



AMERICA'S ESSENTIAL HOSPITALS

June 16, 2015

Mr. Andrew M. Slavitt
Acting 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-1632-P: Medicare Program:

- **Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates**
- **Revisions of Quality Reporting Requirements for Specific Providers, including Changes Related to the Electronic Health Record Incentive Program**

Dear Mr. Slavitt,

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 encourage improved care delivery across the entire health care industry. However, under the current structure, certain programs aimed at improving quality will have a disproportionately negative financial impact on essential hospitals—those driven to serve the vulnerable, first and foremost. To this end, America's Essential Hospitals asks CMS to consider the unique challenges inherent in caring for these patient populations when finalizing this rule.

America's Essential Hospitals is the leading association and champion for hospitals and health systems dedicated to high-quality care for all, including the most vulnerable. Filling a vital role in their communities, our more than 250 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. Nearly half of patients at essential hospitals are

racial and ethnic minorities who rely on the culturally and linguistically competent care that only essential hospitals are able to provide. Our members provide this care while operating on margins substantially lower than the rest of the hospital industry—with an aggregate operating margin of -3.2 percent, compared to 5.7 percent for all hospitals nationwide.¹ Through their integrated health systems, members of America's Essential Hospitals offer the full range of primary through quaternary care, including trauma care, outpatient care in their ambulatory clinics, public health services, mental health services, substance abuse services, and wraparound services critical to vulnerable patients.

Our members also offer specialized inpatient and emergency services not available elsewhere in their communities. The high cost of providing so much complex care to low-income and uninsured patients leaves our hospitals with limited resources, propelling them to find increasingly efficient strategies for providing high-quality care to their patients. But improving care coordination and quality while maintaining a mission to serve the most vulnerable is a delicate balance. This balance is threatened by payment cuts to hospitals, particularly the inequities built into the reductions from the quality improvement programs that were included in the Affordable Care Act (ACA).

Members of America's Essential Hospitals are constantly engaging 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 for patients. To ensure our members have sufficient resources to continue these activities and are not unfairly disadvantaged for serving the most vulnerable among us, CMS should consider the following comments when finalizing the above-mentioned proposed rule.

1. CMS should work to accurately capture uncompensated care data and, as soon as possible, use such data to implement the ACA's changes to Medicare disproportionate share hospital (DSH) payments.

The Medicare DSH program provides crucial financing for the uncompensated care provided by members of America's Essential Hospitals. In 2013, our members provided nearly \$8 billion in uncompensated care, representing 17 percent of all uncompensated care provided nationwide.²

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

¹Reid K, Roberson B, Landry, C, Laycox S, Linson M. Essential Hospitals Vital Data: Results of America's Essential Hospitals Annual Characteristics Survey, FY 2013. America's Essential Hospitals. March 2015. <http://essentialhospitals.org/wp-content/uploads/2015/03/Essential-Hospitals-Vital-Data-2015.pdf>. Accessed June 15, 2015.

²Ibid.

relative to all other Medicare DSH hospitals. While DSH hospitals continue to receive 25 percent of their Medicare DSH payments as a per-discharge adjustment payment, 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 payment). This change was in line with the Medicare Payment Advisory Commission's (MedPAC's) longstanding recommendation to incorporate uncompensated care into the Medicare DSH formula to better target dollars to hospitals with the greatest need. America's Essential Hospitals has long supported this recommendation. And effective implementation of the ACA provision should ensure such targeting occurs.

However, we are concerned about the sustainability of continued reductions to the aggregate uncompensated care-based DSH payments that are occurring as coverage continues to expand and the national uninsurance rate falls. The aggregate amount of uncompensated care payments proposed by CMS for fiscal year (FY) 2016—\$6.371 billion—constitutes a nearly 30 percent reduction from FY 2014 levels. This amount will continue to decline with the national uninsurance rate, which in turn will reduce the amount of Medicare DSH payments distributed to hospitals to help cover the cost of uncompensated care. Furthermore, hospitals in those states that have not expanded Medicaid are not experiencing the drop in uncompensated care that hospitals in expansion states have seen. So such steep cuts in Medicare DSH payments are even more detrimental and unjustifiable for these hospitals.

CMS should consider how its policy choices will impact 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 uncompensated care costs, particularly as data sources evolve. CMS should make transition periods as short as possible and aid the process by clarifying the Medicare cost report and other guidance, so Medicare DSH payments are targeted to the hospitals that need them most.

Below are specific comments of particular importance to ensuring essential hospitals receive adequate Medicare DSH payments to assist them in providing vital care to vulnerable populations.

- a. CMS should continue to use the most recently available estimates for determining the change in the number of uninsured.

America's Essential Hospitals supports using the most recently available estimates for determining the change in the number of uninsured. The ACA directs CMS to reduce the total amount of funds available for the uncompensated care -based Medicare DSH payment by the estimated decline in the national

uninsurance rate. To reach this amount, CMS should continue to use the latest estimates from the Congressional Budget Office (CBO), including any revised estimates issued prior to the final rule. By using the latest estimates from the CBO, CMS will take into account changing assumptions about the level of coverage expansion after the Supreme Court decision rendering the Medicaid expansion for low-income adults optional. CMS has the authority to exercise such flexibility.³ **Therefore, CMS should continue using the latest estimates from the CBO for determining the national 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 ACA-revised Medicare DSH program, we urge CMS to continue to refine its methodology to accurately capture uncompensated care costs. Under the ACA's Medicare DSH methodology, CMS determines a hospital's qualifying uncompensated care burden by estimating the hospital's percentage of the total uncompensated care costs incurred by all DSH hospitals. 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. To date, CMS has concluded that due to shortcomings with worksheet S-10, it must deviate from the common definition of uncompensated care and instead use a proxy to estimate hospital uncompensated care costs. CMS proposes to continue to use a hospital's Medicaid days plus Medicare supplemental security income (SSI) days as the proxy for a hospital's uncompensated care burden under the Medicare DSH methodology. CMS notes the proxy is an interim measure and proposes to continue to monitor alternative proxies and data sources.

America's Essential Hospitals 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

³The ACA specifies that the uninsurance rate for 2013 is to be "calculated by the Secretary [of the U.S. Department of Health and Human Services] based on the most recent estimates available from the Director of the Congressional Budget Office" from immediately prior to the ACA's passage. This rate is to be compared with the uninsurance rate in the most recent period "as so calculated." The requirement that the secretary "calculate" the rate indicates she is to do more than simply use the CBO estimates issued in 2010 for the rate in the most recent year. The phrase "based on" also indicates the secretary has flexibility to use estimates derived from the approach adopted by the CBO but is not required to simply use the CBO's 2010 estimates as the current uninsurance rates. For determining the uninsurance rate for FY 2016 addressed by the proposed rule, the ACA specifies that the secretary use "the most recent period for which data is available." If Congress intended the secretary to determine the uninsurance rate directly from the 2010 CBO estimates, there would be no need to specify the use of the uninsurance rate for "the most recent period for which data is available."

formula.⁴ The ACA specifically references the importance of using data sources that are the best proxy for the costs to hospitals of treating the uninsured. As CMS looks to utilize the S-10 worksheet in the future, it should consider the following refinements to the worksheet so the data captured on the worksheet accurately captures uncompensated care costs.

