracted 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—and CMS has proposed it as a voluntary measure for reporting discharge data in the first two quarters of the CY 2018 reporting period. A hospital’s annual payment would not be affected by this voluntary measure.

Hospital EHRs have the potential to support better data collection and analysis. Rather than relying solely on claims data, the clinical care team can view clinical information from a patient’s EHR at the time treatment is rendered to account for a patient’s severity of illness. However, **CMS should ensure accuracy and completeness of the data being submitted. Further testing and analysis is needed before this measure becomes mandatory in the IQR Program.** CMS is considering requiring the hybrid hospitalwide readmission measure as early as FY 2023, with hospitals being required to submit necessary data as early as CY 2020 to support a dry run. Hospitals and CMS need adequate time to become familiar with the measure and this new hybrid form using more than one data source.

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>23</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. Factors outside of hospitals’ direct control—such as homelessness, income, education, and primary language—can influence patients’ health care outcomes. 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.**

America’s Essential Hospitals supports hospital quality improvement efforts through public reporting. We caution that thorough public testing and vetting for accuracy and

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<sup>23</sup>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 June 13, 2017.

usability must be undertaken before CMS makes any data publicly available. CMS also should provide hospital-specific, confidential reports to hospitals to allow them to undertake quality improvement efforts, without the measures' inclusion in the IQR Program and public reporting.

- d. CMS should provide confidential preview reports to hospitals and seek further input from stakeholders before publicly reporting stratified quality data.

CMS is seeking comments on potential options for confidential and public 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 for comparison of those differences across hospitals.

America's Essential Hospitals supports the stratification of quality measurement data to discern potential disparities and support active improvement. We have long supported the collection of race, ethnicity, and language (REAL) data to allow health care organizations to monitor and improve the quality of care for diverse populations. In fact, the association developed and deployed the Ask Every Patient: REAL training module to show hospital staff how to collect REAL data in culturally appropriate ways.<sup>24</sup>

As proposed, CMS would report stratified data for the two pneumonia measures—readmissions and mortality—by dual eligibility, as a method “to distinguish vulnerable patients with social risk factors, such as poverty.” We applaud CMS for the direction it is taking to develop stratified performance rates by social risk, which is supported by recommendations contained in the ASPE report to Congress. **These results should be provided to hospitals, confidentially, and we urge CMS to seek further input from stakeholders before publicly reporting stratified data.**

Further, we urge CMS to expand social risk beyond dual eligibility as a marker of poverty. CMS should consider the full range of 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, 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.**

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<sup>24</sup>America's Essential Hospitals. Ask Every Patient: REAL An eLearning Module for Training Staff in REAL Data Collection. Help Sheet. October 2014. <https://2c4xez132caw2w3cpr1il98fssf-wpengine.netdna-ssl.com/wp-content/uploads/2017/01/Help-Sheet-eLearning-Works-for-Collection-of-REAL-Data.pdf>. Accessed June 13, 2017.

- e. CMS should seek further input from accrediting organizations (AOs) and other stakeholders before publicly releasing survey reports and plans of correction (PoCs) to determine the most appropriate format for public consumption.

CMS proposes changes relating to survey and certification requirements—specifically, the transparency of AO survey reports and PoCs of providers and suppliers. AOs perform their own accreditation surveys and issue their own survey reports, which provide information on accredited facilities’ compliance with federal standards. AOs do not make their survey reports and accompanying PoCs publicly available.

CMS proposes requiring AOs with CMS-approved accreditation programs to make all Medicare provider or supplier final accreditation survey reports, as well as acceptable PoCs, publicly available online for the most recent three years. These reports describe any findings of noncompliance with federal requirements—referred to as “deficiencies”—that the surveyors found. If there are cited deficiencies, a facility must submit to CMS an acceptable PoC for achieving compliance.

