AMERICA'S
ESSENTIAL
HOSPITALS

June 30, 2014

Ms. Marilyn Tavenner
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-1607-P: Medicare Program:

- **Hospital Inpatient Prospective Payment System (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2015 Rates;**
- **Quality Reporting Requirements for Specific Providers;**
- **Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals;**
- **Provider Administrative Appeals and Judicial Review;**
- **Enforcement Provisions for Organ Transplant Centers; and**
- **Electronic Health Record (EHR) Incentive Program**

Dear Ms. Tavenner,

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. As

essential community providers (ECPs), our more than 220 member hospitals fill a vital role in their communities, serving the uninsured and patients covered by public programs. Specifically, our members provide a disproportionate share of the nation's uncompensated care and devote more than half of their inpatient and outpatient care to uninsured or Medicaid patients. Our members provide this care while operating on margins substantially lower than the rest of the hospital industry—with an aggregate operating margin of -0.4 percent, compared to 6.5 percent for hospitals nationally.[1]

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 the payment cuts to hospitals, such as 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 innovations. Members have implemented initiatives to prevent falls, created programs to break down language barriers, and engage in a variety of other programs aimed 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 (UC) 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 UC provided by members of America's Essential Hospitals. In 2012, 15 percent of our members' costs were uncompensated, compared to 6 percent of costs for hospitals nationally.

Under Section 3133 of the ACA, Congress directed a large portion of Medicare DSH payments to be distributed based on a hospital's UC level relative to all other Medicare DSH hospitals. While DSH hospitals will continue to receive 25 percent of their Medicare DSH payments as a per-discharge adjustment payment, the remaining 75 percent will be adjusted to reflect the change in the national uninsurance rate and distributed based on UC burden (referred to as UC-based Medicare DSH payment). This change is in line with the Medicare Payment Advisory Commission's (MedPAC's) longstanding recommendation to incorporate UC into the Medicare DSH formula to better target dollars to hospitals with the greatest need. America's Essential Hospitals has

[1]America's Essential Hospitals Annual Hospital Characteristics Survey. 2012. Results to be published.

long supported MedPAC's recommendation to account for UC in the DSH formula. Effective implementation of the ACA provision should ensure such targeting occurs.

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 UC for purposes of allocating the UC-based Medicare DSH payments among eligible hospitals. CMS should continue to work on accurately capturing UC 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 are able to provide access to vital care.

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 UC-based Medicare DSH payment by the estimated decline in the national uninsurance rate. To reach this estimate, 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. Not only does CMS have the authority to exercise such flexibility,[2] but this practice also ensures an adequate level of Medicare DSH resources remain available to high UC hospitals. **Therefore, CMS should continue using the latest estimates from the CBO for determining the national uninsurance rate.**

[2]The 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 FYs 2014 and 2015 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."

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

Given the importance of UC to the ACA-revised Medicare DSH program, we urge CMS to continue to refine its methodology to accurately capture UC costs. Under the Medicare DSH methodology, CMS determines a hospital's qualifying UC burden by estimating its percentage of the total UC costs incurred by all hospitals. Hospitals are required to report their UC 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 UC and instead use a proxy to estimate hospital UC 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 UC 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 formula.[3] 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 UC costs.

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

The current worksheet S-10 does not take into account all patient care costs when converting charges to costs. The ACA specifically references the importance of using data sources that are the best proxy for the costs to hospitals of treating the uninsured. That said, as CMS considers whether and how to use worksheet S-10 as the data source for measuring UC 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.

[3]See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare Payment Policy. March 2000. http://www.medpac.gov/documents/Mar00%20Entire%20report%20.pdf. Accessed June 2014.

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

ii. CMS should issue clarifying guidance as soon as possible to improve the consistency and accuracy of worksheet S-10 data.

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 and 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, CMS should address current underreporting of charity care by revising its instructions to worksheet S-10. The current instructions call for charity care that was *provided* (not necessarily written off) during the period to be recorded in line 20.[4] 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. 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 UC 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 UC, 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 not an accurate way to measure shortfall. Second, the current worksheet does not permit governmental hospitals to reduce their Medicaid

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

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. To allow offsets for one such type of contribution, i.e., provider taxes and assessments, and not others distort shortfall amounts and may create inequities among hospitals. This is particularly detrimental in a context where the shortfall is counted as UC and the UC-based DSH payments are determined on a relative basis. If hospitals are to receive a portion of their DSH payments based on their relative UC, 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 UC 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 UC 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 UC 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 UC, 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 UC hospitals provide.** Accounting for these voluntary funding sources in the determination of the full UC 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 indicator 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 UC.*

CMS should not use data from Line 18 of the S-10 in calculating the value of UC. Line 18 requires hospitals to report all government grants, appropriations, or transfers for 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 UC. 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. Different hospitals may use this funding in different ways, which would lead to inconsistencies when comparing hospitals for the purpose of calculating UC. **Therefore, CMS should not use this data in determining the uncompensated care amount for hospitals.**

vi. *CMS should consider additional implications when evaluating its proposed UC proxy.*

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

- The use of only inpatient days, as proposed, does not capture the extent to which low-income patients make up a hospital's overall patient population.
- The use of inpatient days does not capture the significant amount of low-income care hospitals provide in the outpatient setting.
- The use of 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 UC data so CMS can refine its methodology for distributing UC-based Medicare DSH payments. At the very least, until CMS is able to refine its methodology to distribute the UC-based Medicare DSH payments using UC 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 the two-midnight policy so it preserves physicians' clinical judgment and limits the unbridled discretion of review contractors.