- i. CMS should include all patient care costs if using worksheet S-10 to determine uncompensated care costs.*

The current worksheet S-10 does not take into account all patient care costs when converting charges to costs. As CMS considers whether and how to use worksheet S-10 as the data source for measuring uncompensated care costs, the agency should refine the worksheet to incorporate all patient care costs, including teaching costs, into any determination of costs for use in the cost-to-charge ratio. In particular, CMS should follow these guidelines:

- 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.
- Use worksheet C, column 8, line 200, as the charge component.

Because the line items noted above include additional patient care costs, such as the cost of graduate medical education (GME), the result would more accurately reflect the true total cost of hospital services provided than does the cost-to-charge ratio currently used in worksheet S-10.

CMS should also 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 physician 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 worksheet S-10 to reflect these issues, CMS will accurately measure uncompensated care costs to hospitals of treating low-income and uninsured patients.**

- ii. 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.*

⁴See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare Payment Policy. March 2000. http://www.medpac.gov/documents/reports/Mar00_Entire_report.pdf. Accessed June 2015.

A review of worksheet S-10 data indicates an inconsistency in how hospitals categorize and report charity care versus bad debt. Some hospitals report all such costs as charity care, others report all as bad debt, and still others split the costs between charity care and bad debt. While CMS can overcome this data limitation by using the sum of charity care and bad debt, the agency should still issue clarifying guidance so there is consistency across the hospital industry in how charity care and bad debt are reported.

In addition, we continue to urge CMS to address current underreporting of charity care by revising its instructions for worksheet S-10. As is, the use of charity care from the S-10 provides an incomplete picture of actual costs of charity care and thus is not ready for use in a hospital's uncompensated care calculation. The current instructions call for charity care that was *provided* (not necessarily written off) during the period to be recorded in line 20.⁵ However, hospitals often determine and write off charity care outside of the FY 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 worksheet S-10 for any year. This results in an understatement of actual charity costs. For this reason, CMS should revise its instructions to capture all charity care written off (as opposed to provided) during the period so that all charity care is taken into account.

CMS should also treat the uncompensated 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 uncompensated portion (i.e., the shortfall) should be treated the same as charity care.

Moreover, should CMS decide to incorporate Medicaid shortfall into uncompensated care, the agency must revise the current worksheet S-10 so data better resemble actual shortfalls hospitals incur. The current data on Medicaid shortfalls underestimate the amount of shortfall. First, GME-related costs are excluded, while GME-related reimbursements are included. Without the necessary revision to the cost-to-charge ratio mentioned above, counting payments but not costs is an inaccurate way to measure shortfall. Second, the current worksheet does not permit government-owned hospitals to reduce their Medicaid revenues by the amount of intergovernmental transfers (IGTs) or certified public expenditures (CPEs) they provide. Like provider taxes and assessments, provider-funded IGTs and CPEs are contributions to the nonfederal share of Medicaid payments and are often critical to a state's ability to make such payments. Allowing offsets for one such type of contribution, i.e., provider taxes and assessments, and not others distorts shortfall amounts and may create inequities among hospitals. This is particularly detrimental in a context where the

⁵Medicare Provider Reimbursement Manual, Part 2, Provider Cost Reporting Forms and Instructions, Form CMS 2552-10S-10 Instructions, § 4012.

shortfall is counted as uncompensated care and the uncompensated care-based DSH payments are determined on a relative basis. If hospitals are to receive a portion of their DSH payments based on their relative uncompensated care, relative amounts must be calculated in an equitable and uniform manner. **Thus, to create more consistency and accuracy in worksheet S-10 data, CMS should make the above-mentioned adjustments.**

- iii. CMS should clarify that only payments actually received offset charity care costs.*

To appropriately determine the uncompensated care costs associated with charity care patients, CMS should clarify that only payments actually received from patients, and not merely those expected to be received, offset charity care costs. Despite patients' cost-sharing responsibility, many charity care patients may not pay their share. It makes no sense—and would be factually incorrect—to count expected payments when determining the costs that remain uncompensated. **Therefore, CMS should ensure uncompensated care costs associated with charity care accurately reflect the true payments received.**

- iv. CMS should not use private grants, donations, or endowment income to determine the value of uncompensated care provided by hospitals.*

Worksheet S-10 requires hospitals to report private grants, donations, or endowment income restricted to funding charity care on line 17. While this line is under the heading of uncompensated care, the instructions are silent as to how the information from this line will be used. **America's Essential Hospitals strongly urges CMS to clarify that line 17 is for informational purposes and not for use in determining the value of uncompensated care hospitals provide.**

Accounting for these voluntary funding sources in the determination of the full uncompensated care provided to charity care patients understates the true cost of serving these patients and could jeopardize the future availability of these funds if grantors and donors realize their contributions will be offset against any supplemental funding from the Medicare program. Moreover, the amount of funding hospitals receive from voluntary, philanthropic sources can vary substantially from year to year, making it an unreliable factor for formulating hospital payment policy.

In addition, while line 17 is appropriately limited to private grants, donations, or endowment income restricted to funding charity care, it neglects to account for the cost of complying with rules associated with receiving these funds. **America's Essential Hospitals believes CMS should only capture the net value of these funds on the S-10 worksheet.**

- v. CMS should not use government grants, appropriations, or transfers in its calculation of uncompensated care.*

CMS should not use data from Line 18 of the S-10 in calculating the value of uncompensated care. Line 18 requires hospitals to report all government grants, appropriations, or transfers in support of hospital operations. **As with line 17, CMS should clarify that this line is for informational purposes only and should not be used in determining the value of uncompensated care.** The purpose of these sources of funding, which are for hospital operations, could be vastly different than funding uncompensated care. For example, these sources of funding could be used for a wide range of purposes including the construction of new hospital clinics and paying salaries of non-medical staff. What's more, different hospitals may use this funding in different ways, which would lead to inconsistencies when comparing hospitals for the purpose of calculating uncompensated care. **Therefore, CMS should not use this data in determining hospitals' uncompensated care amount.**

- vi. CMS should consider current shortcomings of the uncompensated care proxy when evaluating alternatives or modifications to the proxy.*

As CMS evaluates alternatives or modifications to its uncompensated care methodology, the agency should consider the following additional implications:

- The current methodology, which uses only inpatient 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.
- 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. At the very least, until CMS is able to refine its methodology for distributing the uncompensated care-based Medicare DSH payments using uncompensated care data, the agency should weigh each hospital's SSI and Medicaid days by its total patient days, rather than using the SSI and Medicaid days without any weights, so the data used to compare hospitals capture the disproportionate nature of some hospitals' commitment to low-income populations.