America’s Essential Hospitals supports transparency and the sharing of meaningful hospital quality information with patients. However, if CMS’ intent in requiring public release of the surveys is to provide information patients might use when deciding where to receive care, this information must be presented in an accurate and useful way. It is unlikely that a survey report—based on a single point in time and anecdotal in nature—is a suitable metric for consumers to use when choosing a provider or hospital, nor is there evidence that making these reports public will improve patient safety. If these reports are displayed, especially if in a way that is not user friendly and tailored to the patient, the information might lead a patient to make choices against their best interests. It is important to provide the public context and an understanding of the range of deficiencies and their meaning. In addition to introducing potential confusion and uncertainty in patient choice, there is a risk of creating an unintended chilling effect, or decline, in the reporting of events and opportunities to address patient safety issues. CMS should ensure that these survey reports continue to be used as quality improvement tools, not quality measures. We also urge CMS to maintain patient confidentiality. The public release of these reports should ensure the privacy of patients and providers remains intact, including the removal of patient identifiers and location of service information. **We urge CMS to seek further input from AOs and other stakeholders before implementing this proposed requirement and to determine the most appropriate format for public consumption**—e.g., a summary versus entire report findings.

- 6. CMS should only include measures in the Hospital VBP program that have been proved to improve patient outcomes, do not overlap with existing measures, and incorporate adjustment for social risk factors.**

The VBP program, authorized by the ACA, continues CMS’ efforts to link Medicare payments to improved quality of care in inpatient hospital settings. The program evaluates hospital performance on quality measures and provides incentives to encourage hospitals to improve the quality and safety of care for all patients. The incentive payments are funded through a reduction in diagnosis-related group base

operating payments for each hospital discharge. Hospitals will have a chance to earn back the reduction, plus additional incentives, based on their performance relative to other hospitals. As the program evolves, CMS should ensure the measures by which hospitals are evaluated are proved to actually improve patient outcomes and increase quality for all patients.

For comments and discussion on how to account for social risk factors in Medicare programs, including the VBP program, we refer to above comments in Section 2.

- a. CMS should ensure the validity of the hospital 30-day, episode-of-care, risk-standardized payment measure for pneumonia before implementation in FY 2022.

To better understand the service utilization and costs associated with pneumonia, CMS proposes to expand the VBP program in FY 2022 by adding a condition-specific payment measure to the efficiency and cost-reduction domain. This domain now consists of one measure: payment-standardized Medicare spending per beneficiary (MSPB). The pneumonia measure calculates payments for the included cohort over a 30-day episode of care, beginning with admission, using administrative claim data.

America's Essential Hospitals supports the evolution of value-based purchasing as it shifts the health care market from volume to value. Essential hospitals continuously work to increase coordination between hospitals and physicians to optimize care. One essential hospital in Colorado uses care managers and adds social workers to their personnel to address the social determinants of health that often drive cost. However, improving care coordination and quality while maintaining a mission to serve the most vulnerable is a delicate balance.

A key component of defining value is appropriate measurement. It is important for policymakers to seek guidance from organizations with measurement expertise, such as NQF and the MAP. NQF endorsement and MAP approval are imperative to ensure measure validity and reliability. Through these processes, CMS, the public, and other stakeholders can fully vet and approve measures through an unbiased, consensus-building approach. The proposed pneumonia episode-based payment measure did not receive MAP support. CMS should not add measures about which MAP members raised concerns during measure development processes.

MAP members expressed concern that condition-specific payment measures might overlap and double count services already captured in the MSPB measure. Additionally, these stakeholders expressed a desire to gain more experience with the measure in the IQR Program to understand whether there might be unintended consequences or a need to adjust for social risk factors. This measure also is included in the NQF Sociodemographic Status (SDS) Trial Period, the results of which are forthcoming. It would be premature for CMS to adopt these measures before first closely examining the recommendations of NQF related to risk adjustment.

We urge CMS to use the years leading up to FY 2022 to ensure the validity of this measure and to resolve MAP stakeholder concerns about incorporating social risk

factors into the measures to improve quality of care while not unduly penalizing essential hospitals.

- b. CMS should remove the patient safety indicator (PSI) composite score, PSI 90, measure from the VBP program and ensure measures in the program more accurately reflect hospitals' quality of care.

CMS has indicated it is not able to calculate performance scores for the current PSI 90 measure for FY 2019, as these scores include ICD-10 data for which the agency does not have the appropriate software. CMS proposes to remove the current PSI 90 measure from the VBP program beginning with the FY 2019 program year, and to adopt the modified version of the PSI 90 in the FY 2023 program year. New data on the modified PSI 90 measure are expected to be publicly reported in July 2017.