CMS should work with stakeholders to revise the two-midnight policy so physicians' judgment of the most appropriate level of care for a patient is preserved and not overturned by the retrospective evaluation of review contractors. In the FY 2014 IPPS final rule, CMS finalized its two-midnight policy, under which 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.

Since the announcement of the two-midnight policy, 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 March 31, 2015, to comply with a requirement in the Protecting Access to Medicare Act of 2014. The extension of this ban further 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.

In addition to the confusion the policy creates for physicians and hospital staff, the two-midnight policy 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 when the original physician inpatient admission decision was made correctly in the first place. 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. Essential hospitals, which already provide a disproportionate amount of 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.**

Until CMS is able to resolve these issues surrounding short inpatient stays, we urge CMS to add exceptions to the two-midnight policy and limit the ability of RACs to overturn admission decisions made by physicians. CMS is also seeking comment on an alternative short-stay methodology. Specifically, in the proposed rule, the agency is soliciting input on how to define short-stays and how to reimburse hospitals for these short-stays. America's Essential Hospitals looks forward to reviewing any details the agency can provide on such a short-stay methodology. As CMS formulates the details of this short-stay methodology, 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 last year's final rule, CMS announced that due to an expected increase in inpatient stays under the two-midnight policy, the standardized payment amount 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.[5] 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, we urge CMS to not subject hospitals to a reduction in their inpatient payments until CMS fully understands the impact of the policy.**

b. CMS should add exceptions to the two-midnight policy for short inpatient stays.

Using feedback from provider groups and relevant stakeholders, CMS should add exceptions to the two-midnight policy for certain types of stays that may last fewer than two midnights but are appropriate for the inpatient setting. The clinicians at our member hospitals tell us that certain services are best provided in the inpatient setting and should be added as exceptions to the two-midnight policy. Note that we are not suggesting these services be added to the inpatient-only list, but rather that they be added only to the list of services considered exceptions to the two-midnight policy. This is the list of current procedural terminology (CPT) codes recommended by clinicians at our member hospitals as appropriate exceptions to the two-midnight policy:

- General procedures:
    - insertion of non-tunnel central venous catheter (CPT code 36556)
    - prostate surgeries, including transurethral resection of the prostate and prostatectomy (CPT code 52601)
    - tube thoracostomy (CPT code 32551)
    - incarcerated hernia (CPT code 49561)
    - modified radical mastectomy (CPT code 19307)
    - partial thyroidectomy (CPT codes 60210 and 60212)
    - total thyroidectomy (CPT code 60240)
    - drainage of hematoma/fluid (CPT code 10140)
    - laryngoscopy with tumor excision and scope (CPT code 31541)
    - laparoscopy appendectomy (CPT code 44970)
    - laparoscopic cholecystectomy (CPT code 47562)

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

- Cardiac procedures:
    - pacemaker, automatic implantable cardioverter defibrillators, and other implantable defibrillator placement/replacement/repositioning/removal, including removal of implantable cardioverter defibrillator (CPT code 33244) and biventricular cardiac defibrillator placement[6]
    - insert intracoronary stent (CPT code 92980)
    - left heart artery/ventricle angiography (CPT code 93458)
    - percutaneous aortic valvuloplasty (CPT code 92986)
    - percutaneous mitral valvuloplasty (CPT code 92987)
    - pericardiocentesis (CPT code 33010)
- Neurological procedures:
    - one-level cervical spine fusion (CPT 22554)[7]
- Oncological procedures:
    - hepatic transcatheter arterial chemoembolization[8]
    - elective chemotherapy cases for patients that have adverse effects
    - radioactive thyroid treatment, after which certain patients must be isolated due to high radiation levels
    - biopsy/removal of lymph nodes (CPT code 38525)
- Gynecological procedures:
    - closure of vagina (CPT code 57120)
    - myomectomy vaginal method (CPT code 58145)
    - vaginal hysterectomy (CPT code 58260)
    - vaginal hysterectomy, including tube(s) and/or ovary(ies) (CPT code 58262)
    - laparoscopy, surgical, with total hysterectomy, with tube(s) and ovary(ies) 250g or less (CPT code 58571)

These exceptions are especially important to essential hospitals, which provide the type of high-acuity care to complex and vulnerable patient populations that often necessitates short-term inpatient stays. The complexity observed in our hospitals' patient populations can result from multiple factors, including patient comorbidities and social factors. For example, our hospitals treat a racially and ethnically diverse mix of patients. This diversity may predispose patients to specific conditions, such as sickle cell anemia and thalassemia, which expose them to greater risk when undergoing certain procedures. Because conditions such as these may complicate a patient's care, the physician often will determine that a procedure is most appropriately performed in an inpatient setting to manage these complexities. Patients with underlying conditions or complications will frequently require the resources available only in the hospital inpatient setting, even if that patient ultimately requires only a short stay that does not cross the two-midnight threshold.