2. CMS should collaborate with stakeholders to refine its payment policy and medical review criteria so it preserves physicians' clinical judgment and limits the unbridled discretion of review contractors.

CMS should work with stakeholders to devise a policy that preserves physicians' judgment of the most appropriate level of care for a patient and that ensures physician judgment is not overturned by the retrospective evaluation of review contractors. Since it first announced the two-midnight policy for FY 2014, and in response to concerns raised by providers and Congress, CMS put in place a partial enforcement ban and has repeatedly extended the ban. Most recently, CMS extended the ban until September 30, 2015, to comply with a requirement in the Medicare and CHIP Reauthorization Act of 2015. CMS notes in the rule that it will be reviewing policies on Medicare payment for short inpatient stays and long outpatient stays in future rulemaking.

Under the two-midnight policy, hospital stays crossing two midnights are presumed to be appropriate for inpatient reimbursement and would generally not be reviewed by Medicare administrative contractors (MACs) or recovery audit contractors (RACs). Stays lasting fewer than two midnights can still be reviewed by MACs and RACs. However, in these cases, an admitting physician's expectation that the patient would need to remain in the hospital for at least two midnights would be considered favorably in determining whether an inpatient stay was necessary, even if the stay did not last the expected two midnights.

The repeated extension of the enforcement ban indicates that the agency, hospitals, and other stakeholders are not prepared to implement the two-midnight policy. The two-midnight policy will require thorough hospital and staff education to ensure they can fully understand and comply with the new requirements regarding what constitutes an appropriate inpatient admission. Concerns about the ramifications of the policy on providers also led MedPAC to recommend that CMS withdraw the two-midnight policy and significantly limit RAC authority.⁶

In addition to the confusion the policy creates for physicians and hospital staff, it does not address unresolved issues with excessive audits of inpatient admission decisions. Audits by review contractors are often inaccurate and overturned when appealed. The high rate of reversal is indicative of the underlying problems with RAC audits. Having to appeal these incorrect decisions consumes substantial hospital resources, which is especially burdensome when the original physician inpatient admission decision was made correctly in the first place.

Moreover, due to the clinical complexity of the patients treated at essential hospitals, it is of utmost importance that physicians are allowed to make appropriate care determinations based on patients' specific needs and comorbidities instead of being bound by a rigid assessment of the projected length of stay. Clinical judgment should not be overruled by post facto assessments. Essential hospitals, which already provide a disproportionate amount of

⁶See, e.g., Medicare Payment Advisory Commission. Transcript of Public Meeting, April 2, 2015. http://medpac.gov/documents/april-2015-medpac_transcript.pdf. Accessed June 2015.

uncompensated care compared to other hospitals, will face an increased uncompensated care burden if they are not adequately reimbursed for stays most appropriately paid at inpatient rates. To preserve physician judgment and protect hospitals from unnecessary audits of short stays, **CMS should continue to delay the parts of the two-midnight policy that would allow contractors to review inpatient stays lasting fewer than two midnights for appropriateness of admission until the agency has comprehensively addressed the outstanding issues with the policy.**

In addition, until CMS is able to resolve these issues surrounding short inpatient stays, the agency should limit RACs' ability to overturn admission decisions made by physicians. CMS notes that it is considering stakeholder feedback and MedPAC recommendations pertaining to short inpatient stays and long outpatient stays, which it says it will address in the calendar year 2016 Outpatient Prospective Payment System proposed rule to be issued this summer. America's Essential Hospitals looks forward to reviewing the agency's proposals on these issues. As CMS considers any changes relating to short inpatient stays, the agency should work collaboratively with interested stakeholders through a transparent process to ensure any methodology allows hospitals to provide the best care for patients in the most appropriate setting, as determined by the physician. We look forward to working with CMS during this process.

- a. CMS should not have inappropriately reduced hospital payments under the IPPS to offset the two-midnight policy.

In the FY 2014 IPPS final rule, CMS announced that due to an expected increase in inpatient stays under the two-midnight policy, the standardized inpatient hospital payment for hospitals would be reduced by 0.2 percent. However, empirical and anecdotal evidence from hospitals suggest that since CMS announced the two-midnight policy, more stays are shifting from the inpatient to the outpatient setting.⁷ CMS should not have cut hospital inpatient payments when the policy was not fully implemented and the anticipated shift to inpatient stays has not occurred. **Going forward, CMS should not subject hospitals to a reduction in their inpatient payments unless, after the implementation of a rational and fair payment policy for short-term inpatient stays, CMS empirically determines that the policy has increased the number of inpatient stays.**

- b. CMS should deem patients to have been admitted after 72 hours of observation services and pay hospitals a diagnosis-related group (DRG) payment for these patients.

⁷Sheehy AM, et al. Observation and Inpatient Status: Clinical Impact of the 2-midnight Rule. *Journal of Hospital Medicine*. February 2014;9:203-209.

In cases involving a patient in outpatient observation status, CMS should deem patients to have been admitted to the hospital after 72 hours of observation services and pay hospitals a DRG payment for these “deemed-admitted” patients. Hospitals provide observation services to patients based on a physician’s clinical judgment that this is the most appropriate setting for the patient. In certain cases, a physician may decide that a patient’s condition requires further treatment in the hospital under observation status. To provide further clarity on the blurred line between payment for inpatient and outpatient services, CMS should consider a patient who has been receiving observation services for 72 hours as “deemed admitted” for payment purposes. Cases involving extended observational services are more akin to an inpatient admission in terms of the complexity and level of care required to treat the patient. To ensure the hospital is being reimbursed appropriately for these cases, CMS should bundle the outpatient services provided during the 72 hours into the DRG payment.