The modified PSI 90 measure includes an expansion from eight to 10 component indicators and a new weighting system of the component indicators. The weighting of the component indicators no longer would be based solely on volume of events; instead, the volume and “harm weights” associated with the events would be incorporated through the methodology. The agency believes that these refinements to the PSI 90 measure will provide a more reliable and valid signal of patient safety events.

America’s Essential Hospitals continues to be concerned that both the current and modified PSI 90 composite measure remain an unreliable indicator of quality of care. The events in this claims-based measure occur infrequently; are susceptible to surveillance bias; lack appropriate and necessary exclusions; might not be preventable through evidence-based practices; and are based on administrative claims data that cannot capture the full scope of patient-level risk factors.<sup>25,26</sup> Placing excessive emphasis on claims-based data unreliably represents a hospital’s actual progress in improving quality. **We support and praise CMS for its proposed removal of the current PSI 90 measure beginning in FY 2019.**

Further, until flaws in the modified PSI 90 are adequately addressed, we strongly urge CMS to refrain from future adoption of the composite measure in Medicare performance and penalty programs. It is imperative that CMS fully vet the modified PSI 90 measure approve it through a consensus-building approach that involves the public and interested stakeholders to ensure measure validity and reliability. CMS also should ensure it has sufficient time to identify any unintended consequences of measure collection with use of ICD-10. **America’s Essential Hospitals encourages CMS to allow adequate time for hospitals to understand and become familiar with the measure’s refinements, and ensure the agency is able to identify any unintended consequences of the modified measure.**

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<sup>25</sup>Rajaram R, et al. Concerns About Using the Patient Safety Indicator-90 Composite in Pay-for-Performance Programs. *JAMA*. 2015;313(9):897-898.

<sup>26</sup>Cassidy A. Medicare’s Hospital-Acquired Condition Reduction Program. *Health Affairs: Health Policy Briefs*. August 6, 2015. [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=142](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=142). Accessed June 13, 2017.

**7. CMS should ensure the risk-adjustment methodology and the quality measures in the Hospital-Acquired Condition (HAC) Reduction Program are tailored to accurately measure hospitals' improvements on HACs and do not disproportionately penalize certain types of hospitals.**

CMS should continue to examine its methodology for determining whether a hospital is penalized under the HAC Reduction Program because the methodology is skewed against large hospitals and teaching hospitals, which provide essential care to vulnerable populations. The ACA requires the secretary of HHS to adjust payments to hospitals with high rates of HACs. Specifically, for hospitals that rank in the top quartile nationally for HACs during the applicable period, CMS will adjust payments to 99 percent of what they otherwise would have been. The ACA also requires the secretary to provide confidential HAC reports to applicable hospitals so they can review and correct the information. Information pertaining to hospitals' performance on HAC measures subsequently will be posted on the Hospital Compare website.

America's Essential Hospitals supports the reduction of HACs that create serious adverse outcomes for patients and can lead to death or disability. HACs also burden hospitals and the overall health care system. Essential hospitals are committed to improving quality by eliminating HACs and are at the forefront of using evidence-based guidelines to prevent HACs and improve the overall patient experience. However, the nature and volume of care essential hospitals provide to vulnerable populations make our members likely to be disproportionately included in the top quartile of hospitals, based on the total HAC score. As highlighted in a research brief by America's Essential Hospitals, patient acuity and status as an essential hospital were associated with a higher proportion of penalties under the HAC Reduction Program.<sup>27</sup> Our analysis found that even though mortality rates among essential hospitals either were lower or not statistically different than those of other hospitals, essential hospitals were nearly 8 percentage points more likely to be penalized under the HAC Reduction Program.

Further analysis shows that the HAC Reduction Program in its current form has severely impacted DSH hospitals, teaching hospitals, and urban hospitals. Many of the measures in the HAC Reduction Program occur disproportionately in teaching hospitals and hospitals providing highly specialized services and should not be measured as a true difference in performance when compared with other types of hospitals. For example, many essential hospitals provide high-risk procedures—such as cancer surgery and other procedures that involve a higher risk of acquiring an accidental puncture, laceration, or other condition—not often performed at the facilities against which our members are measured.<sup>28</sup> In these cases, the higher risk of infection does not reflect poor quality of care at the hospital, but rather reflects the types of procedures performed. Thus, essential hospitals might report higher infection rates than other hospitals. Even a minimal increase in the number of infections could place a hospital in the top quartile for these measures. **To provide the most accurate assessment of care**

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<sup>27</sup>Essential Hospitals Institute. HAC Reduction Program Penalties: An Undue Burden on Essential Hospitals? December 2014. <http://essentialhospitals.org/wp-content/uploads/2014/12/HAC-research-brief-12-18.pdf>. Accessed June 13, 2017.