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[6]Biventricular cardiac defibrillator placement requires an inpatient stay overnight to monitor complications, such as internal bleeding.

[7]Other comparable spine fusion procedures are on the inpatient-only list (e.g., CPT code 22585), and the one-level procedure requires care and treatment similar to these inpatient-only procedures.

[8]An inpatient stay is required to monitor when the tumor breaks down. There is a risk of kidney failure, and this is best treated in an inpatient setting.

Therefore, we ask CMS, as it continues to revise the two-midnight policy, to incorporate feedback from providers and develop clear guidance. By adapting the policy to include these exceptions, for example, CMS will serve the interests of beneficiaries and providers alike.

c. CMS should reiterate through guidance the presumption that stays lasting longer than two midnights are appropriate for inpatient reimbursement and thus not subject to MAC and RAC review.

The two-midnight presumption, which minimizes the ability of RACs and MACs to review claims for stays that last more than two midnights, is a positive step toward decreasing the number of long observation stays. Long observation stays are not optimal for patients and hospitals, when compared with inpatient stays, because they result in higher cost-sharing for patients and may not fully reimburse hospitals for the costs of providing care. Furthermore, treatment for high acuity cases provided to complex patients is best provided in the inpatient setting. For these reasons, CMS should continue to implement this part of the two-midnight policy, so hospitals can be assured that inpatient stays that cross the two-midnight threshold will be reimbursed at inpatient rates.

In conjunction with the necessary steps to revise its policy for short stays by adding exceptions and limiting the scope of review contractor authority, CMS will ensure hospitals can continue providing high-quality care in the setting that is in the best interests of their patients' health.

d. 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.

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 would 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 recently addressed it in the context of pioneer accountable care organizations (ACOs) by waiving the three-day SNF coverage requirement for beneficiaries in certain 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 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 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 agrees with Congress' desire to reduce HACs as they 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 the occurrence of 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 program are unreliable indicators of quality of care. For example, the Agency for Healthcare Research and Quality (AHRQ) patient safety indicator (PSI) measure is claims-based, and the events in this measure occur infrequently. As detailed in subsection (a) below, these factors make this measure a poor indicator of the true quality of care being provided. America's

Essential Hospitals believes the PSI 90 measure should be weighed less and is pleased that CMS proposes to reduce domain 1, which consists of the PSI measure, to 25 percent of the total score for the FY 2016 HAC Reduction Program. CMS should continue to decrease the weight of this measure in future program years.

Additionally, the nature and volume of care our hospitals provide to vulnerable populations makes them likely to be disproportionately included in the top quartile of hospitals based on the total HAC score. 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 HAC Reduction 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 laceration.[9] 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 and exclude measures that are infrequent and more likely to occur in essential hospitals that serve as referral centers and emergency care providers. **Therefore, CMS should reevaluate the measures in the HAC Reduction Program because they are unreliable measures of quality and they are biased against hospitals providing essential care to vulnerable populations.**

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

Some measures that CMS has included in the HAC Reduction Program, such as the AHRQ PSI measure and Healthcare-Associated Infection (HAI) measures, are not appropriate quality indicators. AHRQ PSI measures, for example, are administratively measured using claims data and are not clinically reported. Since the claims data used in calculating the AHRQ PSI 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 AHRQ PSI measures are rare events and do not meet the high-volume requirement for the HAC Reduction Program.

The Healthcare-Associated Infection (HAI) 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

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

infections is not necessarily a result of poor quality of care but instead the large number of high-risk procedures these hospitals perform. Members of America's Essential Hospitals provide a high volume of emergency trauma and burn care, and thus may receive higher HAI scores 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 bump a hospital into the next, higher decile. The movement into the next decile increases the hospital's score on that measure by a whole point. Rather than a gradual increase in score, the current scoring system penalizes 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 skewed against teaching hospitals, large hospitals, and hospitals that provide care to vulnerable populations.**

b. 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 socioeconomic 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 infections and complications. For example, residence is an important determinant of a patient's condition prior to coming to the hospital and patient's primary language can impact his or her ability to communicate with hospital staff—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. 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] **Factors such as these should be included in the HAC Reduction Program's risk-adjustment methodology, so the measures more accurately reflect quality outcomes within hospitals' control.**

c. 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.

The ACA states that the adjusted payment under the HAC Reduction Program 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

[10]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.

[11]Social Security Act § 1886(p)(1).