Through separate rulemaking, CMS can modify its requirement for skilled nursing facility (SNF) coverage so the period of observation care in the hospital counts toward meeting the three-day Medicare payment requirement for patients who are admitted to the hospital, and then receive treatment in a SNF. Medicare will only cover SNF stays for beneficiaries who were inpatients for at least three days during the preceding hospital stay. This requirement is confusing for beneficiaries, who often don’t know their status as inpatients or outpatients. CMS has acknowledged this issue and addressed it in the context of pioneer accountable care organizations (ACOs) by introducing a waiver of the three-day SNF coverage requirement for beneficiaries in pioneer ACOs. This flexibility is a step in the right direction, but does not go far enough to cover all hospitals. CMS should extend this policy beyond the demonstration to apply to all hospitals. **For these reasons, CMS should deem patients under observation status to have been admitted for inpatient payment purposes after 72 hours and should count the time in observation care toward the three-day SNF coverage requirement.**

3. CMS should ensure the methodology and 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 reevaluate 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 the U.S. Department of Health and Human Services (HHS) to adjust payments to hospitals with high rates of HACs. Specifically, for hospitals that rank in the top quartile of hospitals nationally for HACs during the applicable period, CMS will adjust payments to 99 percent of what they would otherwise have been. The ACA also requires the secretary to provide confidential HAC reports to applicable

hospitals so the hospitals can review and correct the information. Information pertaining to hospitals' performance on HAC measures will then be posted publicly on the Hospital Compare website. CMS finalized guidance on implementing the HAC Reduction Program in the FY 2014 IPPS rule, with the program beginning in FY 2015.

America's Essential Hospitals supports Congress' aim to reduce HACs that create serious adverse outcomes for patients and can lead to death or disability. HACs are also a burden to hospitals and to the overall health care system. Our 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, many of the measures included in the HAC Reduction Program are unreliable indicators of quality of care. For example, the Agency for Healthcare Research and Quality (AHRQ) patient safety indicator 90 (PSI 90) measure is claims-based, and the events in this measure occur infrequently. As detailed below in subsection (a), these factors make this measure a poor indicator of the true quality of care being provided.

In the IPPS FY 2015 final rule, CMS reduced domain 1 of the HAC Reduction Program, which includes the PSI 90 measure, to 25 percent. America's Essential Hospitals believes the PSI 90 measure should be weighed less, and **supports CMS' proposed further reduction of domain 1, to 15 percent of the total score, for the FY 2017 HAC Reduction Program.** CMS should continue to decrease the weight of this measure in the future.

The nature and volume of care essential hospitals provide to vulnerable populations makes them likely to be disproportionately included in the top quartile of hospitals based on the total HAC score. As highlighted in a December 2014 America's Essential Hospitals research brief,⁸ patient acuity and status as an essential hospital were associated with a higher proportion of penalties under the HAC Reduction Program. Our analysis found that even though mortality rates among essential hospitals were either 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 of the effects of the HAC Reduction Program on hospitals shows that DSH hospitals, teaching hospitals, and urban hospitals will be severely impacted by the program in its proposed form. For example, many of our hospitals are teaching hospitals and tertiary care centers that provide highly specialized care including high-risk procedures that are not often performed at the hospitals our members are being measured against. These procedures, such as cancer surgery, involve a higher risk of acquiring a condition such as an accidental puncture or

⁸HAC Reduction Program Penalties: An Undue Burden on Essential Hospitals? *Essential Hospitals Institute*. December 2014. <http://essentialhospitals.org/wp-content/uploads/2014/12/HAC-research-brief-12-18.pdf>. Accessed June 2015.

laceration.⁹ In these cases, the higher risk of infection is not a negative reflection of the hospital's quality of care, but is explained by the types of procedures being performed at this hospital.

To ensure hospitals are not unfairly penalized for providing essential specialty care and serving the most vulnerable, **CMS should include appropriate risk-adjustment methodology in the HAC Reduction Program.**

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 develop measures for the HAC Reduction Program that more accurately reflect hospitals' quality of care.

Some measures CMS has included in the HAC Reduction Program, such as the PSI 90 measure and the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) healthcare-associated infection measures, are not appropriate quality indicators. PSI 90 measures, for example, are administratively measured using claims data and are not clinically reported. Since the claims data used in calculating the PSI 90 metrics are not clinically validated, the data do not accurately represent the quality of care provided at a hospital. Hospitals are able to track clinically based data and monitor patients' progress based on the entirety of their clinical record. Placing excessive emphasis on claims-based data unreliably represents a hospital's actual progress in improving quality. In addition, many of the PSI 90 measures are rare events and do not meet the high-volume requirement for the HAC Reduction Program.

The measures currently included in the program are also problematic because many of them occur disproportionately in teaching hospitals and hospitals providing highly specialized services. The frequency of these infections is not necessarily a result of poor quality of care but instead reflect the large number of high-risk procedures essential hospitals perform, such as in their emergency trauma and burn units. Thus, essential hospitals may report higher infection rates than other hospitals. Even a minimal increase in the number of infections can place a hospital in the top quartile for these measures. As hospitals are assigned points that correlate to a measure's nationally ranked performance range, the addition of one infection could increase the hospital's score on that measure by a whole point. Rather than a preferred gradual increase in score, the current scoring system lends itself to sharp score increases, not necessarily indicative of poor quality of care, which penalize hospitals that provide high-volume and high acuity care. **For these reasons, CMS should only include measures in the HAC Reduction Program that accurately gauge quality and are not inherently**

⁹Kin 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.

skewed against teaching hospitals, large hospitals, and hospitals that provide care to vulnerable populations.

- b. CMS should delay the timing of any proposed refinement to the CLABSI and CAUTI measures to include select ward (non-intensive care unit [ICU]) locations.

CMS proposes to refine the central line-associated bloodstream infection (CLABSI) and the catheter-associated urinary tract infection (CAUTI) measures from the NHSN. These measures were previously adopted for the HAC Reduction Program in the ICU setting. However, CMS is now proposing to include select ward (non-ICU) locations such as adult and pediatric medical, surgical, and medical/surgical wards, beginning in FY 2018. CMS notes that it had considered delaying implementation of this proposal until FY 2019, but ultimately opted for FY 2018 implementation. CMS only recently implemented these measure refinements in the IQR Program (January 1, 2015), after deferring the implementation a full year, based on comments CMS received from stakeholders. Such comments reflected hospitals' need for time to implement electronic collection of the denominator data and time to expand best practices outside the ICU. America's Essential Hospitals encourages CMS to reconsider FY 2019 implementation to allow adequate time for hospitals to understand and become familiar with the refinements in the IQR Program for at least two years. For these reasons, **CMS should delay any refinement to the CLABSI and CAUTI measures until FY 2019.**

- c. CMS should postpone the CDC's updated standard population data, used to calculate the NHSN measures including the CAUTI and CLABSI measures, until FY 2019.