<sup>28</sup>Kin C, et al. Accidental Puncture or Laceration in Colorectal Surgery: A Quality Indicator or a Complexity Measure? *Diseases of the Colon & Rectum*. 2013;56(2):219-225.

**quality, CMS should only include measures in the HAC Reduction Program that accurately gauge quality, include appropriate risk-adjustment, and are not inherently skewed against teaching hospitals, large hospitals, and hospitals that provide care to vulnerable populations.**

The following comments provide specific recommendations for ensuring the HAC Reduction Program accurately measures hospitals' performance and does not unfairly penalize certain hospitals.

- a. CMS should include additional risk-adjustment factors in the HAC Reduction Program quality measures.

To more precisely gauge a hospital's performance on HAC measures, CMS should consider sociodemographic factors, such as the patient's location before admission or after discharge, primary language, and income. The risk-adjustment used for the HAC measures both in domains 1 and 2 is insufficient to account for the many variables outside hospitals' control that can affect rates of infection and complications. For example, a patient's residence can determine their condition before coming to the hospital and primary language can affect their ability to communicate with hospital staff and follow discharge instructions—and both factors can contribute to a higher risk of infection or other complications. Having a lower income also can greatly affect a patient's chance of developing a complication after high-risk procedures. Studies have shown that lack of resources, both financial and educational, are associated with worse pressure ulcer outcomes following care for a spinal cord injury.<sup>29</sup>

The populations essential hospitals serve are among the most complex and vulnerable. For them, even common conditions—such as high blood pressure, diabetes, and asthma—often become worse because of social risk factors (e.g., having no place to properly store medications or syringes). **Sociodemographic factors should be included in the HAC Reduction Program's risk-adjustment methodology to ensure the measures more accurately reflect quality outcomes within hospitals' control.**

Further discussion about incorporation of social risk factors in Medicare payment programs, including the HAC Reduction Program, can be found in Section 2.

- b. CMS should use its exceptions and adjustment authority to ensure payment reductions under the HAC Reduction Program are applied only to base operating diagnosis-related group (DRG) payments—not to indirect medical education (IME) and DSH payments.

As noted above, the ACA states that the payment penalty for hospitals that rank in the top quartile of hospitals nationally for HACs should be “equal to 99 percent of the amount of payment that would otherwise apply to such discharges under this section or section 1814(b)(3).”<sup>30</sup> The unspecified section referred to is Section 1886 of the Social Security Act, which includes not only the base operating DRG payment, but also add-on

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<sup>29</sup>Saunders LL, et al. The Relationship of Pressure Ulcers, Race, and Socioeconomic Conditions After Spinal Cord Injury. *Journal of Spinal Cord Medicine*. 2010;33(4):387-395.

<sup>30</sup>Social Security Act § 1886(p)(1).

payments that are critical to essential hospitals, including IME and DSH payments. Due to the high volume of low-income patients our member hospitals treat, as well as the fact that a large number of our members are teaching hospitals, cuts to IME and DSH payments in addition to base operating DRG payments would be unsustainable.

Essential hospitals already operate on significantly lower margins than other hospitals nationally. Without IME and DSH payments, essential hospitals face difficult financial decisions that could affect their ability to maintain vulnerable patients' access to care. The secretary of HHS has authority under Section 1886(d)(5)(I)(i) of the Social Security Act to make exceptions and adjustments to payments made for inpatient hospital services. To maintain the purpose of these add-on payments—which is to help account for the increased resources needed to care for complex patients and train future physicians—and to minimize the disproportionate effect of the HAC Reduction Program on essential hospitals, the secretary should use his authority to apply the HAC reduction only to base operating DRG payments.