DRG payment but 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. Without these support payments, essential hospitals would face difficult financial decisions that could impact their ability to maintain vulnerable patients' access to care. The secretary 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. **In order to maintain the purpose of these support payment programs, and to minimize the disproportionate effect of the HAC Reduction Program on essential hospitals, the secretary should use her authority to apply the reduction to base operating DRG payments only.**

d. CMS should provide hospitals with more information regarding a HAC Reduction Program standardized electronic composite of all-cause harm measure so they can provide feedback.

CMS is soliciting feedback on whether an electronic composite all-harm measure should be included in the HAC Reduction Program. However, CMS has not provided enough detail to allow hospitals to provide the agency informed feedback. Hospitals need more insight into what CMS envisions this measure would include and how the measure will be reported through the EHR system. **Therefore, CMS should provide hospitals more information to enable informed feedback and thoughtful judgment on the inclusion of the measure in the HAC Reduction Program.**

e. CMS should adopt an extraordinary circumstance exception that allows for 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, inclusion of 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, member hospitals in New York mobilized to manage the aftermath of Hurricane Sandy. One member 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 (EHR) system and had to use paper forms as they treated patients, which created serious data lags. Another New York member 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.

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 for the HAC Reduction Program and allow hospitals to be exempt from the program for at least one year.**

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, 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.

Based on the floor adjustment factors established by the ACA, hospitals currently face up to a 2 percent payment reduction in FY 2014 and a 3 percent reduction beginning in FY 2015. Given their already low operating margins, if the necessary adjustments are not made to accurately measure readmissions, our members face cuts to their base operating DRG payments that would have a profound impact on their ability to provide care to all patients, including our nation's most vulnerable.

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

CMS should ensure the methodology for calculating a hospital's number of excess readmissions includes adequate risk-adjustment for the three existing applicable conditions and for the conditions proposed for inclusion in the FY 2015 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 that accounts for socioeconomic 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 socioeconomic 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, such as including adequate risk-adjustment in measures that would also mitigate the disproportionate effects of the program.

Further underscoring this issue is the fact that hospitals with high readmissions rates but low mortality rates would receive higher penalties under the program as it currently stands. 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.[14] 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.[15] America's Essential Hospitals previously noted that CMS' Hospital Compare data illustrate that hospitals providing care to vulnerable populations are achieving lower mortality rates than the national average while patients are in the hospital. Thus, when outside socioeconomic factors are minimized patients have better health outcomes when they receive inpatient hospital care. However, the FY 2013 Readmissions Reduction Program has already disproportionately penalized many of these 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.[16] And teaching hospitals and large hospitals, both of which tend to provide care to vulnerable populations, more often face higher penalties.[17] 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. Hospitals should not be punished for their readmission rates when high readmission rates are associated with lower mortality rates and good access to inpatient hospital care.

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

[13]See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare and the Health Care Delivery System. June 2013. http://www.medpac.gov/documents/Jun13_EntireReport.pdf. Accessed June 2014.

[14]Ibid.

[15]Ibid.

[16]Joynt 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.

[17]Ibid.

America's Essential Hospitals urges CMS to include factors relating to a patient's background—socioeconomic status, language, and postdischarge support structure—in its risk-adjustment methodology. These underlying factors, as opposed to the quality of care provided, frequently drive readmissions to essential hospitals. Recently, a National Quality Forum (NQF) expert panel released a draft report recommending risk-adjusting certain quality measures for socio-demographic factors. The panel was charged with addressing NQF's current policy, which does not adjust for sociodemographic factors, and whether the lack of adjustment may lead to incorrect conclusions about quality. The panel concluded that the current policy could lead to greater disparities in care, as disadvantaged populations could lose access to care if other providers become more hesitant to treat them.[18] Additionally, without proposer risk-adjustment, essential hospitals could have their funding cut, which leaves them with 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 racial and socioeconomic minorities, as well as the uninsured.

In addition, adding additional 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, CMS should include a sufficient risk-adjustment methodology that accounts for patient socio-demographic factors in the Readmissions Reduction Program.**

b. CMS should consult with NQF on the proposed update to the readmissions algorithm prior to removing procedures from the list of potentially planned readmissions in the readmissions adjustment factor calculation.

CMS should consult with NQF on the proposed update to the readmissions algorithm, which recommends removing two cancer-related procedures in the calculation of a hospital's readmissions adjustment factor. CMS is proposing to remove two procedures from the table of planned readmissions—therapeutic radiation (CCS 211) and cancer chemotherapy (CCS 224). The proposed removal of these procedures modifies how the algorithm treats planned readmissions for patients undergoing chemotherapy treatment. The impact of this change would be substantive enough for CMS to thoroughly evaluate the exclusion of these procedures prior to finalizing the proposed change. Although CMS' validation study found that admissions for these two procedures were largely unplanned, the agency should consult with NQF to determine whether that is always the case and if this change in algorithm is warranted

[18]See, e.g., NQF Draft Technical Report for review. Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors. March 2014.
file:///C:/Users/zgontscharow/Downloads/draft_report_commenting%20(1).pdf. Accessed June 2014.