As part of routine measure maintenance, the CDC will be updating the standard population data to use CY 2015 data as the "new standard population data" for HAI measures. CMS anticipates that the new standard population data will affect the HAC Reduction Program beginning in FY 2018. However, CMS intends to postpone the use of the new standard population data in the Hospital Value-Based Purchasing (VBP) Program until FY 2019. America's Essential Hospitals supports the use of contemporary data for calculating performance standards and measure scores, however, **the new baseline for standard population data should be applied uniformly in FY 2019 across all applicable programs (i.e., VBP and HAC) to minimize potential confusion for hospitals.**

- d. 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, the patient's primary language, and the patient's income. The risk-adjustment used for the HAC measures in both 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, residence is an important determinant of a patient's condition prior to coming to the hospital. Patients' primary language can impact their ability to communicate with hospital staff. And both can contribute to a higher risk of developing an infection or other complications. Having a lower income can also greatly impact a patient's chance of developing a complication after high-risk procedures. For example, 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.¹⁰ The populations served by essential hospitals are among the most vulnerable. For them, even common conditions such as high blood pressure, diabetes, and asthma often become worse because of social determinants of health (e.g., having no place to store medications or syringes properly).

Sociodemographic factors should be included in the HAC Reduction Program's risk-adjustment methodology so the measures more accurately reflect quality outcomes within hospitals' control.

- e. CMS should use its exceptions and adjustment authority to ensure payment reductions under the HAC Reduction Program are applied to base operating DRG payments only and 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)."¹¹ 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 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 with much lower margins than other hospitals nationally. Without these supplemental payments, essential hospitals face difficult financial decisions that could impact 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**

¹⁰Saunders 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.

¹¹Social Security Act § 1886(p)(1).

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 her authority to apply the HAC reduction to base operating DRG payments only.

- f. CMS should adopt an extraordinary circumstance exception that allows for at least a one-year exemption from the HAC Reduction Program.

CMS should finalize its proposal to adopt an extraordinary circumstance exception in the HAC Reduction Program and should allow hospitals to be exempt from the program for at least the year in which the extraordinary circumstance occurs. Similar to what the agency finalized for the Hospital Value-Based Purchasing (VBP) Program and Hospital Inpatient Quality Reporting (IQR) Program, including an exemption for extraordinary circumstances for the HAC Reduction Program would allow hospitals enough time to assess any data gaps and recover from the circumstance that impacted their hospital.

In 2012, essential hospitals in New York mobilized to manage the aftermath of Hurricane Sandy. One hospital took in patients and staff from other hospitals and care facilities. A federal disaster medical assistance team arrived quickly and stayed for weeks to aid staff. Many of these temporary staff members were unfamiliar with the hospital's electronic health record (EHR) system and had to use paper forms as they treated patients, which created serious data lags. Another essential hospital in New York sustained heavy damage that closed many of its facilities. It took many months to assess whether it was possible for the damaged hospitals to reopen. Essential hospitals are already operating on limited resources which, when combined with an event such as Hurricane Sandy, results in even higher than normal demands on staff, delays in data entry, and an overall need for time to recover.

Implementing an extraordinary circumstance exception to the HAC Reduction Program, with an exemption of at least one year from the program, would allow hospitals to focus on and address their immediate needs during a time of crisis and to recover from physical damage and data lags. Hospitals struggling with an extraordinary circumstance may face a truncated reporting period and may have a low volume of data to report. This could lead to inconsistent, unreliable outcomes resulting in unjust fiscal penalties. **For these reasons, CMS should finalize its proposal to adopt an extraordinary circumstance exception in the HAC Reduction Program and allow hospitals to be exempt from the program for at least one year.**

- g. CMS should, as in previous years, publish a regulatory impact analysis on the HAC Program prior to IPPS final rule publication.

CMS did not provide hospital-level data or a hospital-level payment impact in conjunction with the FY 2016 proposed rule for the HAC Program. CMS provided these data in previous years to assist hospitals in quantifying the projected effects of the various pay-for-performance programs. Hospitals value the information gained from these analyses, and to withhold such information, when available, is a detriment. **CMS should provide timely (i.e., in conjunction with the proposed rule) impact and data files for all pay-for-performance programs.**

4. Before expanding the Hospital Readmissions Reduction Program to include additional conditions, CMS should develop a sufficient risk-adjustment methodology, amend the program's definition of transfers, and add exclusions to the definition of readmissions to ensure essential hospitals are not disproportionately penalized.

Reducing preventable readmissions is of paramount concern to America's Essential Hospitals and its members, but any program directed at reducing readmissions must target readmissions that are preventable and must include appropriate risk-adjustment methodology. America's Essential Hospitals has previously expressed concern that the Hospital Readmissions Reduction Program unduly penalizes hospitals that serve the nation's most vulnerable populations because external factors that explain higher readmission rates are not taken into account. The recently proposed bipartisan bills S. 688 and H.R.1343, Establishing Beneficiary Equity in the Hospital Readmission Program Act, echo the importance of and vital need for risk-adjustment methodology. These bills recognize the socioeconomic complexities of vulnerable populations when calculating quality measures to ensure that hospitals are assessed on the work they do, rather than on the patients they serve.

Based on the floor adjustment factors established by the ACA, hospitals will face a 3 percent reduction for FY 2016 and beyond. Given essential hospitals' already low operating margins, their ability to provide care to all patients, including our nation's most vulnerable, will be profoundly impacted if the necessary risk adjustments are not made to accurately measure readmissions.

- a. CMS should include risk-adjustment methodology that accounts for social and community-level factors in the existing and proposed applicable conditions.

CMS should ensure the methodology for calculating a hospital's number of excess readmissions includes adequate risk-adjustment for the five existing applicable conditions and for the refinements proposed for inclusion in the FY 2016 program. The current Hospital Readmissions Reduction Program tracks a hospital's readmissions based on five applicable conditions: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), acute exacerbations of chronic obstructive pulmonary disease (COPD), and elective total hip arthroplasty

(THA) or total knee arthroplasty (TKA) (hip or knee replacement, respectively). The methodology used in calculating these readmission measures does not incorporate appropriate risk-adjustment for sociodemographic status, language, insurance status, postdischarge support structure, or other factors that reflect the unique difficulties involved in providing care to vulnerable populations.¹²

In its June 2013 report to Congress, MedPAC underscored the connection between sociodemographic status and readmission rates, emphasizing the strong correlation between a hospital's share of low-income Medicare patients and its readmission rate.¹³ Due to the disproportionate effect of readmission penalties on hospitals treating a larger share of low-income patients, MedPAC suggests that in calculating a penalty, hospitals be compared to a peer group of hospitals with a similar share of low-income patients. This type of change requires Congress to take legislative action. But there are other avenues that CMS might take, such as including adequate risk-adjustment in measures, which would also mitigate the disproportionate effects of the program.