**8. Before considering any payment changes, CMS should work with providers to better understand the difference between services performed in different settings.**

In the proposed rule, CMS refers to differing payment rates across the inpatient and outpatient settings and seeks comment on ways to “identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings.”<sup>31</sup> America's Essential Hospitals urges CMS to work with providers to understand the reasons for performing a service in an inpatient setting instead of as an outpatient procedure. Implementing policies that seek to minimize the payment differential or equalize the payment rate would fail to account for the many case-specific reasons a hospital might need to admit a patient.

CMS attempted to resolve the issue of short inpatient stays and excessively long outpatient stays through its two-midnight policy, but ultimately provided additional flexibility and exceptions that would defer to the clinician's judgment on the most appropriate care setting. In deciding whether to treat a patient in the inpatient or outpatient setting, a provider accounts for the patient's specific needs and comorbidities. Any policies that undermine clinician judgment run counter to CMS' stated goals of moving toward patient-centered care and “ensur[ing] that patients and their providers and physicians are making the best health care choices possible.”<sup>32</sup> Therefore, we recommend that CMS defer to clinicians' judgment and the individual needs of the patient in making any future policy recommendations on inpatient and outpatient payment policy.

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<sup>31</sup>Centers for Medicare & Medicaid Services. Fiscal Year 2018 Inpatient Prospective Payment System Proposed Rule. 82 Fed. Reg. 19796, 20001. April 28, 2017.

<sup>32</sup>Centers for Medicare & Medicaid Services. Fiscal Year 2018 Inpatient Prospective Payment System Proposed Rule. 82 Fed. Reg. 19796, 20158. April 28, 2017.

**9. CMS should continue to seek feedback about ways to reduce regulatory burden on hospitals, physicians, and patients.**

America's Essential Hospitals appreciates the opportunity to respond to CMS' request for information about achieving transparency, flexibility, program simplification, and innovation in the Medicare program. We are pleased to suggest the following recommendations for the agency's consideration.

- a. CMS must develop and implement a comprehensive approach to risk adjustment, when supported by compelling evidence, within the Medicare program.

As noted in previous sections of this letter, America's Essential Hospitals supports including sociodemographic and socioeconomic factors in the risk adjustment of outcomes measures when conceptual and empirical evidence warrants doing so. This will improve the science of performance measurement by increasing precision and delivering more accurate information to providers, payers, and the public.

We are pleased to see provisions in the 21st Century Cures Act related to risk adjustment in the HRRP. We see this as a first step toward true risk adjustment for hospitals treating patients with social and economic challenges. We also hope CMS extends this approach to other quality programs when the evidence for risk adjustment is compelling.

Further, CMS must go a step further to adjust measures so quality comparisons are fair. For example, 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 that patients receive accurate information about a hospital's performance.

- b. CMS should indefinitely delay Stage 3 of the EHR Incentive Program.

CMS should delay Stage 3 indefinitely until it can ensure all involved stakeholders are prepared for its complex requirements. We are concerned that some aspects of Stage 3 impose unnecessary burdens on providers instead of incorporating meaningful metrics that facilitate the provision of health care and improve the provider-patient relationship. In some respects, Stage 3 requirements merely build on many flawed elements of the existing program, simply raising thresholds for measures already demonstrated to be unfeasible to achieve. The requirements of the EHR Incentive Program so far have proved quite onerous for some providers, particularly essential hospitals with scarce resources and diverse patient populations. CMS should not rush providers into Stage 3 without requisite advances—truly interoperable products, standards that ensure the seamless exchange and use of health information, and adequate testing of these standards and of electronic clinical quality measures, for example.

In addition to the more difficult requirements of Stage 3, vendors still are preparing compliant EHRs . As previously cited, very few EHR products are certified to the 2015 Edition, which is required for Stage 3 reporting. Given the shortage of EHR products, there are significant doubts about vendors' ability to deliver the systems in time for providers to successfully test and deploy them by January 1, 2018. Without these systems, providers face rushed implementation, which might jeopardize patient safety and result in substantial financial penalties.

Stage 3 contains new requirements, including the use of APIs, that can give patients access to their health information through mobile applications. However, much work remains for ONC to develop certification criteria that ensure these APIs meet meaningful use program requirements and have mature standards. There also are serious privacy and security concerns about the use of APIs and third-party applications. Recent cybersecurity threats to providers, including in the form of ransomware attacks, are a reminder of the need to ensure the security of new capabilities before rushing into their implementation. CMS must thoroughly vet these issues before APIs are ready for Stage 3.