and would lead to better patient outcomes. The proposed exclusion of these procedures from the list of planned readmissions could penalize hospitals for admitting cancer patient for needed treatment. America's Essential Hospitals supports CMS' work to continue to refine the readmissions algorithm. **However, CMS should consult with NQF on the proposed removal of the cancer-related procedures as planned readmissions prior to finalizing the update to the algorithm.**

c. CMS should adapt 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.[19] 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 more the need for CMS to adopt the recommendations in this letter. **Given that hospitals' efforts to improve quality of care will not immediately be reflected in their readmissions adjustment factors, CMS should adapt the Readmissions Reduction Program to ensure hospitals are not unduly penalized while they are reducing unnecessary readmissions.**

d. CMS should exclude the coronary artery bypass graft (CABG) surgery measure from the FY 2017 Readmissions Reduction Program.

CMS should exclude the CABG surgery measure from the FY 2017 Readmissions Reduction Program until hospitals gain experience reporting on this measure. While CMS does not propose any additional measures for the FY 2016 Readmissions Reduction Program, the agency is proposing to add the CABG surgery measure to the FY 2017 program. However, CMS is also proposing to add the CABG surgery measure to the FY 2017 Inpatient Quality Reporting (IQR) Program.

America's Essential Hospitals supports CMS' decision to maintain status quo in measures for the FY 2016 Readmissions Reduction Program. This will allow hospitals to become more familiar with reporting on existing measures. Likewise, hospitals must also have time to gain experience reporting on the CABG measure in the IQR Program before the measure is included in the Readmissions Reduction Program. **For these reasons, CMS**

[19]See, e.g., Medicare Payment Advisory Commission. Comment Letter to CMS on FY 2013 IPPS Proposed Rule. June 2012. http://www.medpac.gov/documents/06222012_MedPACFY2013IPPS_COMMENT.pdf. Accessed June 2014.

should exclude the CABG surgery measure from the FY 2017 Readmissions Reduction Program.

e. CMS should adopt an extraordinary circumstance exception that allows hospitals 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 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 are considered topped out by CMS.

CMS should finalize its proposal to remove the following measures from the FY 2017 VBP Program:

- **initial antibiotic selection for cap in immunocompetent patient (PN-6)**
- **surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period (SCIP-Card-2)**
- **prophylactic antibiotic selection for surgical patients (SCIP-Inf-2)**
- **prophylactic antibiotics discontinued within 24 hours after surgery end time (SCIP-Inf-3)**

- **urinary catheter removed on postoperative day one or postoperative day two (SCIP-Inf-9)**
- **surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery (SCIP-VTE-2)**

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 2017 program.**

b. CMS should suspend inclusion of the central line–associated bloodstream infection (CLABSI) measure in the FY 2017 VBP Program.

CMS should wait to include the CLABSI measure in the VBP Program, or any other quality improvement program, until the new, reliability-adjusted measure is endorsed by the NQF. America's Essential Hospitals supports tracking and measuring the CLABSI measure, which assesses the rate of laboratory-confirmed cases of bloodstream infection or clinical sepsis among patients in the intensive care unit (ICU). The measure is reported through the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN). However, because CDC has submitted a revised, reliability-adjusted measure to NQF for endorsement, CMS should wait until the revised measure is finalized instead of adopting the existing CLABSI measure for the FY 2017 program.

Many hospitals are having difficulty reporting the current measure due to obstacles such as the significant amount of training and staff time required to collect and report this measure. As a result, all hospitals are not reporting the CLABSI measure to the CDC with the same level of accuracy. In addition, since CLABSIs are so rare, any small deviations in reporting can mean profound differences in comparative performance between hospitals. A new, reliability-adjusted CLABSI measure will work to address these issues. **Therefore, CMS should suspend inclusion of the CLABSI measure in the VBP Program, or any other quality improvement program, until the revised, reliability-adjusted measure is endorsed by the NQF and hospitals are given time to gain experience reporting the revised measure.**

c. CMS should exclude the methicillin-resistant Staphylococcus aureus (MRSA) bacteremia and the *Clostridium difficile (C. difficile)* standardized infection ratio measures from the FY 2017 VBP Program.

CMS should exclude the MRSA and the *C. difficile* standardized infection ratio measures from the VBP Program, as these measures have been finalized for the FY 2017 HAC Reduction Program. Hospitals could face penalties in both programs if the MRSA and *C. difficile* measures are also included in the VBP program. America's Essential Hospitals supports quality improvements to decrease the incidence of these infections. However, inclusion of these measures in the VBP Program as well will expose hospitals to multiple penalties for the same measures under different programs. **Therefore, CMS should exclude these infection ratio measures from the FY 2017 VBP Program.**

d. CMS should exclude the elective delivery prior to 39 completed weeks gestation (PC-01) measure from the FY 2017 VBP Program.