The Readmissions Reduction Program has already disproportionately penalized many providers. For instance, an analysis of the penalties for FY 2013 shows that 44 percent of hospitals serving a large proportion of the poor receive high penalties as compared to 30 percent of other hospitals.¹⁴ And teaching hospitals and large hospitals, both of which tend to provide care to vulnerable populations, more often face higher penalties.¹⁵ These data support the proposition that higher readmissions are partly caused by socioeconomic and social support factors in patients' communities rather than by the quality of care provided by the hospital.

Empirical research shows that for certain conditions, such as HF, low mortality corresponds with high readmission rates, and therefore readmissions may be a necessary measure to stabilize certain patients and prevent death.¹⁶ However, as the program stands, hospitals with high readmissions rates but low mortality rates would receive higher penalties. MedPAC's June 2013 report identified this inverse relationship between readmission rates and mortality rates for HF as one of four issues of concern with the Readmissions Reduction Program.¹⁷ America's Essential Hospitals previously noted that CMS' Hospital Compare data illustrate that hospitals providing care to vulnerable populations are achieving lower mortality

¹²Nagasko EM, et al. Adding Socioeconomic Data to Hospital Readmissions Calculations May Produce More Useful Results. *Health Affairs*. 2014; 33(5): 786-791.

¹³See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare and the Health Care Delivery System. June 2013.

http://www.medpac.gov/documents/reports/jun13_EntireReport.pdf. Accessed June 2015.

¹⁴Joynt KE, Jha AK. Characteristics of Hospitals Receiving Penalties Under the Hospital Readmissions Reduction Program. *Journal of the American Medical Association*. 2013;309(4):342-43.

¹⁵*Ibid.*

¹⁶*Ibid.*

¹⁷*Ibid.*

rates than the national average while patients are in the hospital. Thus, when outside sociodemographic factors are minimized, patients at essential hospitals have better health outcomes when they receive inpatient hospital care.

America's Essential Hospitals urges CMS to include factors relating to a patient's background—sociodemographic status, language, and postdischarge support structure—in its risk-adjustment methodology. These underlying factors frequently drive readmissions to essential hospitals. In addition, the timing of a readmission may have different causal factors, including social determinants of health. A retrospective study of an academic medical center found that late readmissions (8 to 30 days after discharge) were associated with markers of chronic illness burden, including social determinants of health.¹⁸ Such research further emphasizes the need to risk adjust for sociodemographic factors, which greatly affect the populations served by essential hospitals, in the Hospital Readmission Reduction Program.

Recently, the National Quality Forum (NQF) convened an expert panel to examine whether the lack of sociodemographic adjustment may lead to incorrect conclusions about quality (i.e., conclusion that hospitals with a disproportionate share of disadvantaged patients provide lower quality simply as a function of their case mix). The panel, which ultimately recommended risk-adjusting certain quality measures for sociodemographic factors, found that excluding such factors could lead to greater disparities in care. For example, disadvantaged populations could lose access to care if providers who work primarily with them are asked to achieve the same results as those who work with wealthier populations.¹⁹ Without proper risk-adjustment, those 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.

By not taking into consideration the full range of differences in patients' backgrounds that may affect readmission rates, readmission measure calculations will inevitably be skewed against hospitals providing essential care to low-income individuals, including the uninsured.

In addition, adding new measures to the Hospital Readmissions Reduction Program without first addressing the inadequacies in the existing methodology would further exacerbate the already negative impact this program could have on essential hospitals and the vulnerable populations they treat. **For these reasons,**

¹⁸Graham KL, Wilker EH, Howell MD, Davis RB, Marcantonio ER. Differences Between Early and Late Readmissions Among Patients: A Cohort Study. *Annals of Internal Medicine*. 2015;162:741-749.

¹⁹See, e.g., NQF 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. Accessed June 2015.

CMS should include a sufficient risk-adjustment methodology that accounts for patient sociodemographic factors in the Readmissions Reduction Program.

- b. CMS should only include measures that have NQF endorsement in the Hospital Readmissions Reduction Program and should not expand the patient population for the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization measure for FY 2017.

CMS proposes to refine the above-mentioned measure for FY 2017 by including hospitalizations for patients with a principal discharge diagnosis of aspiration pneumonia and for patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia present on admission. **The changes to this measure are not NQF endorsed, and the revised measure has not yet undergone the vetting process necessary for such a complex clinical measure.** The scope of the pneumonia hospitalization measure should be clearly defined and clinically appropriate. The proposed addition of hospitalizations for patients discharged with a secondary diagnosis of pneumonia and a principal diagnosis of either sepsis or respiratory failure diffuses the meaning of the original measure – to capture hospitalizations for patients with a principal discharge diagnosis of pneumonia, indicating viral or bacterial pneumonia. **In its effort to enhance or broaden the cohort for the current pneumonia hospitalization measure, CMS is risking being overly inclusive.** It is critically important that the measure go through the NQF endorsement process so it can be properly vetted for clinical appropriateness. Each measure adopted by CMS should have a clear purpose and be accompanied by guidance for implementation by hospitals to avoid confusion.

CMS also proposes expanding the pneumonia hospitalization measure in the IQR Program for FY 2017. Hospitals, CMS, the public, and other stakeholders should have time to gain experience with this revised measure in the IQR Program before the measure is included in the Readmission Reduction Program. America's Essential Hospitals supports CMS' work to continue to refine the readmissions algorithm. **However, CMS should obtain NQF endorsement and allow participants time to gain experience with this refinement before including it in the Hospital Readmissions Reduction Program.**

- c. CMS should re-evaluate the Readmissions Reduction Program to mitigate the effects that a decrease in the national readmissions rate can have on a hospital's readmissions penalty.

Under the existing method for calculating a hospital's readmission penalty, hospitals may continue to be penalized even while they reduce their excess readmissions as long as the national readmission rate continues to improve.

MedPAC has noted that the manner in which the readmission penalty is calculated is counterintuitive because improvements in readmission rates nationally can result in higher penalties for individual hospitals.²⁰ We recognize that CMS does not have authority to change the formula for calculating the readmissions penalty because the formula was codified in the ACA. However, the fact that hospitals continue to receive increasing penalties even while they make significant improvements indicates even further the need for CMS to adopt the recommendations in this letter. **CMS should re-evaluate the Readmissions Reduction Program to ensure hospitals are not unduly penalized while they are reducing unnecessary readmissions, given that hospitals' efforts to improve quality of care will not immediately be reflected in their readmissions adjustment factors.**

- d. CMS should adopt an extraordinary circumstance exception that allows hospitals at least a one-year exemption from the Readmissions Reduction Program.