- c. CMS should eliminate the all-or-nothing structure of the EHR Incentive Program for eligible hospitals.

To encourage eligible hospitals to adopt and meaningfully use EHRs and focus on patient-centered care, CMS should change the all-or-nothing structure of the program. CMS responded to the need for flexibility on the eligible clinician side in its Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) rulemaking for the Quality Payment Program (QPP), and we believe this flexibility is equally imperative for eligible hospitals. Hospitals already struggle with difficult measures in the program, 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. Under the program's existing structure, a hospital that meets all but one measure under a single objective is not deemed a meaningful user and will be penalized. Penalizing a hospital that is willing and able to meet the thresholds, but misses the threshold for one or two measures, is a disincentive to program participation. The rigid requirements of the program can be an obstacle to fulfilling the true promise of EHRs to empower providers to offer the most appropriate care to their patients.

To alleviate this concern and align the program across provider types, CMS should extend flexibility to the EHR Incentive Program for eligible hospitals similar to the flexibility it has provided to eligible clinicians in the QPP. Allowing hospitals flexibility in choosing meaningful use objectives will be consistent with the direction the program is taking for eligible clinicians as required by MACRA. Giving hospitals similar discretion and moving the program away from the all-or-nothing approach would align the two programs. Shifting providers to alternative payment models (APMs) is one of the primary goals of MACRA, with CMS offering bonus payments to physicians who are part of an advanced APM. As both hospitals and physicians are encouraged to move into APMs, such as accountable care organizations, CMS should maintain parity between the structure of physician and hospital measures.

The meaningful use statute provides the agency with broad authority to determine the requirements of information exchange and meaningful use of CEHRT.<sup>33</sup> Using this discretion, the agency should allow hospitals to choose a subset of measures and report on measures without failing the entire program for falling short on percentage thresholds.

- d. CMS should review and revise obsolete, unnecessary, or burdensome provisions in CoPs to ensure continued patient safety, as well as reduce the regulatory burden placed on 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, some of the requirements might become obsolete as the health care system evolves over time. In addition, compliance with frequently changing CoPs can place administrative burden on some hospitals, as well as financial stress to invest funds into compliance efforts. Specific ideas to improve CoPs are included below.

- i. CMS should further clarify the discharge planning process.*

America's Essential Hospitals supports CMS' goal of promoting uniformity among providers and improving care transitions and outcomes by establishing standards for the actions hospitals must take before a patient's discharge. As CMS clarifies the discharge planning process, we ask the agency 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, lack of access to medications, and poor availability of needed non-health care services.

- ii. CMS should issue interpretive guidance to support Medicare- and Medicaid-participating providers and suppliers in advance of the date upon which hospitals must be in compliance with a final rule.*

The services that essential hospitals offer are vital in emergency response efforts nationwide. This fall, hospitals will be required to comply with CoPs to create a consistent foundation of emergency preparedness across the health care system, ensuring that providers across the spectrum are better positioned to respond to disasters and to ensure continuity of care for our most at-risk populations. CMS does not anticipate providing formal technical assistance, such as agency-led trainings. Further, CMS only recently released interpretive guidance for this regulation, for which hospitals must be in compliance before November 2017. Hospitals require adequate time to become familiar with new regulations, engage all levels within their facilities as well as build necessary relationships with community-related resources, to come into compliance. America's Essential Hospitals urges CMS to issue interpretive guidance at least 60 days in advance of the compliance date for any final regulation. Otherwise,

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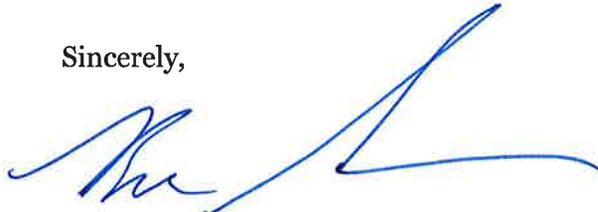
<sup>33</sup>Social Security Act § 1886(n)(3)(A)(i)-(iii)(2010).

hospitals and other Medicare- and Medicaid-participating providers and suppliers will not have adequate time to ensure full compliance.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Director of Policy Erin O'Malley at 202-585-0127 or [eomalley@essentialhospitals.org](mailto:eomalley@essentialhospitals.org).

Sincerely,



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