CMS should exclude the PC-01 measure from the FY 2017 VBP Program until it is determined that there is sufficient room for making additional substantive improvements that would results in better patient care. Hospitals, including the members of America's Essential Hospitals, have already recognized the need to actively reduce the number of early elective deliveries (EEDs) among their patients. For example, in 2011, one member hospital adopted a new policy that standardizes acceptable medical indications for deliveries before 39 weeks and has enhanced patient and clinician education efforts. In less than 1 year, this transformation resulted in a zero EED rate and continued results.[20] America's Essential Hospitals supports quality improvements to reduce EEDs. However, given current efforts that are under way, CMS should consider whether this measure promotes good patient care. Hospitals will begin reporting the PC-01 measure in FY 2015 in the IQR Program. **CMS should review the hospital data reported through the IQR Program, to determine whether substantive care improvements can be made moving forward to warrant inclusion of the PC-01 measure in the VBP Program.**

e. CMS should exclude the patient safety for selected indicators (PSI-90) composite measure from the FY 2019 VBP Program, as it does not accurately reflect hospitals' quality of care and has been finalized for inclusion in the HAC Reduction Program.

CMS should exclude the AHRQ PSI-90 measure from the VBP Program and develop a more accurate measure to capture hospital quality. The PSI measure is administratively measured using claims data and is not clinically reported. Since the claims data used in calculating the AHRQ PSI metrics are not clinically validated, these 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. As noted for the HAC Reduction Program, placing excessive

[20]See, eg. Essential Hospitals Institute Transformation Center. Maricopa Sustains Zero EEDs through Standardization, Education. October 2012. http://essentialhospitals.org/institute/sustaining-zero-standardization-education-avert-eeds-at-maricopa/. Accessed June 2014.

emphasis on claims-based data unreliably represents a hospital's actual progress in improving quality. **For these reasons, CMS should propose more accurate measures for the VBP Program that better gauge quality and exclude the PSI-90 measure from the FY 2019 Program.**

6. CMS should restructure the domains and weights in the VBP Program to focus on measures that improve patient outcomes.

CMS is proposing to remove a number of measures from the FY 2017 VBP Program. This impacts the current, finalized domain and weight structure. To address the shift in measures, CMS is proposing a revised structure for the domains and weights for the FY 2017 program. CMS' proposal would include the following domain and weight structure:

- safety – 20 percent
- clinical process of care – 5 percent
- patient experience of care – 25 percent
- outcome – 25 percent
- efficiency – 25 percent

America's Essential Hospitals is concerned about the proposed domain and weight structure, as it does not focus on improved patient outcomes.

a. CMS should raise the proposed weight for the clinical process of care domain for FY 2017 to focus on improved patient outcomes.

CMS should raise the weight (e.g., to 15 percent) for the proposed FY 2017 weighting for the clinical process of care domain. Raising the weight for this domain would increase the emphasis on clinical process of care measures, allows 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 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 2017.**

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

CMS should lower the proposed weight (e.g., to 15 percent) for the efficiency domain to more equally balance the domain weights. For the FY 2017 measure set, CMS proposes a 25 percent weight for the new efficiency domain, which only has one measure—the new 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, CMS should ensure that 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 2017.**

7. CMS should allow sufficient time to analyze the potential impact of the transition to International Classification of Diseases (ICD)-10 before penalizing hospitals in the VBP and other quality programs.

CMS should ensure performance scoring under the VBP and other quality programs is accurately adjusted to accommodate quality data submitted under ICD-10. Hospitals will transition to ICD-10 beginning Oct. 1, 2015. Although many hospitals are far along in the implementation process, the ICD-10 transition will not be without issue. CMS should make sure hospitals have all the information they need, such as general equivalence mappings or crosswalks, to be able to successfully report on the VBP measures as they transition from ICD-9 to ICD-10. CMS should make time to analyze the comparability of data from year to year and the potential impact on hospital performance data. As CMS considers future VBP and quality program policies and measures, it should ensure hospitals are not unfairly penalized as they work through this transition. **Therefore, CMS should ensure sufficient time to analyze the potential impact of the ICD-10 transition and address potential issues before penalizing hospitals in future VBP, and other quality program, years.**

8. 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 Readmissions Reduction or HAC Reduction Program.

CMS proposes to remove 20 measures from the IQR Program for the FY 2017 payment determination but retain 10 of these measures as voluntary electronically reported measures. 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 eleven measures to the IQR Program. Six of those are proposed as voluntary electronic clinical quality measures (eCQMs). Five of the eleven are not endorsed by the NQF. CMS should not add measures that have not yet received NQF endorsement. 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 following are the proposed measures not endorsed by the NQF:

- hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following CABG surgery
- hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following CABG surgery
- hospital-level, risk-standardized 30-day episode-of-care payment measure for pneumonia
- hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure
- CAC-3 home management plan of care (HMPC) document given to patient/caregiver

NQF endorsement and MAP approval are imperative to ensure measure validity and reliability. The endorsement and approval processes require that measures be fully vetted and approved through a consensus-building approach that involves the public and interested stakeholders. Because the above measures have not been evaluated through this review process, they are not ready to be included in a public reporting program.

b. CMS should risk adjust measures in the IQR Program for socioeconomic factors and other appropriate factors.