America's Essential Hospitals supports the addition of an extraordinary circumstance exemption to the Readmissions Reduction Program. CMS should allow hospitals to be exempt from the program for at least the year in which the extraordinary circumstance occurs. As noted earlier in comments on the HAC Reduction Program, implementing an extraordinary circumstance exception to the Readmissions Reduction Program would allow hospitals to address gaps in data and recover from the extraordinary circumstance before facing penalties. Hospitals should be given the time to focus on their immediate needs during an extraordinary circumstance rather than worrying about penalties they may face due to a situation outside of their control. **For these reasons, CMS should finalize its proposal to adopt an extraordinary circumstance exception for the Readmissions Reduction Program and allow hospitals to be exempt from the program for at least one year.**

5. CMS should only include measures in the Hospital VBP Program that have been proven to improve patient outcomes.

The VBP Program was authorized by the ACA and 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 DRG base operating payments for each hospital discharge. Hospitals will have a chance to earn back the reduction, plus additional incentives, based on their performance

²⁰See, e.g., Medicare Payment Advisory Commission. Comment Letter to CMS on FY 2014 IPPS Proposed Rule. June 2013. <http://www.medpac.gov/documents/comment-letters/medpac's-comment-on-cms's-acute-and-long-term-care-hospitals-proposed-rule.pdf?sfvrsn=0>. Accessed June 2015.

relative to other hospitals. As the program evolves, CMS should ensure the measures hospitals are evaluated on are proven to actually improve patient outcomes and increase quality for all patients.

- a. CMS should remove measures from the VBP Program that it considers topped out.

CMS should finalize its proposal to remove the following measures from the FY 2018 VBP Program:

- Influenza Immunization (IMM-2)
- Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival

CMS proposes to remove these measures, as the agency considers the measures topped out, which means they meet the following criteria: 1) measure data show statistically indistinguishable performance levels at the 75th and 90th percentiles, and 2) measure data show a truncated coefficient of variation less than 0.10. America's Essential Hospitals appreciates any efforts by CMS to reduce the reporting burden on hospitals. By removing measures that no longer show improvements in quality, CMS will enable hospitals to use their limited resources for quality improvement as opposed to reporting activities. **Therefore, CMS should finalize its proposal to remove these measures from the FY 2018 program.**

- b. CMS should provide further discussion and instruction to hospitals regarding the implementation of the proposed addition of 3-Item Care Transition Measure (CTM-3) to the FY 2018 VBP Program.

America's Essential Hospitals supports the use of measures to evaluate care coordination but requests further discussion by CMS as to whether this proposed measure aligns with existing measures such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.

- c. CMS should ensure the validity of the Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate Following COPD Hospitalization measure before moving forward with implementation in FY 2021.

America's Essential Hospitals has general concerns about the methodology of CMS' mortality measures. We urge CMS to use the years between now and FY 2021 to ensure the validity of the measure and determine that information obtained from using the measure can be used to improve quality of care before moving forward with implementation in FY 2021.

- d. CMS should be consistent in any proposed refinement to the CLABSI and CAUTI measures across all programs to include select ward (non-ICU) locations.

As noted in the discussion of the HAC Reduction Program, the proposed refinement of the CLABSI and CAUTI measures to include data from select non-ICU wards should be delayed until FY 2019. **CMS should maintain consistency in the various programs and not expand the measure data to non-ICU wards until FY 2019.** America's Essential Hospitals supports quality improvements to decrease the incidence of these infections. However, any future rulemaking to expand this measure should be consistent with the HAC Reduction Program to avoid confusion among hospitals.

6. CMS should continue to adapt the domains and weights in the VBP Program to emphasize the importance of measures that improve patient outcomes.

CMS is proposing to remove two measures from the FY 2018 VBP Program. This impacts the current, finalized domain and weight structure. To address the shift in measures, CMS is proposing to remove the clinical care-process subdomain, rename the subdomains, and revise the structure for the domains and weights for the FY 2018 program. CMS' proposal would include the following domain and weight structure:

- safety – 25 percent
- clinical care – 25 percent
- efficiency and cost reduction – 25 percent
- patient- and caregiver-centered experience of care/care coordination – 25 percent

America's Essential Hospitals supports CMS' continued efforts to appropriately define the domain and weight structure and includes specific recommendations below.

a. CMS should raise the proposed weight for the newly named clinical care domain for FY 2018 to focus on improved patient outcomes.

Raising the weight for this domain would increase the emphasis on clinical process of care measures, allowing hospitals to identify and institute improvements, which translates into improved patient outcomes. To ensure the focus of the VBP Program is on improving patient outcomes, the clinical process of care domain should have an appropriate, corresponding weight. **For these reasons, CMS should raise the weight of the clinical process of care domain for FY 2018.**

b. CMS should lower the proposed weight for the efficiency domain.

CMS should lower the proposed weight for the efficiency domain to more equally balance the domain weights. For the FY 2018 measure set, CMS

proposes a 25 percent weight for the new efficiency and cost reduction domain, which only has one measure—the Medicare spending per beneficiary measure. Giving a domain with only one measure a 25 percent weight effectively gives that single measure much more weight—and therefore importance—than any other measure in the VBP Program. The VBP Program was created to improve quality and patient outcomes. The measure included in the efficiency domain does not lead to quality improvements because it solely reflects Medicare payments for services provided. Efficiency is an important component of overall hospital performance improvement; however, this measure does not truly address hospital efficiency because Medicare payments are more reflective of the services a hospital provides and the patients it cares for rather than the efficiency of a hospital. CMS should ensure the domains are more equally balanced so hospitals are focused both on improving patient outcomes and increasing efficiency. **For these reasons, CMS should lower the weight of the efficiency domain for FY 2018.**

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

CMS should continue to tailor the IQR Program measure set so the measures included are useful to hospitals as they work to improve the quality of their care and beneficial to the public by accurately reflecting the care being offered by hospitals. America’s Essential Hospitals supports the creation and implementation of measures that lead to quality improvement. However, CMS must verify that the measures are properly constructed and do not lead to unintended consequences prior to including them in the IQR Program. CMS should also ensure new measures are included in the IQR Program for at least two years before adding those measures to the VBP or HAC Reduction Program. As highlighted by the Committee on Core Metrics for Better Health at Lower Cost, appointed by the Institute of Medicine, there is a need to reduce the burden of unnecessary and unproductive reporting by reducing the number, sharpening the focus, and improving the comparability of measures.²¹ 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 may 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 proposes to remove nine measures from the IQR Program for the FY 2018 payment determination. Of these measures, six will be removed in their chart-abstracted form but kept as voluntary electronic clinical quality measures

²¹Institute of Medicine Committee on Core Metrics for Better Health at Lower Cost. Blumenthal, D, Malphrus, E, McGinnis, J.M. *Vital Signs: Core Metrics for Health and Health Care Progress*. Washington, DC: The National Academies Press; 2015.