CMS should incorporate risk adjustment for socioeconomic 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. The IQR measure set already contains seven readmissions measures. CMS proposes to add an eighth measure— readmission rate following CABG surgery. **CMS should not add this proposed measure until it is appropriately risk-adjusted and 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 socioeconomic 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 socioeconomic factors into account has been increasingly suggested for quality measurement programs. For example, MedPAC made this recommendation for the Medicare Hospital Readmissions Reduction Program.[21] As mentioned above, NQF has also convened a panel on this issue that has issued draft recommendations proposing that certain quality measures be risk adjusted for socioeconomic and demographic factors. This growing consensus lends support to the importance of risk adjustment to ensuring accurate and useful information in quality programs. **Therefore, CMS should not include measures in the IQR Program until they are risk adjusted for socioeconomic factors.**

c. CMS should not include in the IQR Program episode-of-care payment measures that hold hospitals responsible for care provided outside of the hospital after a patient is discharged.

CMS proposes to add two episode-of-care payment measures to the IQR program—one for pneumonia (PN) and one for heart failure (HF). The proposed payment measures are in addition to an existing acute myocardial infarction (AMI) payment per episode-of-care measure. Neither of the two proposed episode-of-care payment measures, nor the existing AMI payment measure, is NQF-endorsed.

Episode-of-care measures are intended to assess a hospital's cost efficiency in treating Medicare patients by capturing the costs of treating patients within 30 days of the initial hospital admission. This also includes the cost of care provided at post-acute care institutional settings, such as skilled nursing facilities (SNFs), home health agencies, and rehabilitation facilities, after the hospital discharges the patient. Additionally, care provided to a patient in an outpatient setting or a physician's office would count toward spending as long as it was part of the same episode of care. However, hospitals do not have direct control over a patient's treatment by other providers after discharge, and in fact, under Medicare rules, may not direct patients toward high-quality, cost-efficient providers. Due to this issue, inefficient care provided after a patient is discharged would be attributed to the admitting hospital and would reflect negatively on the hospital, even when not caused by the hospital.

In addition, these measures do not have sufficient exclusion criteria for certain high-cost patients with chronic diseases such as end-stage renal disease, cancer, or HIV/AIDS. **Until these types of issues are addressed and the measures are endorsed by NQF, CMS should remove the episode-of-care payment measures from the IQR program.**

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[21]See, e.g., Medicare Payment Advisory Commission. Report to Congress, Medicare and the Health Care Delivery System. June 2013. http://www.medpac.gov/documents/Jun13_EntireReport.pdf. Accessed June 2014.

d. CMS should only include the influenza vaccination for healthcare personnel measure in the Outpatient Quality Reporting (OQR) Program.

CMS clarifies in the rule that beginning with the FY 2016 payment determination (for the 2014-2015 influenza season), hospitals will be required to collect one vaccination count for the inpatient and outpatient setting for the influenza vaccination coverage among healthcare personnel measure and submit this single count through CDC's NHSN. This information will then be published on the Hospital Compare website as the percentage of healthcare personnel who received the vaccination in the entire facility. Previously, counts for this measure were collected separately for the inpatient and outpatient settings and reported separately in the IQR and OQR programs, respectively. America's Essential Hospitals supports requiring only one aggregate count for an entire facility under one CMS certification number, because separating inpatient and outpatient data collection is difficult and often unfeasible. However, the measure should be included only for one public reporting program and is more appropriate as a requirement in the OQR Program rather than the IQR Program.

9. CMS should ensure electronic reporting is a viable option for all hospitals and address the discrepancies between electronic and chart-abstracted measures.

CMS should work with EHR vendors to make electronic reporting of measures a viable option for all hospitals. For the FY 2017 payment determination, CMS proposes to allow hospitals to voluntarily electronically report 16 of the 28 eCQMs in the IQR Program. Currently, hospitals participating in the EHR Incentive Program must report on 16 of the 29 eCQMs in the EHR Incentive Program to receive incentive payments through that program (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. CMS acknowledges some of the issues with data validation in the proposed rule. The data extracted from EHRs differs from the data that is obtained from chart-abstracted measures and is therefore not reliable for display in a publicly reported program. Due to the differences between data extracted from eCQMs and chart-abstracted quality measures, CMS should adopt a validation process that would ensure data being extracted from eCQMs is accurate and comparable to chart-abstracted data.

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. And without the inclusion of a diverse group of hospitals

using various EHR vendor products, CMS will be unable to accurately gauge the unique challenges faced by different hospitals that have varying levels of capital and human resources. If these challenges remain unaddressed, they will continue to plague hospitals as they voluntarily electronically report measures for the IQR program. **Therefore, CMS should continue to work with EHR vendors to make electronic reporting a viable option for all hospitals.**

CMS also proposes to align the timelines of the EHR Incentive Programs and the IQR Program. Currently, measure reporting and submission are done on an FY basis for the EHR Incentive Program and on a calendar year (CY) basis for the IQR Program. CMS' proposed changes will shift the electronic reporting periods for eCQMs in the EHR Incentive Program from an FY timeline to a CY timeline to more closely mirror the IQR Program. For 2015 and 2016, CMS is proposing electronic reporting of measures for the EHR Incentive Program for the first three quarters of the CY so hospitals can meet the current data submission deadline of November 30 to avoid penalties and receive incentive payments. Hospitals choosing to report measures electronically for the IQR Program will have to report and submit measure data on a quarterly basis for an entire year instead of the current minimum of one quarter.

While the alignment of the time periods will streamline the process for hospitals reporting electronically under both programs, the requirement to report measures for the entire CY is burdensome for hospitals that are already facing challenges meeting exacting meaningful use requirements. **Therefore, America's Essential Hospitals encourages CMS to allow hospitals to electronically report data for one calendar quarter instead of an entire CY.**

10. CMS should not require hospitals to include claims for specific items on their Medicare cost reports as a condition of reimbursement.

CMS proposes to revise the cost reporting regulations to require providers to include appropriate claims for specific items in their Medicare cost report as a condition for receiving Medicare payment for those items. The requirement to include a claim for a specific item already exists in the appeals regulations as a condition of establishing jurisdiction for appeals to the Provider Reimbursement Review Board (PRRB). To avoid duplicative requirements, CMS is proposing to remove this requirement from the appeals regulations and instead only include it in the cost reporting regulations.

Moving the requirement from the appeals stage to the cost reporting stage imposes an automatic additional requirement on all hospitals and may result in excessive discretion being vested in MACs. Under the proposed regulations, a MAC will make the determination as to whether to accept a hospital's cost report or amendments to specific items on the cost report. The version of the cost report accepted by the MAC is the cost report that is used to determine whether there is an appropriate claim for an item, and thus whether the hospital will be reimbursed for that item. If the MAC does not accept a

hospital's amended cost report with an adjustment to a particular item, that cost report would not be used to consider whether there was an appropriate claim for reimbursement.

Furthermore, if a hospital were to appeal a claim to the PRRB, the determination of whether the PRRB has jurisdiction over a specific item would depend on whether the MAC accepted the version of the provider's cost report in question. If the MAC did not accept an amended cost report in which a hospital makes a change to a specific item, the PRRB would not have jurisdiction over a claim in the amended cost report. In this way, the proposed regulation would be an impediment to hospitals by delegating an inordinate amount of decision-making authority to the contractor. Thus, **CMS should not finalize its proposal to require hospitals to include claims for specific items on their Medicare cost report as a condition of reimbursement.**

11. CMS should reconsider the agency's proposal to synchronize the effective dates of the full-time equivalent (FTE) resident cap, the three-year rolling average, and the IME intern and resident-to-bed ratio (IRB) cap.

CMS should reconsider its proposal to synchronize the effective dates of the FTE resident cap, three-year rolling average, and IRB ratio cap and, instead, set the effective date beginning with the hospital's cost reporting period that follows (as opposed to precedes) the start of the sixth program year after when the first new residency program started. In the rule, CMS proposes to synchronize the effective dates beginning with the hospital's cost reporting period that precedes the start of the sixth program year of when the first new residency program started. Currently, FTE resident caps are calculated beginning with the sixth program year of the first new residency program's start. America's Essential Hospitals supports CMS' efforts to streamline policies relating to IME and GME payments to reduce burden on providers. However, the effective date that CMS has selected for synchronizing the FTE resident cap, three-year rolling average, and IRB ratio cap is problematic. By proposing to set the effective date at the beginning of the cost reporting period that precedes the start of the sixth program year, CMS proposes to impose a cap prior to the end of the cap-building window. In certain circumstances, this effectively denies hospitals the ability to be reimbursed for the actual number of residents participating in the new program in the fifth year. Hospitals incur significant expense in establishing new training programs and should be permitted the benefit of the full five-year cap-building window to grow their program and be paid for the actual number of resident FTEs. Therefore, **CMS should synchronize the effective dates of the FTE resident cap, three-year rolling average, and IRB ratio cap beginning with the hospital's cost reporting period that follows the start of the sixth program year after when the first new residency program started.**

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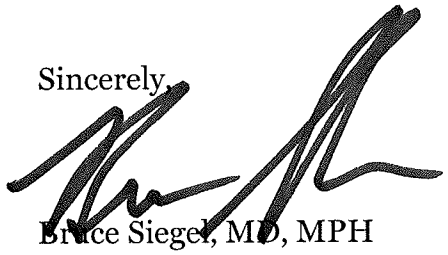
America's Essential Hospitals appreciates the opportunity to submit these comments. If you have any questions, please contact Xiaoyi Huang at 202-585-0127.

Sincerely,



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