(eCQMs). America's Essential Hospitals supports the removal of measures that are topped out and thus no longer accurately capture distinctions in quality of care. Removing these measures reduces the administrative burden on hospitals and ensures the IQR measure set is kept up to date. Any new measures that are added should be reliable, valid, and useful in improving the quality of hospital care.

- a. CMS should only include measures in the IQR Program that are NQF-endorsed and supported by the Measure Applications Partnership (MAP).

CMS proposes to add eight measures to the IQR Program. None of the proposed measures has been endorsed by NQF, nor has any been supported by the MAP, a multistakeholder partnership that guides HHS on the selection of performance measures for federal health programs. NQF endorsement and MAP approval are imperative to ensure measure validity and reliability. Through these processes, measures are fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders. CMS should not add measures that have not yet been through these processes. Additionally, CMS should continuously monitor the measures in the program for NQF endorsement status and remove existing measures that are not endorsed or have had their endorsement withdrawn.

The below proposed measures for FY 2018 have not been evaluated through these review processes. Even after these measures have been endorsed and approved, hospitals should be provided adequate time to gain experience in capturing the following measures prior to public reporting:

- Hospital Survey on Patient Safety Culture (structural)
- Kidney/UTI Clinical Episode-Based Payment Measure (claims-based)
- Cellulitis Clinical Episode-Based Payment Measure (claims-based)
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based)
- Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment Measure (claims-based)
- Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based)
- Excess Days in Acute Care after Hospitalization for AMI (claims-based)
- Excess Days in Acute Care after Hospitalization for HF (claims-based)

In addition, the intent or purpose for adding two of the measures – Excess Days in Acute Care after Hospitalization for AMI and Excess Days in Acute Care after Hospitalization for HF – is unclear from the proposed rule. CMS noted its concern that hospitals may be changing behavior in response to changing hospital payment incentives (i.e., using hospital observation stays as an alternative to short-stay inpatient hospitalizations). However, **it remains unclear how these two**

proposed quality measures would directly address CMS' concerns over institutional behavior.

Further, as noted in our prior discussion of CMS' two-midnight policy, due to the clinical complexity of the patients treated at essential hospitals, it is of utmost importance that physicians are allowed to make appropriate care determinations, such as providing observation services to patients based on their specific needs and comorbidities. CMS should work collaboratively with interested stakeholders through a transparent process to ensure any policy, including quality measures, allows hospitals to provide the best care for patients in the most appropriate setting, as determined by the physician.

Regarding the other six proposed measures, CMS should wait for NQF endorsement and MAP approval, and then allow hospitals the opportunity to gain experience with these measures before they are publicly reported through the IQR Program.

America's Essential Hospitals supports hospital quality improvement efforts gained through public reporting. However, **thorough public testing and vetting must be undertaken before CMS makes any data available to the public. CMS should also 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.**

- b. CMS should seek NQF endorsement and limit the refinement of pneumonia hospitalization measures.

CMS proposes refining two previously adopted measures for the FY 2018 payment determination – the Hospital 30-Day, All-cause, Risk-Standardized Mortality Rate following Pneumonia Hospitalization and the Hospital 30-day, All-cause, Risk-Standardized Readmission Rate following Pneumonia Hospitalization measures. As outlined above regarding the Hospital Readmission Reduction Program, these measures have not been appropriately vetted through the NQF endorsement process. Both coding and clinical complexities exist in these refinements that need to be addressed. Plus, these refinements are overly broad in their effort to capture a more complete population across hospitals. **For these reasons, CMS should obtain NQF endorsement before taking any steps to include these measures in the IQR Program.**

- c. CMS should risk adjust measures in the IQR Program for sociodemographic factors and other appropriate factors.

CMS should incorporate evidence-based risk adjustment for sociodemographic factors in its methodology for calculating outcome measures in the IQR Program so the results are accurate and reflect

differences in the patients being treated by hospitals. 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.

Outcomes measures, especially readmissions measures, do not accurately reflect hospitals' performance if they do not take into account socioedemographic 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.

The need to take sociodemographic factors into account has been increasingly suggested for quality measurement programs. For example, MedPAC made this recommendation for the Medicare Hospital Readmissions Reduction Program.²² As mentioned above, an NQF panel issued recommendations proposing that certain quality measures be risk adjusted for sociodemographic factors. This growing consensus lends support to the importance of risk adjustment to ensuring accurate and useful information in quality reporting programs. **Therefore, CMS should not include outcome measures for which sociodemographic factors have shown to be important in the IQR Program until they are risk adjusted for such factors.**

8. CMS should ensure electronic reporting is a viable option for all hospitals and address the discrepancies between electronic and chart-abstracted measures before requiring hospitals to electronically report measures.

CMS should not require providers to electronically report CQMs until 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. For the FY 2018 payment determination (using measure data collected in calendar year 2016), CMS proposes to require hospitals to electronically report 16 of the 28 eCQMs in the IQR Program. Currently, hospitals participating in the Medicaid and Medicare EHR Incentive Programs must report on 16 of the 29 eCQMs to receive incentive payments (one of these eCQMs is an outpatient measure and is not part of the IQR Program). While America's Essential Hospitals supports this effort to align the IQR Program with the EHR Incentive Programs, we remain concerned about outstanding issues with the reliability of data produced from certified EHR technology. The data extracted from EHRs differ from the data that are obtained from chart-abstracted measures and are therefore not reliable for display in a publicly reported program. Due to

²²See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare and the Health Care Delivery System. June 2013.
http://www.medpac.gov/documents/reports/jun13_EntireReport.pdf. Accessed June 2015.

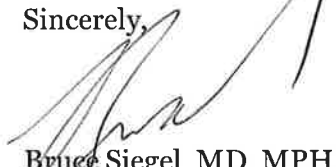
the differences between data extracted from eCQMs and chart-abstracted quality measures, CMS should adopt a validation process and conduct robust testing that would ensure data being extracted from eCQMs are accurate and comparable to chart-abstracted data.

Further, for CMS to finalize this requirement before all measures are fully electronically specified and field tested would be premature. 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 far enough in advance, many providers will not have enough time to bring their reporting systems up to date to report these measures when required. In addition, 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.

In addition, to secure sufficient vendor participation, CMS must be more flexible with patient-level data transfer standards—e.g., by adopting data transmission standards EHR vendors are already using. Without vendor support, most hospitals find it impossible to report measures electronically. If these challenges remain unaddressed, they will continue to plague hospitals as they electronically report measures. **Therefore, CMS should continue to work with EHR vendors to make electronic reporting a viable option for all hospitals.**

America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Maryellen Guinan, Esq., policy analyst, at 202-495-3354.

Sincerely,



Bruce Siegel, MD, MPH
President and CEO